Submitter : **Mr. Steve Wallace** **Date: 03/26/2004**

Organization : **DPT, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

Issues 1-10

6. Rural Providers Exception

With the new OMB definitions redefining almost all rural areas as micropolitan statistical areas, do the rural provider exceptions still apply to providers now in micropolitan areas? Most micropolitan areas are still very rural and significantly medically underserved. If the exception is eliminated for rural providers now located in micropolitan areas, could a new exception be defined for a combined micropolitan and medically underserved area? If the goal is to bring more DHS providers into rural/micropolitan areas, why not add the medically underserved designation as a qualifier for former rural providers now classified as micropolitan area providers? Thank you for your response.

Submitter : **Yvette Windham** **Date: 03/29/2004**

Organization : **Yvette Windham**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

After reviewing the regulation, I detected that several sections have been omitted. Please direct me on where I can locate the missing information. Thanks in advance.

Yvette Windham
ywindham@bassberry.com

Submitter : **Ms. Attracta Abulu** **Date: 03/29/2004**

Organization : **Thomson West**

Category : **Media Industry**

Issue Areas/Comments

GENERAL

GENERAL

Good morning,

My name is Attracta Abulu and I am an attorney editor with Thomson West. My question relates to the Federal Register (FR) of Friday March, 26, 2004.

On page 16126 of the FR there are instructions to revise among other sections 411.352, 411.355 and 411.361 of Title 42 of the Code of Federal Regulations (CFR).

While looking at the text of the revisions to those sections on pages 16131 (for Section 42 CFR 411.352), 16135 (for Section 42 CFR 411.355) and 16142 (for Section 42 CFR 411.361) I noticed that the section headings (Definitions-411.351, 411.355-General exceptions to the referral prohibition related to both ownership/investment and compensation, 411.361-reporting requirements) have been removed.

My question is whether the headings for those section have been revised as well or whether they may have been erroneously omitted? If they were revised, what is the change?

I would really appreciate some clarification to this. I may be reached at e-mail address or telephone number listed below.

Thank you so much for your help with this.

Sincerely,

Attracta N. Abulu, J.D.
Senior Attorney Editor
Codes Content Center
West, a Thomson business
Telephone: 651-848-5653
E-mail: attracta.abulu@Thomson.com

Submitter : **Mr. Richard Goodenbour** **Date: 03/30/2004**

Organization : **Mr. Richard Goodenbour**

Category : **End-Stage Renal Disease Facility**

Issue Areas/Comments

Issues 11-20

15. Anti-Kickback Safe Harbor Exception

Dialysis facilities that the referring physician has a financial interest in should not be allowed. This creates a quality of care conflict. For example, if the patient has a complaint about the quality of care the physician has no incentive to improve the quality of care since he has a financial interest in the clinic. An example of this would be cleaing dialysis machines less frequently to save on cost of bleach and other cleaners, using non-sterile supplies to dress puncture sites, and having less medically strained (RN's) on each shift.

Submitter : **Ms. Edwina Lopiano** **Date: 04/02/2004**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

how can i receive a medicare insurance card?

Submitter : **Date: 04/04/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

Issues 1-10

6. Rural Providers Exception

This comment relates to the new exception for intra-family rural referrals. It is unclear whether the requirements of this exception contain a knowledge standard. Assume that the referring physician or the immediate family member do investigate the availability of other DHS providers, and that quality of this investigation is what CMS would agree was a 'reasonable inquiry'. Assume further that no other DHS providers are located pursuant to the reasonable inquiry. If, in fact, there was another available DHS provider, but the existence of this other available DHS provider was not ascertained after the reasonable inquiry, would the exception still be available?

Submitter : **Date: 04/05/2004**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues 11-20

13. Definitions

In regard to the definition of fair market value, one of the methodologies used to calculate hourly payment for a physician's personal services references a compensation survey that does not contain any phsyician compensation data (69 FR 16128). Specifically, William M. Mercer's "Integrated Health Networks Compensation Survey" does not contain physician compensation data, and has not for approximately the last 5 years. Thus, this survey would be of no use in helping to determine an appropriate, fair market value for an hourly rate paid to a physician.

Submitter : **Dr. Robert McArdle** **Date: 04/12/2004**

Organization : **Chest Medicine Associates**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

9. Personal Services Exception

Re: Personal Service Arrangements

In identifying formulas for physician compensation that would satisfy as safe harbors you state two methods, the first averages the hourly emergency physician rate from 3 facilities and the second uses the median salary averaged from several compensation surveys. These surveys generally identify salary seperately from the additional cost of providing fringe benefits which may add an additional 15 to 25% cost to a physician's total compensation. When negotiating compensation for physician services it would seem appropriate to add the cost of fringe benefits to the hourly salary rate. Do you have a position on this?

Thank you

Submitter : **Mr. Harold Freehling Jr.** **Date: 04/13/2004**

Organization : **O.E. Meyer Co.**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

When a hospital ownes a home care business, i.e. home health, home medical equipment, etc. and the physician is a staff member of that facility, does this constitute a indirect financial arrangement? As a medical staff member the hospital can exert undue pressure to refer to the hospitals home care services based on the needs of the physician to utilize the facilities that the hospital provides for the general population of his or her practice. Indirectly the physician can benefit financiallly based on inpatient charges and utilization of diagnostic equipment etc. that can generate a profit. This does appear to be a relationship that could prevent an independent home care service from receiving referrals for a staff member of a given hospital that also provides home care services.

Submitter : **Mr. Timothy Conan** **Date: 04/15/2004**

Organization : **Costello, Cooney and Fearon, PLLC**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

In think that in the final regulation, you should clarify 42 CFR 411.353(e)(4) (ii), (iii) to state that in the case of an income guarantee made by a hospital to a recruited physician who joins a physician practice, that other than for actual costs incurred by the physician practice in recruiting the new physician, the remuneration from the hospital is either passed directly through to the recruited physician (which would be the salary guarantee) or is used by the physician practice to pay the actual additional incremental costs attributable to the recruited physician. If you read 42 CFR 411.357(e)(4) (ii), it appears that you require all money the hospital pays to be passed through to the recruited physician. However in the next subsection you allow the remuneration to be used for the new physician's actual additional incremental costs. Therefore in the case of an income gurantee, I think the regulation would be clarified by using an either/or to join the two subsections together. Thank you.

Submitter : **Date: 04/30/2004**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

I have a question regarding the following comment and response in the March 26, 2004 Federal Register:

"Comment: A commenter sought clarification that the new exception for ASC implants applies whether the ASC bills the insurer or the physician bills.

Response: The exception applies to a financial relationship between the physician and the ASC (as the DHS entity) and to a referral for an implant used during an ASC procedure. Accordingly, the exception applies when the implant is billed by the ASC. When a physician bills for an implant, the physician is the DHS entity (as defined in ? 411.351), rather than the ASC. In other words, not all implants qualify for this exception; implants implanted in an ASC qualify only if the ASC is the entity furnishing the implant. When a physician bills for the implant, another exception would need to be satisfied, such as the in-office ancillary services exception."

69 Fed. Reg. 16136

My question is whether, in light of the above comment and response, the implant exception applies if the ASC furnishes and bills for the implant procedure, but if the physician furnishes, and bills the patient or insurer for, the implant device itself.

Thank you very much.

Submitter : **Date: 05/06/2004**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

Under this exception, payments to a physician who is joining a group practice cannot include shared overhead. They can only include payment for the 'actual additional incremental expenses' incurred by the group. When a new physician joins a group practice, the group has a commercially reasonable and legitimate expectation that the physician will share in the existing overhead costs. The prohibition against shared overhead will have the effect of greatly reducing the number of group practices who will agree to recruit a physician to join the group. As a result, hospitals will either have to forego recruiting physicians into a needy community, or will be forced to recuit the practitioner into a solo practice at considerably greater expense. This added expense will serve only to drive up health care costs to beneficiaries who receive services as hospitals seek to recover the expense through other means.

Stark was intended to prohibit improperly influencing physician referral patterns. It is tenuous at best to infer that allowing recruited physicians to share in existing overhead will influence a group practice's referral patterns. The recruitment exception already has safeguards to prevent this from occurring: (1) recruited physicians must be able to have privileges at other facilites, (2) existing group's can no longer utilize noncompete covenants, and (3) the incentive amount cannot be linked to the volume or referrals. If there is a concern that sharing in overhead will influence a group's referrals, then an additional element could be added to this exception requiring the group to sign an attestation statement that it will not base its referral decisions on the income assistance it receives from the hospital (through the recruitment arrangement)and it will make patient referral decisions solely on the basis on patient choice, insurer requirements, and the medical judgement of the physician. I appreciate your consideration of this comment.

Submitter : **Date: 05/10/2004**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

File Code CMS-1812-IFC

V. Exceptions Applicable to Ownership and Compensation Arrangements
B. In-Office Ancillary Services Exception
5. The Billing Requirement (Section 1877(b)(2) of the Act; Phase I-66 FR 893; 411.355(b)(3))

The billing requirement of the in-office ancillary services exception requires that the DHS be billed by one of the following: The physician performing or supervising the service; the group practice of which that physician is a member under that group practice?s billing number; or an entity wholly owned by the referring or supervising physician or the referring or supervising physician?s group practice. This comment deals with entities wholly owned by the group practice.

Just as with the concern about group practices in more than one contiguous state that was addressed in the Group Practice Definition section of Phase II, there may be non-healthcare related issues influencing a group?s choice of structure for the ownership for its DHS. At times there can be state and/or federal tax advantages to having DHS provided and billed by an entity which, instead of being owned by the group, is owned by the physicians comprising the group. For example, if DHS are provided through a limited liability company, the distributions from the limited liability company would be taxed twice if it were a wholly-owned subsidiary of a C corporation but only once if each shareholder of the C corporation held an identical ownership interest in the limited liability company.

So long as the ownership and governance are identical to the group practice entity?s ownership and governance and mechanisms are put in place in the organizational documents of both entities so that (i) withdrawal or removal from one automatically causes withdrawal or removal from the other and (ii) admission to one is not allowed unless the physician also becomes an owner of the other, and all the other elements of the in-office ancillary services exception are met, then it seems that this ownership structure is consistent with the policies behind the billing requirement of the in-office ancillary services exception and a reasonable interpretation of this requirement would permit this ownership structure. We are requesting that CMS provide guidance that it agrees with this interpretation.

Submitter : **Dr. James Londis** **Date: 05/11/2004**

Organization : **Kettering Medical Center Network**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

To whom it may concern:

This is a comment on the interim final rule to be effective on July 26, 2004, Phase II issues.

No one quarrels with the need to control and/or limit how much money may be spent on physicians who refer to the hospital per Stark and anti-kickback. What is problematic about this rule is the $300 limit.
It does not realistically take into account the cost of simply doing business with physicians in leadership or who volunteer to sit on our committees.

These days a business lunch, one golf outing, one ball game and one modest gift of a pen exceed the $300 limit for physicians in leadership or for physicians needing to work out some important business arrangement (joint venture, you name it). Things of importance cannot always be fruitfully discussed during working hours or on-site. It seems to me that a minimum of $500 (or more) with an inflationary factor built in to the formula would be more reasonable.

No physician I know would be unduly influenced in decision-making about referrals over such trivial expenditures.

Submitter : **Dr. Kumud Tripathy** **Date: 05/13/2004**

Organization : **Cancer Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

This comment is about reimbursement for chemotherapy agents administered in a physician office.For many chemotherapy agents, medicaire allowable is very close to what we pay our vendors to buy those drugs. When these drugs are administered, patients do not pay us immediately (like a grocery store or an airline ticket purchase, where payment is made at the time of transaction). We submit a claim form to yoou in expectation of being paid at a future date. Quite often we have to appeal due to your processing error, and at times some claims get lost in this shuffle and we do not get paid at all. In the most optimistic senerio, medicaire pays us 80% of our cost basis(actually less if you consider cost of ordering, storing, spillage etc.) and we still have to collect 20% from another source JUST TO BREAK EVEN! Now you tell me which business will spend a million dollars if in the best senerio it could barely recover its cost?

So starting January 2005, we will be forced to send all medicaire patients to hospital where you and patients will be paying more for the same service and the inefficieny and other problems of in hospital dervices should be well known to you. Also most hospitals can not handle the volume of chemotherapy tha is currently administered in the offices.

Submitter : **Date: 05/13/2004**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

13. Definitions

My question is whether or not it would be permissible to have a services agreement with payments based on percentage of collections under the indirect compensation exception. The indirect compensation exception found at Section 411.357(p) requires, among other things, that compensation received must be fair market value for services and items actually provided and "not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physicians for the entity furnishing DHS."

The new regulations appear to permit percentage of collections under the indirect compensation exception for the following reasons-

1. CMS recognizes that its original position on percentage compensation arrangements was overly restrictive. 69 Federal Register at page 16068. CMS modified its rules to permit percentage compensation arrangements if a specific formula for determining the compensation is set forth in sufficient detail so that it can be objectively verified and the formula may not be changed or modified during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician at Section 411.354(d)(1).

2. In discussing the "volume or value" standard found in the indirect compensation exception, CMS stated that the issue boils down to whether or not the compensation is fair market value and not inflated to compensate for the generation of business. 69 Federal Register at 16069. So, assuming that a percentage compensation arrangement is at FMV and that it does not involve paying an inflated percentage to reflect generation of business, then the indirect compensation exception should permit the arrangement.

3. There is further support for this position in that CMS has stated that it intends to apply its interpretation of the "volume or value" standard in a uniform manner throughout the regulations. 69 Federal Register at 16068. So, if CMS were to interpret the "volume or value" standard to prohibit percentage compensation arrangement in the indirect compensation exception, then this interpretation, consistently and uniformly applied to other compensation exceptions (e.g., equipment rental, personal services arrangements, academic medical centers) would likewise prohibit percentage compensation arrangements under those exceptions. Yet, that result would be inconsistent with CMS position that it has reconsidered its original position on percentage compensation as overly restrictive.

Thank you for your thoughtful consideration of this matter.

Submitter : TRISHA CATON-TRUJILLO **Date:** 05/14/2004

Organization : VALLEY HEALTHCARE SUPPLY

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

IN ORDER TO HAVE SERVICES PERFORMED IN A MORE TIMELY MANNER A DME COMPANY HAS BEEN REQUESTED TO ALLOW A RESPIRATORY THERAPIST EMPLOYED BY THE REFERRING PHYSICIAN'S OFFICE TO SET UP CPAP OR BIPAP THERAPY WHILE THE PATIENT IS BEING SEEN AT THE DOCTOR'S OFFICE. THE THERAPIST WOULD BE PAID A FLAT FEE PER SET UP. DOES THIS FALL INTO THE EXCEPTIONS OR IS THIS A FINANCIAL RELATIONSHIP WITH THE PHYSICIAN?

Submitter : **Mr. Wallis Stromberg** **Date: 05/18/2004**

Organization : **Stromberg Cleveland Crawford**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

This comment relates to 411.357(e)(4)(vi), and the non-compete agreement example of an improper restriction, and the relationship to state laws.

State laws often prohibit the enforcement of non-compete agreements between physicians. Colorado, for example, has a statute that says that any covenant not to compete between physicians that restricts the right of a physician to practice medicine upon termination of the agreement shall be void (CRS 8-2-113). However that same law goes on to specifically permit contractual provisions that require a physician to pay damages in an amount reasonably related to the injury suffered by the group practice following termination of the agreement, including economic damages resulting from competition by the departing physician. Thus, state law distinguishes between a non-compete that prohibits the practice of medicine and a contractual obligation to pay damages resulting from competition. Colorado also permits the enforcement of restrictive provisions that do not directly prevent the practice of medicine, but which may indirectly impact a physician's new practice after she leaves employment with the group, such as covenants not to disclose or use the proprietary information and trade secrets of the employer group after the termination of employment.

The language of 411.357(e)(4)(vi) is not clear as to whether it covers only restrictions that actually seek to prevent a recruited physician from practicing medicine (similar to Colorado's statute), or whether it would prohibit a contractual obligation to pay damages or a restriction on disclosure of proprietary information (permitted in Colorado and not considered to be a restriction on practicing medicine). The former interpretation would be consistent with the concept of community need that usually justifies the recruitment agreement in the first place, and would further be consistent with state law in states similar to Colorado. The latter type of contractual obligations, however, allow the recruited physician to practice, but seek to protect the integrity and financial stability of the existing group that already provides services in the community - why permit damage to an existing practice when the recruited doctor is free to compete. To prevent the latter type of contractual obligation, which potentially could have only an indirect effect on the recruited physician's continued practice of medicine, would contradict state laws such as Colorado's that expressly permit such provisions because they do not prohibit or restrict the practice of medicine by the departing physician.

Permitting these non-restrictive contract provisions would also seem to fit well with the provisions of 411.357(e)(4)(iii). That regulation prevents the employing existing group from benefiting directly from the recruitment support arrangements by limiting the allowable overhead to incremental costs directly related to the addition of the recruited physician. Since the group cannot benefit directly from the recruitment support, it would be fair to permit contractual obligations on the recruited physician that are designed to protect the group from suffering damages upon the departure of the recruited physician.

As 411.357(e)(4)(vi) is now worded, the application of Colorado law to that section would mean that only non-compete restrictions seeking to prevent the actual practice of medicine are prohibited in recruitment arrangements through existing groups, since the Colorado statute says that other contractual obligations, including the payment of monetary damages resulting from competition, are not restrictions on the practice of medicine. The regulation should be clarified as to whether the term "practice restrictions" means only provisions that prevent or restrict the actual practice of medicine or whether it includes all post-employment contractual obligations of the recruited physician.

Submitter : **Mr. Greg Folta** **Date: 05/18/2004**

Organization : **The Coker Group**

Category : **Individual**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

If a hospital provides an income guarantee to a physician joining an existing physician practice where the existing physician is reducing his/her practice, can an exception be made to the "costs allocated by the physician practice to the recruited physician may not exceed the actual additional incremental costs to the practice attributable to the recruited physician" condition? The argument is that the existing physician is sharing his/her patient volume and is reducing his/her individual practice while the new physician is growing his/her practice. In this case, the incremental costs would be minimal, but the costs attributable to the new physician should be greater than the incremental costs because the existing physician has reduced his/her practice and accordingly, his/her costs. Thus, the costs should be split between the existing physician and the new physician based on individual patient volume, work hours, or some other reasonable method.

Submitter : **Dr. M. Thomas Edwards** **Date: 05/23/2004**

Organization : **Dr. M. Thomas Edwards**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Stark II rules don't go far enough to prevent physician abuse of imaging, hurting smaller hospitals and costing medicare. Example, we have an orthopedics group that will move ~400 MR cases/yr out of hospital to their new MR scanner (low field that before was unacceptable for imaging) and estimate they will do at least 1800-2200 exams next yr. Money is the reason. CMS and insurance pay for this sudden increase in use (abusive overuse), and the local hospital loses income to pay for services that all physicians require at a high level of quality. If you don't correct these problems, they will only grow and continue to cost all of us. This won't be fixed by lowering general reimbursement, but by getting rid of these 'loopholes' that go on being abused.

Submitter : **Dr. Cornelius Murphy** **Date: 05/25/2004**

Organization : **Pullman Memorial Hospital**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

10. Remuneration Unrelated to DHS Exception

My wife, a RN employed at a hospital where I am a medical staff member, recieves certain financial bemefits as an employee of said hospital. She is reimbursed for any university educational courses she completes. But she is a medical staff members wife. This may violate the Stark II Regs. I recieve medical treatment at this hospital and, as the spouse of an employee, I get a reduction in the amount I have to pay out of pocket if I get my medical care at this hospital . Does this violate Stark II regs?
Since many physicians have spouses that are employed by a hospital at whick the physician is a medical staff member, should the Stark II Regs not exempt benefits that accrue to medical staff members if that benefit is the result of a close family member's employment at the hospital?

Submitter : **Mr. Chris Phillips** **Date: 05/26/2004**

Organization : **Kutak Rock LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

7. Space and Equipment Rental Exception

The lease exceptions are unclear on the following points; please clarify:
1 Is a provision in a lease that provides for holding over at a higher rental permissible? It should be, since this is a set-in-advance lease rate triggered by a form of renewal.
2 When you say that if a lease is terminated, the parties cannot enter into another agreement during the first year of the original term, do you mean any agreement of any kind, another lease of the same space, another lease of any space, or something else? Where a physician leases an office and needs larger space within a year, the parties should be able to enter into a new lease for different space.

Submitter : **Mr. Christopher Phillips** **Date: 05/26/2004**

Organization : **Kutak Rock LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

Our comments are attached.

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : **Dr. James Peyton** **Date: 06/02/2004**

Organization : **UMC Cancer Care Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am writing about the impending change of chemotherapy reimbursement from AWP to 106% of ASP. I am sure that you already know that this will impact the ability of physicians to provide valuable care for their patients. In other words, the physician will not be able to afford the support staff (chemotherapy nurses, lab techs, nurses, front desk clerks, medical records personnel, psychologists and billing agents). If we cannot pay our staff from the meager reimbursement for intellectual services, then the hospital will become the administrator of chemotherapy. I cannot imagine how this will save any money. The patient will be billed for an admission, and for the cost of chemotherapy. The hospital will only order the drug once the admission orders are received by the pharmacy. The hospital then has 23 hours to get the drug. At my hospital, there are not enough chemotherapy trained nurses, and they currently ask my nurses to administer the drug. Think about the paradigm shift that this reimbursement scheme will create for patients who deserve to be treated with compassion and convenience; it will not be convenient if patients have to wait 23hours to receive chemotherapy and then they have a $500 bill in addition to the drug. Patients typically come in to the office for a few hours and then go home. If this is the end result of this legislative blunder, then I will feel as if I have failed my patients in an attempt to make their cancer care as unobtrusive as possible.

Submitter : **Dr. James Whitfield, MD** **Date: 06/03/2004**

Organization : **Rehoboth Mckinley Christian Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs:

I am commenting on the proposed Stark 2 rules regarding patient referrals to medical facilities. I am a nephrologist in an underserved area in western New Mexico. I serve a large geographical area populated predominantly by Native American patients. I am medical director for 3 hospital owned dialysis units, 2 of which are on reservation land. Our unit in Gallup, NM, operates 4 shifts of patients daily, and the other units 3. As such, I am responsible for what occurs at the dialysis units from 0400 until 2200 or 1900 daily. I donot consider myself an hourly employee. I donot feel that what I do as medical director is limited to any specific hour. Frequently there are water issues or other unique issues which can occur throughout the day requiring my attention. Since I am legally responsible for what occurs at the dialysis units, I believe that my job as medical director reflects all the hours of operation of the facility. I have seen other nephrologists sued for errors which occurred at the unit for all hours of operation, often for things which a tech or other personel did which either was an accident or violated established protocol. Quite frankly, if the reimbursement for medical director is to be figured only for the hours doing direct administrative work, and not represent recognition for all the additional situations which relate to the functioning of the units, I will gladly give up my medical directors position and let someone else deal with all the water, patient, and employee issues, and assume the liability for the operation for the units. I believe for the responsibilities assumed and the expertise required, along with the long hours of operation of the units, appropriate compensation should be recognized and afforded.

Thank you,
Jim Whitfield, MD

Submitter : **Dr. James Yegge** **Date: 06/11/2004**

Organization : **Dr. James Yegge**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I am writing with concern to dialysis unit medical director reimbursement. The current proposal, if employed, will immediately cause the majority of nephrologist to enter the dialysis business; thereby negating the medical director fee. Should ownership of dialysis units be disallowed, the future of nephrology will be threatened in totality. As the patient population ages and enters dialytic therapy at more advanced state of morbidity, the difficulty in caring for these patients will escalate. The government should carefully study the demographics and continue with the current capitalistic system or face political humiliation.

Submitter : **Mr. Chris Phillips** **Date: 06/15/2004**

Organization : **Kutak Rock LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

7. Space and Equipment Rental Exception

Space and Equipment Rental Exception. The regulations require that space not be used by the lessor while leased to the lessee. Shared office arrangements providing for allocation of rental and other expenses are common. We believe that where the parties determine a reasonable percentage allocation, that should be sufficient to establish that the lessee is exclusively using office and examination rooms while in those rooms; waiting areas, etc. should be considered common areas. We believe that requiring a log of actual use would be unreasonably burdensome. We assume that the purpose of this requirement is to prevent a lessee from subsidizing a lessor and that this potential abuse is adequately addressed by a reasonable percentage allocation.

Submitter : **Dr. Edward Jones** **Date: 06/15/2004**

Organization : **Renal Physician Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1810-IFC

I am writing in reference to the recently released Interim Final Rule on Physician Self Referral. A number of issues arise. First, inserting such guidelines at this late of date does not allow comment by the community. Indeed, it appears that at this point the regulations are final and therefore provide no legitimate opportunity for change. Second, medical directors are not hourly employees. Indeed our responsibility entails much more than meeting in the governing body, or quality assurance. Rather time spent away from the facility spending unquantifiable time on medical director activities including dealing with physician activity, evaluating water logs, worrying about water standards, discussing staffing patterns etc, These many activities are all poorly quantifiable by time yet necessary to fulfill our role as medical director. Some have compared the role of the medical director more like a CEO. Clearly the activity is unrelated to an hourly rate like an emergency room physician who does time-specific activities. Third, introducing this unique proposal within Safe Harbors without investigation is untenable.
Once again, CMS introduces guidelines that will become standards in that it is clear that owners of facilities will take the lowest cost denominator in particular if it ensures them to be within the safe harbor. At the low cost denominator, CMS is ensuring they will get what they pay for and unlikely will physicians accept roles that are not adequately reimbursed.

CMS is providing guidelines that are slanted to facility owners. I would suggest that CMS leave the fair market terminology as they exist and allow the medical director and facility owners are responsible for ensuring it is FMV. The OIG will be the final determinant. Why would CMS involve themselves in this matter?

I encourage CMS not to involve itself in defining parameters of the medical director fees to fall within the safe harbor.

I urge you to withdraw this proposal (CMS-1810-IFC) prior to implementation of the final rule.

Edward R. Jones, MD
Nephrologists
70 Hogan Lane
Ambler, Pa. 19002
1-215-844-2505
dredj@comcast.net

Submitter : **Date: 06/16/2004**

Organization :

Category : **Hospital**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

The suggestion that noncompete provisions would not be allowed will be a significant burden for hospitals working with recruiting young physicians into established practices that cannot recruit physicians by themselves. Many of our established practices in Pennsylvania have been unable to retain and recruit young physicians because of the harsh economic practice climate in this State. However, many of the established practices welcome the idea of working with their primary hospital in recruiting new physicians under the Physician Recruitment Exception. Long term, there is a much higher success rate when a young physician joins an established practice to retaining the physician in the community. Unfortunately, disallowing the use of noncompetes will discourage and threaten established pratices from truly sharing their patients with the young physician when there is a possibility that the young physician may walk out the door someday with the establised practice's patients and economically threaten the viability of the established practice. Therefore, I hope you will reconsider this provision. Thank you for your consideration.

Submitter : **Mr. Robb Menaul** **Date: 06/16/2004**

Organization : **Washington State Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

June 16, 2004

Centers for Medicare and Medicaid Services
Reference: CMS-1810-IFC

Physician Recruitment Exception:

Washington State Hospital Association (WSHA) appreciates the opportunity to comment on the proposed interim final rule for Physicians Referrals to Health Care Entities With Which They Have Financial Relationships.

WSHA supports the forthcoming letter from the American Hospital Association that addresses many aspects of the rule. We support the national body's concerns over income guarantees, practice restrictions in the form of non-compete clauses, and the definition of geographic area.

I would like to comment further on one particular concern. On page 16096 in the March 26, 2004 Federal Register, addressing income guarantees, the rule prohibits cost allocations greater than actual incremental costs to the practice attributable to the recruited physician. This very narrow approach prohibits common business practice of allocating ongoing overhead from an established medical practice to a new physician, for example, when a physician partner retires or dies and a replacement is recruited. Not making the allocation could actually result in higher costs if the new physician must create in essence a new office with separate rents, equipment, and staff.

Large regions of Washington State are very rural with very low population density and six or fewer physicians in entire communities. The proposed rule discussed above will make recruiting to rural Washington State even tougher. It would be better and more realistic to specifically allow the allocation of ongoing overhead as part of an income guarantee when replacing deceased or departing physicians.

Sincerely,

Robb Menaul
Sr. Vice President
Washington State Hospital Association
206.216.2514

Submitter : **Date: 06/17/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

POPTS (Physician Owned Physical Therapy Services) are potentially abusive, and fraudulent, when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. This arrangement is anti-competitive, not necessary, and a conflict of interest.

1. Anti-competitive. When a physician refers patients to his or her employees, the patient's choice is taken away. The independent PT simply cannot provide services to these patients. The patient cannot go to a more qualified, more convenient, or less expensive PT provider. The independent PT provider no longer has access to those patients seen by the physician's employee, which hurts the independent PT's business. The patient cannot benefit from the expertise of an independent provider. Former patients I have treated have been "taken away" by physicians who direct the patient to their employee. The patient goes where the physician directs them, sometimes against their wishes.

2. POPTS are not necessary. There is rarely a situation where a community would not have availability of independent PT services, if the physician didn't invest in the PT business. It is not necessary for physicians to invest in the PT business. By eliminating this in-office exception, patients would still be able to access PT services in non-physician owned PT businesses. Independent therapists will provide services, when they have the opportunity, but when a physician monopolizes a market by controlling all of the referrals, an independent PT cannot succeed in business. However, if POPTS were not allowed, independent PT providers could succeed.

3. The conflict of interest is both financial and ethical. Utilization for financial gain will guide referral and treatment decisions. Over-utilization for financial gain is unethical, but not illegal. Physicians employ PTs, athletic trainers and other non-qualified physician-extenders to provide treatment "incident to" their license. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. These abusive situations are avoidable. In the past 5 years, nearly half of the out patient PT providers in my local area have become physician employees. Often, these PT employees supervise other "extenders" who, by law, can provide care under the M.D. or P.T. supervision. This is done for financial reasons, and can be prevented, by simply eliminating the in-office exception.

Thank you for the opportunity to offer comments.

Submitter : **Mr. Jim Wortley** **Date: 06/17/2004**

Organization : **RMTS**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I amadamantly opposed to physicians referring to therapy clinics owned wholly or in part. I recently had a patient enter my office very upset about her doctor requiring her to travel 90 miles to see "his" therapist for hot packs, ultrasound, and massage. My office was 10 miles closer than the "doctors therapist" and so she came to me. She was very angry when I told her there was an excellent therapist 1 mile from her home. Her doctor required her to travel a great distance solely because he made money off of each visit to "his therapist". POPTS are bad for the public and for the profession of physical therapy. Improper referrals are made based completely on financial gain of the referral source.

Submitter : **Ms. Debra Christian** **Date: 06/17/2004**

Organization : **Norman Regional Hospital**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist working in a hospital based out-patient physical therapy clinic. I have 24 years experience in my field and 13 years in my current practice setting. I have had ample experience with the negative effects of allowing physicians to own their own physical therapy clinics or provide "physical therapy" treatments out of their offices.

Physician owned physical therapy practices in our area have frequently hired primarily new graduates who historically stay in those clinics for a very short time. The reason for this is that as they work in this setting they become more and more uncomfortable with being pressured to practice in a manner they consider unethical and often illegal. They receive pressure to see high volumes of patients and allow unlicensed personnel to perform procedures for which they are not qualified. They are sometimes asked to see patients beyond the point that the therapist believes they require skilled therapy services.

On nearly a weekly basis in our own clinic we are told by current patients that the new specialis they have been referred to insists that they start receiving care in the physicians own clinic. When they explain that they are happy with the services they are already receiving they are told that their physician can keep a closer watch on their therapy if it is done in his or her clinic. Some are even told they "must" receive their services there. It is rare that a patient actually stands up to their physician and does what they want. Some even express concern that they will receive a lower quality of service from their physician if they stand up to him or her.

The worst case scenario is when "therapy" is provided by untrained and unlicensed individuals and billed under the physician's provider number. Physicians receive limited education regarding physical therapy interventions (usually no more that a couple of hours). They are not only unqualified to train others in therapy interventions, they usually have little or no understanding of the indications and contraindications for specific therapy interventions. Patients are unlikely to benefit from such interventions and may be harmed. Further, physicians tend to provide only passive interventions such as ultrasound or electrical stimulation because they take little time and are relatively easy to perform (understanding appropriate use is another matter). Physical therapists use these interventions only as an adjunct to more involved manual therapy, therapeutic exercise and patient education. Paying for these services in the absense of a therapeutic treatment plan developed by a licensed therapist is a waste of Medicare funds.

Our Medicare dollars will be best spent and patient interests best served if the ability of physicians to provide services in their offices or in physician owned practices are closely restricted and not by allowing more loopholes to Stark II.

Thank you for considering my comments.

Debra Christian, P.T.
3001 Thunderbird Ridge
Norman, OK 73026

Issues 1-10

2. In-Office Ancillary Services Exception

This exception has created a loophole allowing expansion of the number of physician practices that own physical therapy services. These services are often provided by unlicensed and untrained individuals and billed under the physician's provider number as "physical therapy". Without a full assessment of functional abilities these services are palliative at best, may in fact be harmful and are a waste of Medicare money.

The potential for abuse in these situations is enormous since the physician stands to profit from every patient that receives physical therapy. Patient choice is effectively taken away. In our area of practice not only do physicians who own their own physical therapy practice not inform the patients of their right to receive care at a clinic of their choice, they actively restrict their choice by telling them they must receive their care in the physician's clinic. Even patients who are well informed of their rights and seek to exercise them have backed down for fear of alienating their physicians. These are problems I hear about on a weekly basis and at least five of my personal friends or relatives have experienced this situation over the past year.

Submitter : **Mr. Jim** **Date: 06/17/2004**

Organization : **APTA**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. McClellan,
I am a Graduate Physical Therapy Assistant practicing in Oklahoma and I am very concerned about the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase 11)." I would hope the unchecked power and monopoly possibilities are obvious enough to kill this before it gets any further. At this moment Physicians' referrals for physical therapy are costing Medicare and Medicaid millions by allowing doctors to use up a patient's Medicare and Medicaid benefits for simple pathologies they can?t ?fix? before referring them to physical therapy. Direct access for physical therapy would save Medicare and Medicaid millions or billions. The possibilities of further and more serious abuse if Phase 111 does not kill this would almost be unlimited. In this time of corporate scandals by the numbers we can't assume ethical purity from any group and the "very loose" "in office ancillary services" exception virtually leaves it wide open for abuse. The excuse some doctors use as to why they should make referrals to physical therapy is therapist's lack of education. This is strange since they feel they should refer to a ?Professional with a Master's degree? (therapist) and yet allow their physician's assistant with a four year degree to diagnose, treat, and dish out medication like a doctor. My mother received an itemized bill from a specialist she was referred to by her doctor and it included a referral charge. She called the specialist?s office and questioned them about it and they were very bold to tell her basically that is the way it is. My question is; do we want to further empower that sort of business? A person would not have to investigate very far to see the folly of allowing this kind of referral power, if common sense didn?t rule the decision. This is not a job to me and I am a patient advocate. Our citizens are being victimized already are we not going to stand up for them. Predators prey on the old, young, sick, and weak. Sadly some are uncivilized enough to be that way. I pray you will not allow this to happen. Thank you Sir for considering my comments,
Jim L.

Submitter : **Date: 06/17/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

TO: Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

SUBJECT: Medicare Program: Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

I am a physical therapist who has worked in my field for 12 years. I have treated in the outpatient setting all of these years where I have treated a variety of diagnoses. My strongest areas are spine rehabilitation and lymphedema rehabilitation. Neurological rehabilitation and geriatric rehabilitation are other areas that I have strong interests in and have treated frequently. For two years, I also managed a work hardening program in Texas. I received my Bachelor's of Science degree at the University Health Science Center in San Antonio, TX in May of 2002.

I am writing in regard to the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I am very concerned about the ambiguity in the explanation regarding exceptions to the rules and hope that these could be more distinct in the subsequent "phase III" regulations.

Due to the ambiguity of the the exceptions, physicians would have a tendency to abuse the use of clinics that they have a vested interest because they would have a fiscal incentive to treat the patient beyond what is reasonable and necessary. It is the responsibility of a therapist to use his evaluative skills to determine if a patient has met his or her goals and is able to independently able to continue progression at home, but this can be compromised when a physician who has vested interest in a clinic dictates to the therapist to continue treatment beyond what is reasonal and necessary. The potential for conflict of interest is huge, and the result is abuse of Medicare dollars, job loss, and the therapist being fined or jailed due to this abuse. if he/she follow through with the physician's orders.
If physical therapists were given some autonomy to monitor established patients without subsequent referrals from the physician, some of the above mentioned issues could be alleviated.

Another reason that I feel that this ruling should be clarified is because I have personally run into patients that were forced to go to a physician-owned clinic regardless of the fact that they wished to return to our clinic. According to my knowledge of patient's rights, the patient has the right to choose where they receive physical therapy services. Unfortunately, the patients that were very adamant about returning to our clinic were told that they could no longer be that physician's patient if they chose to come to us. I also have noticed incidences where private outpatient clinics have made "arrangements" with physicians to promote a referral base for their clinic. Some patients again wished to come back to our clinic but were coerced into going to another clinic despite their wishes. Since I work for a hospital-based outpatient clinic, we are required to show no favoritism or set up "arrangements" with physicians.

I have also heard of physicians performing modalities in their clinic by unqualified staff and billing them as physical therapy. If a therapist did this and billed for it, it would be considered fraudulent and he or she could be fined. The "in-office ancillary services" provision does not prevent this from happening in physicians' offices.

I hope that my comments help to shed some light on the abuses that are currently occurring and would continue to occur with the current ruling. Thank you for your time and consideration.

Submitter : **Mr. Morgan Hills** **Date: 06/17/2004**

Organization : **Nayden Rehabilitation Clinic, UConn.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Morgan Hills MBA, PT CHE
Director of Clinical Operations, Nayden Rehabilitation Clinic
University of Connecticut, Storrs CT 06269- 4249

I wish to comment on the March 26 interim final rule on 'Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).'

I am concerned about the interim final rule and request a more thorough review of concept of In-Office ancillary services?. The current research indicates there is evidence that increasing the un-regulated supply of medical services drives the utilization for that modality or service upward. Stark II does nothing to curb to economic reality that increasing the un-regulated availability of a service owned by a driver of that service will increase the use of that service.

The lack of evidence-based practice related to orthopedic injuries and their rehabilitation fuels the physician motive to create an internal environment that they can control.

In physicians' offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The 'in-office ancillary services' provision does nothing to prevent this practice from occurring. The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. In an era where each clinical discipline is spending considerable resources to create evidence-based interventions to prove their effectiveness and to ensure that they are a responsible fiduciary, Stark II undermines the efforts of the entire rehabilitation industry.

You will hear and read hundreds of cases of poor care and adverse outcomes stemming from this legislation. I don't believe that physician enter into these relationships with the intent to over utilize services and provide substandard care. While I believe in general the physicians motives are altruistic, the business model and financial incentive system adopted by physicians in these In-office clinics subverts the efforts of physical therapists pursuing clinical excellence through the use of evidence-based practice.

Submitter : **Mr. Craig Jones** **Date: 06/17/2004**

Organization : **Oklahoma Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

The provision in question stipulates that hospitals may only pay for "additional incremental expenses" when assisting an established medical practice with the recruitment of a physician. The provision is intended to eliminate any financial benefit that physicians, who are already established in a community, may gain when a hospital assists them to recruit physicians.

However, it appears an unintended consequence of the provision will severely limit the ability of hospitals to replace deceased or departing physicians. Hospitals will be hampered in their efforts to address their community?s need for medical services through physician recruitment and they will find it more difficult to retain physicians already practicing in their service area.

Prior to this new provision, a hospital could assist an established medical practice to find a new partner by providing a salary or guaranteed income to the incoming physician and allocating to the new physician a pro rata share of office space, equipment, personnel and other expenses associated with the physician's practice for one year. At the end of one year, the new physician, now established in the community, would pay for his or her share of the office overhead. This would stabilize the practice, ensuring the presence of an established physician's staff and preserving continuity of care for the deceased or departed physician's patients.

Because of the new provision, a hospital is prohibited from allocating to a new physician?s practice overhead expenses previously paid for by the deceased or departed physician, such as office space rental, personnel and equipment. In such instances, the established physician who lost a partner would see his or her practice overhead double and in many cases would be unable to recruit a new partner due to the limited assistance available.

To meet the needs of the community, the hospital would then be obliged to recruit a new physician into a solo practice setting, in which case it could assist the new doctor for one year with expenses such as office space rental, personnel and equipment, unnecessarily duplicating such expenses. However, finding physicians willing to practice in a solo setting, particularly in small or rural communities, is very difficult today because the great majority of physicians seek group practice settings. Due to the new Stark II provision many hospitals would find physician recruitment to be prolonged and problematic.

In the scenario above, the established physician who lost a partner would find his/her overhead exceeding revenues since, without a partner, his/her workload would double. The physician then might well relocate to another community, generally a more populous area that can sustain a group practice. This type of doctor attrition is common throughout Oklahoma communities and it compromises both patient care and the viability of community and rural hospitals. Without the option of recruiting into a group practice setting, recruitment becomes exponentially more difficult and the chance of attracting physicians to small or rural areas is severely diminished.

In any scenario involving the death, relocation, or retirement of a physician it can be reasonably argued that no financial gain accrues to an established medical practice when a hospital assists in the replacement of such physicians. Doctors are merely seeking to replace what they have lost due to the death, relocation, or retirement of a physician.

I am asking CMS to consider the creation of a succession exemption to the provision at issue. This would allow hospitals to provide for office space, personnel and equipment rental to an established medical practice in instances where a deceased, relocating, or retiring physician is being replaced. I believe this would keep the intention of the provision intact while allowing hospitals to serve the medical needs of their communities. Thank you for considering this request.

CMS-1810-IFC-37-Attach-1.doc

Attach # 37

June 11, 2004

Mark B. McClellan, M.D., Ph.D.,
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue
Washington, D.C. 20201

RE: STARK II LIMITS ON PHYSICIAN RECRUITING (Sent Via E-Mail, 6-17-04)

Dear Dr. McClellan:

On behalf of the Oklahoma Hospital Association and its 128 member hospitals, I write to express my concern regarding a provision of the Stark II regulations promulgated on March 26, 2004.

The provision in question stipulates that hospitals may only pay for "additional incremental expenses" when assisting an established medical practice with the recruitment of a physician. The provision is intended to eliminate any financial benefit that physicians, who are already established in a community, may gain when a hospital assists them to recruit physicians.

However, it appears an unintended consequence of the provision will severely limit the ability of hospitals to replace deceased or departing physicians. Hospitals will be hampered in their efforts to address their community's need for medical services through physician recruitment and they will find it more difficult to retain physicians already practicing in their service area.

Prior to this new provision, a hospital could assist an established medical practice to find a new partner by providing a salary or guaranteed income to the incoming physician and allocating to the new physician a pro rata share of office space, equipment, personnel and other expenses associated with the physician's practice for one year. At the end of one year, the new physician, now established in the community, would pay for his or her share of the office overhead. This would stabilize the practice, ensuring the presence of an established physician's staff and preserving continuity of care for the deceased or departed physician's patients.

Because of the new provision, a hospital is prohibited from allocating to a new physician's practice overhead expenses previously paid for by the deceased or departed physician, such as office space rental, personnel and equipment. In such instances, the established physician who lost a partner would

see his or her practice overhead double and in many cases would be unable to recruit a new partner due to the limited assistance available.

To meet the needs of the community, the hospital would then be obliged to recruit a new physician into a solo practice setting, in which case it could assist the new doctor for one year with expenses such as office space rental, personnel and equipment, unnecessarily duplicating such expenses. However, finding physicians willing to practice in a solo setting, particularly in small or rural communities, is very difficult today because the great majority of physicians seek group practice settings. Due to the new Stark II provision many hospitals would find physician recruitment to be prolonged and problematic.

Retaining physicians also would become more difficult. In the scenario above, the established physician who lost a partner would find his or her overhead exceeding revenues since, without a partner, his or her workload would double. The physician then might well relocate to another community, generally a more populous area that can sustain a group practice. This type of doctor attrition is common throughout rural Oklahoma communities and it compromises both patient care and the viability of community and rural hospitals. Without the option of recruiting into a group practice setting, recruitment becomes exponentially more difficult and the chance of attracting physicians to small or rural areas is severely diminished.

In any scenario involving the death, relocation, or retirement of a physician it can be reasonably argued that no financial gain accrues to an established medical practice when a hospital assists in the replacement of such physicians. These are succession scenarios, where the established doctors are merely seeking to replace what they have lost due to the death, relocation, or retirement of a physician.

Therefore, on behalf of hospitals across Oklahoma, I am asking CMS to consider the creation of a succession exemption to the provision at issue. This would allow hospitals to provide for office space, personnel and equipment rental to an established medical practice in instances where a deceased, relocating, or retiring physician is being replaced. I believe this would keep the intention of the provision intact while allowing hospitals to serve the medical needs of their communities.

Thank you for considering this request.

Sincerely,

Craig W. Jones, FACHE
President

CWJ/cj
Centers for Medicare and Medicaid
June 11, 2004
Page 2

Submitter : **Mr. Robert Menaul** **Date: 06/17/2004**

Organization : **Washington State Hospital Association**

Category : **Hospital**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

Reference: CMS-1810-IFC

The rules must be changed to recognize the arrangements in already existing contracts, which were made in good faith under the rules and understanding in place when the contracts were made.

Submitter : **Mr. richard carlson** **Date: 06/17/2004**

Organization : **carlson therapy network**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

the regulations purpose was to prevent referral for profit. the new regulation actually makes it easier to refer for profit. to the point where many drs. are now going into the business or taking over existing PT practices because they control the referrals. this is one more example of regulation that is not working for anyone.

Submitter : **Mr. Jonathan Cooperman** **Date: 06/17/2004**

Organization : **Ohio Physical Therapy Association**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Both potential and actual conflict of interest exists when physicians and other referring entities are allowed to have a financial interest in the services to which they refer. My main concern is with physicians who own physical therapy services. This is indistinguishable from physicians having ownership interests in a pharmacy - which is no longer allowed. In these instances, patients are seldom given the choice of facilities to go to to recieve services. Or, the financial interest is not disclosed. The Mitchell Study (1994) demonstrated overutilization in these types of settings.

With regard to "incident to" billing, Medicare will allow a physician to bill incident to their services even when a non-Medicare qualified practitioner delivers the service. In all other instances, Medicare requires the provider to be "qualified", e.g., only a licensed physical therapist or physical therapist assistant can provide physical therapy services. This is inconsistent, to say the least.

Thank you

CMS-1810-IFC-40-Attach-1.pdf

Research Report

A Comparison of Resource Use and Cost in Direct Access Versus Physician Referral Episodes of Physical Therapy

Background and Purpose. Access to physical therapy in many states is contingent on prescription or referral by a physician. Other states have enacted direct access legislation enabling consumers to obtain physical therapy without a physician referral. Critics of direct access cite potential overutilization of services, increased costs, and inappropriate care. **Methods and Results.** Using paid claims data for the period 1989 to 1993 from Blue Cross-Blue Shield of Maryland, a direct access state, we compiled episodes of physical therapy for acute musculoskeletal disorders and categorized them as direct access (n=252) or physician referral (n=353) using algorithms devised by a clinician advisory panel. Relative to physician referral episodes, direct access episodes encompassed fewer numbers of services (7.6 versus 12.2 physical therapy office visits) and substantially less cost ($1,004 versus $2,236). **Conclusion and Discussion.** Direct access episodes were shorter, encompassed fewer numbers of services, and were less costly than those classified as physician referral episodes. There are several potential reasons why this may be the case, such as lower severity of the patient's condition, overutilization of services by physicians, and underutilization of services by physical therapists. Concern that direct access will result in overutilization of services or will increase costs appears to be unwarranted. [Mitchell JM, de Lissovoy G. A comparison of resource use and cost in direct access versus physician referral episodes of physical therapy. *Phys Ther.* 1997;77:10–18.]

Key Words: *Direct access, Episode of care, Physical therapy, Physician referral.*

Jean M Mitchell

Gregory de Lissovoy

In many states, the practice of physical therapy is contingent on the prescription or referral by a physician, a requirement that effectively limits access to physical therapy services. Other states have enacted legislation permitting direct access—the ability of a health care consumer to freely visit a physical therapist without first securing referral from a physician. In these states, licensed therapists may evaluate patients without referrals and make autonomous decisions about subsequent clinical management.[1]

Although direct access in the United States dates back to 1957, the majority of states with direct access statutes have permitted physical therapists to treat and evaluate patients without physician referral only since the 1980s.[2] No published research has evaluated the impact of physician referral versus direct access on utilization and costs of care for persons undergoing physical therapy. This exploratory study compared the utilization of health care resources and third-party medical expenditures for persons receiving physical therapy under direct access versus those referred for such services by a physician.

We begin this report by providing some background on direct access to physical therapy. Next, we describe a study method based on the analysis of episodes of physical therapy created using Blue Cross-Blue Shield claims data. The final section discusses empirical results, study limitations, and implications for public policy.

Background

Thirty states allow physical therapists to treat and evaluate patients without physician referral, and an additional 14 states allow physical therapists to evaluate, but not treat, patients without referral.[2] Twenty states and the District of Columbia require physician referral as a prerequisite for treatment by a physical therapist.[1]

Advocates for physical therapists to have direct access argue that direct access extends consumers' choice of health care providers, improves access to services that promote prevention and rehabilitation, and reduces delays before commencing therapy. Proponents further argue that direct access may result in cost savings by avoiding the referring physician's fees and related ancillary services (eg, roentgenograms, laboratory tests). Supporters of direct access also point out that other nonphysician providers, such as chiropractors and clinical psychologists, do not require physician referrals or screening evaluations.[1,3]

Critics of direct access argue that physical therapists may overlook serious medical conditions and for this reason contend that all patients should be screened initially by physicians.[1,3] The American Medical Association (AMA) contends that although allied health care professionals are useful as physician extenders, they would not serve the public as well in an autonomous role.[4] The AMA and the American Academy of Orthopaedic Surgeons oppose independent practitioner status for physical ther-

JM Mitchell, PhD, is Associate Professor, Graduate Public Policy Program, Georgetown University, 3600 N St NW, Room 105, Washington, DC 20007 (USA) (mitchejm@gunet.georgetown.edu). Address all correspondence to Dr Mitchell.

G de Lissovoy, PhD, MPH, is Vice President, MEDTAP International, 7101 Wisconsin Ave NW, Suite 600, Bethesda, MD 20814.

An earlier version of this article was presented at the Winter Meeting of the Econometric Society, Washington, DC, January 6, 1995.

This research was supported by the American Physical Therapy Association.

This article was submitted November 30, 1995, and was accepted September 23, 1996.

apists because of concerns about improper diagnosis, inappropriate care, and the potential for increased costs.[5] State medical societies and chiropractic groups have also been major adversaries of direct access. A common concern is that direct access legislation may lead therapists to diagnose and treat beyond their level of competency, thus erroneously assuming the role of physician.[6,7]

Previous research on direct access to physical therapy has considered the incidence of direct access practice,[1,8,9] patient and provider satisfaction with physical therapy received under direct access,[2,10] and physical therapist and patient opinions about direct access to physical therapy.[11–13] The limited available evidence from these published studies indicates that direct access has had only a minimal impact on physical therapy practice.[1,8–10] In some of these studies,[1,10] however, physical therapists expressed greater job satisfaction and patients preferred the more expeditious treatment received.[1,10]

Method

The Data

The study is based on health insurance claims data furnished by Blue Cross-Blue Shield of Maryland. This insurer has been reimbursing for physical therapy provided under direct access since 1986, so the coverage is well established. Group insurance paid claims represent a broad cross section of the employed population and their dependents. Because these individuals obtained health insurance through employer-sponsored plans, the effect of adverse selection, which characterizes persons with individual policies (or no insurance), is minimized. Although the data encompassed a number of different employer groups, the range of services covered and the level of reimbursement among groups in the sample were virtually identical. The plans covered only working-age adults and their children; persons eligible for Medicare (age 65 years and over) were not examined.

The data set included all paid claims for the calendar years 1989 through mid-1993. The initial file contained 1.7 million claims in four categories: professional fees, outpatient services (ie, radiology, laboratory, and ancillary services), prescription drugs, and hospitalization. Each record contained a unique beneficiary identification number, date of service, type of service, submitted charge, amount reimbursed by Blue Cross-Blue Shield, and subscriber copayment amount. Claims for professional services also included a designation of clinical specialty (eg, licensed physical therapist, orthopedic physician, chiropractor), Current Procedural Terminology (CPT) code for type of service, and ICD-9-CM (*International Classification of Diseases, 9th Revision, Clinical Modification*) diagnostic code for the condition.

Analytical Framework—Episodes of Physical Therapy

Health insurance claim files comprise a series of discrete transactions that document beneficiary encounters with the medical care system. Claims records can be grouped sequentially to construct "episodes of care" that encompass a series of temporally contiguous health care services related to treatment of a specific illness or health condition.[14] Recent studies have used the episodes framework to examine the decision to seek medical care, subsequent utilization of services, and expenditures.[14–20]

The main advantage of using claims data for health services research is that observations on a large number of individuals over an extended period of time can be obtained at relatively low cost. When compared with audits of medical records, this method for assessing medical care has limitations. First, only sparse information is available for each encounter, and this information has been collected for administrative rather than clinical purposes. Second, the validity of episode construction is contingent on algorithms created by the investigator. Error may arise from either the inclusion of irrelevant transactions or the exclusion of transactions actually related to the condition of interest. Third, a subject's health history and clinical status at the start of an episode must be inferred from the pattern of prior claims. Similarly, outcome of treatment following an episode must also be deduced from the presence (or absence) of subsequent claims. Finally, medical expenditures paid directly by the patient, such as charges for over-the-counter drugs, are not documented (although this is also true of medical records).

Episodes of physical therapy were constructed with guidance from an advisory panel of five licensed health care professionals practicing in Maryland. Panel members were selected from a list of candidates provided by the Maryland Physical Therapy Association in response to a request for names of active practitioners specializing in physical therapy and orthopedic medicine. The panel consisted of three physical therapists and two physicians (an orthopedic surgeon and a physical medicine/rehabilitation specialist). Additional insight on the idiosyncracies of the claims data was provided by the medical director of Maryland Blue Cross-Blue Shield. Panel functions were to develop criteria for constructing episodes of care and to establish rules for classifying episodes as either direct access or physician referral.

An episode of physical therapy should encompass all services provided in relation to a specific illness or condition during a suitable time period.[14] At the time of this study, physical therapy performed by a licensed

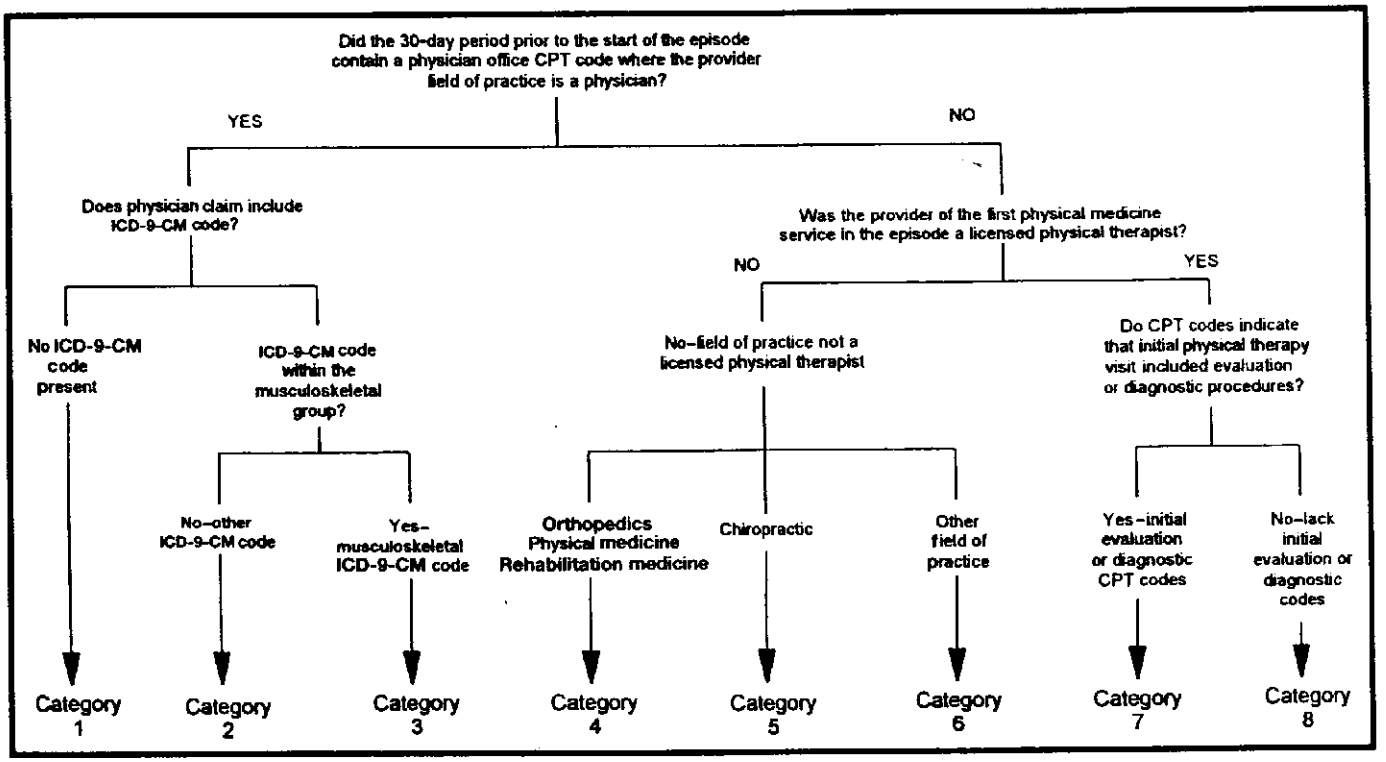

Figure.
Algorithm for categorization of episodes of care (CPT=Current Procedural Terminology, ICD-9-CM=*International Classification of Diseases, 9th Revision, Clinical Modification*). Note: musculoskeletal ICD-9-CM codes include 710–739 and 840–848.

physical therapist was billed under "physical medicine" procedure (CPT) codes. Other health care professionals such as physicians and chiropractors also utilize these CPT codes for services performed, even though they are not licensed physical therapists and thus may not be performing identical services. For purposes of classification, we refer to episodes of care defined by physical medicine procedures as physical therapy, irrespective of the health care provider who rendered the service.

We first identified all individuals who had at least one physical therapy claim during period January 1990 through December 1991. Approximately 11,600 individuals met this criterion. We then sorted each individual's claims for the period 1989 through 1993 in chronological order by date of service and created a window of observation extending from 12 months prior to the date of the first physical therapy service to 12 months after the last physical therapy service. This window contained all or part of one or more episodes of care.

Criteria for marking an episode's beginning and end points were devised by the advisory panel. We examined the 30-day period prior to the first physical therapy claim that occurred during the period January 1990 through December 1991. If no physical therapy claim occurred during the 30 days preceding the first physical therapy service, this date marked the beginning of an episode of care. If a physical therapy claim did occur within that 30-day period, the next 30-day period prior to that claim was reviewed. This process was repeated for each preceding 30-day period until reaching the initial transaction in the data set (January 1, 1989).

We then identified the last physical therapy service that occurred during the period January 1990 through December 1991. The panel recommended examining a 45-day period subsequent to this encounter. If no physical therapy claims were recorded during this 45-day period, then the last physical therapy service marked the end of the last episode. Alternatively, if a physical therapy service was recorded during this subsequent 45 days, the episode was deemed incomplete and the next 45-day period following the physical therapy service was examined. Again, this procedure was repeated until reaching the end of the data set (December 31, 1992). Using this approach, we created a new file containing observations on approximately 3,500 persons who had at least one episode of physical therapy that began and ended during the period 1989 through 1992.

These beginning and end points could actually mark different episodes. For this reason, we next examined the 45-day period occurring after the date established as the commencement point of the episode denoted by the first physical therapy service in order to distinguish among multiple episodes. If a physical therapy encounter occurred within 45 days after the commencement of

Table 1.
Comparison of Mean Values for Resource Utilization and Cost in Direct Access Episodes Versus Physician Referral Episodes

Variable	Direct Access (n=252)	Physician Referral (n=353)	Difference*
Physical therapy claims	20.2 (82.9)	33.6 (39.0)	13.4
Physical therapy office visits	7.6 (9.1)	12.2 (12.8)	4.6
Physical therapy claims paid ($)	566 (716)	890 (941)	324
Drug claims	1.47 (4.0)	3.13 (7.72)	1.66
Drug claims paid ($)	36 (109)	78 (223)	42
Radiology claims	0.32 (1.03)	1.02 (1.86)	0.70
Radiology claims paid ($)	44 (190)	175 (541)	131
Hospital admissions	0.25 (0.80)	0.64 (1.17)	0.39
Hospital admissions paid ($)	83 (402)	397 (1,003)	315
Total claims paid ($)	1,004 (2,030)	2,236 (2,827)	1,232

* $P < .01$.

an episode, the two encounters were considered part of a single episode. This procedure was repeated for all subsequent physical therapy services. If a period of 45 days occurred in which there was no physical therapy service, then the date of the last physical therapy service prior to the 45 days in which no physical therapy services were rendered marked the end of the episode. If another physical therapy service was observed beyond this 45-day posttreatment period, then this date marked the commencement point of another episode.

Classification of Episodes

After creating episodes of physical therapy, the next task was to classify episodes as either direct access or physician referral. Because claims data do not differentiate direct access episodes from those that were referred, we adopted decision rules recommended by the advisory panel. The classification algorithm, depicted in the Figure, differentiated eight categories of episodes.

We first examined the 30-day period prior to the first physical therapy service within each episode to determine whether there was a claim for a physician service with either ICD-9-CM codes or CPT codes indicating a condition that could reasonably lead to the provision of physical therapy. The panel recommended a focus on only acute and sporadic musculoskeletal-related disorders (ICD-9-CM codes 710–739 and 840–848). The 30-day period was deemed conservative because a typical person receiving a prescription for physical therapy could likely schedule an initial appointment within 2 weeks. We then determined whether claims for physical therapy services within the episode were rendered by a licensed physical therapist in order to exclude physical therapy services rendered by other providers (eg, chiropractors). If these criteria were met, the episode was classified as a physician referral (category 3).

Episodes for which there was no indication that a physician encounter occurred in the 30-day period preceding the first physical therapy service were then examined to determine whether services were provided by a licensed physical therapist. Category 7 contained episodes in which claims for diagnostic or evaluation procedures were recorded for the first encounter with the physical therapist. Criteria for category 8 were identical to those for category 7 except that no initial claims for diagnostic evaluation were observed. Categories 7 and 8 were grouped together and comprise the direct access episodes. Other categories (1, 2, 4, 5, and 6) did not meet the criteria for either direct access or physician referral and were excluded from the analysis.

We then visually inspected the set of transactions comprising episodes in categories 3, 7, and 8. Following recommendations of the advisory panel, we excluded episodes that involved claims for chronic musculoskeletal conditions (eg, arthritis, cancer, multiple sclerosis, osteoporosis). We also excluded episodes in which the patient appeared to have multiple comorbidities. These episodes tended to contain visits to a number of different providers for a range of health problems, making it impossible to determine whether physical therapy received by the patient represented treatment for the initial encounter with a musculoskeletal diagnosis. The final analysis file comprised 252 direct access and 353 physician referral episodes.

Statistical Analyses

We first compared the mean values of utilization and cost variables for direct access versus physician referral episodes using a two-tailed test for differences between means, with a null hypothesis of no difference (Tab. 1). Because simple comparisons do not control for confounding factors, we also used multiple regression analysis to compare direct access and physician referral episodes with respect to utilization (number of physical therapy visits) and costs. Definitions of variables used in the analysis are presented in Table 2. Summary statistics for the dependent and explanatory variables follow each definition.

Table 2.
Definitions of Variables Used in Regression Analyses

Variable	Definition
Dependent	
Logarithm-physical therapy visits	Natural logarithm of the count of physical therapy office visits during the episode ($\bar{X}$=1.78, SD=1.12)
Logarithm-physical therapy paid	Natural logarithm of total dollar amount reimbursed by Blue Cross-Blue Shield for physical therapy services received by patient during the episode ($\bar{X}$=6.03, SD=1.26)
Logarithm-total paid	Natural logarithm of total dollar amount reimbursed by Blue Cross-Blue Shield for all services received by patient during the physical therapy episode ($\bar{X}$=6.61, SD=1.48)
Independent	
Direct access	Dichotomous variable: 1 if episode was direct access (category 7 or 8), 0 if episode was physician referral (category 3) ($\bar{X}$=0.58, SD=0.49)
Female	Dichotomous variable: 1 if the beneficiary gender was female, 0 if male ($\bar{X}$=0.63, SD=0.48)
Age	Beneficiary age (in years) ($\bar{X}$=42.19, SD=12.5)
Drugs	Dichotomous variable: 1 if the episode contained any claims for prescription drugs, 0 if otherwise ($\bar{X}$=0.42, SD=0.49)
Hospital	Dichotomous variable: 1 if the episode contained any claims for inpatient or outpatient services provided by an acute care general hospital, 0 if otherwise ($\bar{X}$=0.25, SD=0.44)
Radiology	Dichotomous variable: 1 if the episode contained any claims for diagnostic radiology services provided by a physician or freestanding imaging center, 0 if otherwise ($\bar{X}$=0.29, SD=0.46)
Direct access-drugs	Interaction of "direct access" and "drugs": 1 if a direct access episode contained prescription drug claims; 0 if otherwise ($\bar{X}$=0.12, SD=0.32)
Direct access-hospital	Interaction of "direct access" and "hospital": 1 if a direct access episode contained claims for hospital services; 0 if otherwise ($\bar{X}$=0.55, SD=0.23)
Direct access-radiology	Interaction of "direct access" and "radiology": 1 if a direct access episode contained diagnostic radiology claims performed at a physician office or freestanding imaging center, 0 if otherwise ($\bar{X}$=0.55, SD=0.23)

The total cost of each episode of physical therapy was computed as the sum of all paid claims for services and drugs provided during the episode. A logarithmic transformation was performed on the dependent variables to adjust for observed right-skewed distribution, which is typical of medical utilization and expenditure data.[21] The primary explanatory variable of interest was referral status. The dichotomous variable "direct access" identified episodes in categories 7 and 8 while category 3 (physician referral) served as the reference category. Three dichotomous variables were constructed to identify episodes that contained any claims for hospital services (hospital), pharmaceuticals (drugs), and diagnostic imaging rendered via a physician's office or freestanding center (radiology). All three categories of service must be prescribed by a physician and thus suggest greater severity of illness than episodes not including these services. To further distinguish episodes involving any or all of these services by referral status, we constructed interaction terms. These terms identified direct access episodes that involved claims for hospital services (direct access-hospital), pharmaceuticals (direct access-drugs), and imaging procedures (direct access-radiology). Additional variables controlled for age and gender.

Results

Table 1 shows simple comparisons using tests for differences between means. Physician referral episodes were characterized by 13.4 (67%) more physical therapy claims and 4.6 (60%) more office visits than direct access episodes ($P<.0001$). Reimbursements for physical therapy services were, on average, $324 (57%) more expensive for physician referral episodes when compared with direct access episodes ($P<.0001$). Total paid claims averaged $2,236 for physician referral episodes and $1,004 for direct access episodes; this $1,232 difference signifies that the cost to Blue Cross-Blue Shield for physician referral episodes exceeded the cost for direct access episodes by about 123% ($P<.001$).

Table 3 displays the results of regressions where the dependent variables were the number of physical therapy visits, paid claims for physical therapy services, and total paid claims for all services and drugs. In each case, the dependent variable has been transformed and is expressed as its natural logarithm. Adjusted multiple regression (R^2) values indicate that models account for about 25% of the variation in the logarithm of physical therapy visits and for about 21% for the logarithm of physical therapy claims. The regression explains 48% of

Table 3.
Regression Estimates for Number of Physical Therapy Visits, Paid Claims for Physical Therapy Services, and Paid Claims for All Services[a]

Independent Variable	Number of Physical Therapy Visits (Log)	Paid Claims for Physical Therapy Services (Log)	Total Paid Claims for All Services and Drugs (Log)
Direct access[b]	−0.503** (0.111)	−0.519** (0.134)	−0.864** (0.125)
Drugs	0.361** (0.10488)	0.346** (0.124)	0.425** (0.116)
Hospital	0.268* (0.121)	0.274* (0.142)	0.934** (0.134)
Radiology	0.479** (0.117)	0.534** (0.138)	0.853** (0.130)
Direct access-hospital[c]	0.127 (0.251)	0.106 (0.295)	0.133 (0.269)
Direct access-drugs[c]	0.601** (0.178)	0.644* (0.210)	0.685** (0.198)
Direct access-radiology[c]	−0.298 (0.248)	−0.107 (0.292)	0.249 (0.272)
Female[b]	0.112 (0.083)	0.161 (0.098)	0.149 (0.092)
Age	−5.643 (0.003)	−0.002 (0.004)	−0.002 (0.004)
Constant[c]	1.504** (0.155)	5.756** (0.184)	6.191** (0.173)
Adjusted R^2	.247	.212	.479
F statistic	22.94	17.34	61.79

[a] Standard errors of regression coefficients are in parentheses. Single asterisk (*) indicates $P < .05$, double asterisk (**) indicates $P < .01$.
[b] Reference category for "direct access" is "physician referral"; reference category for "female" is "male."
[c] Interaction term between "direct access" and named variable.

Table 4.
Percentage of Difference in Utilization and Cost for Direct Access Episodes Relative to Physician Referral Episodes[a]

Model Dependent Variable	Difference Relative to Physician Referral Episode
Number of physical therapy visits	−65%
Paid claims for physical therapy services	−68%
Total paid claims for all services and drugs	−137%

[a] Based on regression results shown in Table 3.

the variation in total paid claims for all services and drugs.

In each model, the coefficient for the variable "direct access" was negative ($P<.01$), implying that episodes of physical therapy classified as direct access involved fewer visits and lower costs relative to episodes classified as physician referral. Coefficients for the variables identifying episodes of physical therapy that included claims for drugs, hospitalizations, or radiology were positive and significant at $P<.01$. These findings imply that physician referral episodes with claims for any or all of these services are characterized by more physical therapy visits, higher paid claims for physical therapy services, and higher total costs per episode relative to physician referral episodes that do not involve drugs, hospitalizations, or imaging procedures.

Interaction terms that identified direct access episodes involving hospital inpatient services or imaging were not significant, implying that such services have little bearing on use of physical therapy or episode costs. By contrast, direct access episodes that contained one or more claims for pharmaceuticals were associated with more physical therapy visits, higher paid claims for physical therapy, and higher total episode costs. The variables controlling for gender and age had negligible effects on both utilization and costs.

Because log-transformed results cannot be interpreted directly, the coefficients for the direct access variables have been converted to percentages (Tab. 4). Relative to physician referral episodes, those episodes classified as direct access involved 65% fewer physical therapy visits and 68% lower paid claims for physical therapy services.

The lower utilization rates for all services that characterized direct access episodes is best seen by examining total episode costs. When measured in terms of paid claims, direct access episodes were 137% less expensive than those classified as physician referral.

Discussion

Thirty states have legislation enabling patients to obtain physical therapy services without physician referral (direct access). The public policy objective for direct access statutes is to give the consumer the ability to select the most appropriate source of care. Consumers, however, should be protected against underprovision of care that could occur if physician services were not provided when medically necessary.

Using Blue Cross-Blue Shield claims data from Maryland (a state with direct access statutes), we compared episodes of physical therapy categorized as direct access relative to those classed as physician referral and found substantial differences. Direct access episodes were shorter, encompassed fewer numbers of services, and were less costly than those classed as physician referral. Some direct access episodes included claims for inpatient hospital care, drugs, or outpatient radiology—all services requiring physician prescription. The use of hospital services or imaging procedures during direct access episodes had a negligible relationship with the number of physical therapy visits or episode costs. In contrast, direct access episodes that contained claims for drugs were associated with greater use of physical therapy and higher costs. Physician referral episodes that included any or all of these three items were associated with higher utilization and costs.

Because our study was based on health insurance claims data, these findings must be interpreted with caution. The method relied on sorting algorithms to identify episodes of care and to distinguish direct access from physician referral. We cannot be certain that resource use attributed to episodes and their classification accurately identified each patient's course of therapy. In addition, we have no way of knowing whether the lower cost of direct access episodes was due to underprovision of care or whether the greater resource intensity and cost of physician referral episodes reflects overprovision of care.

Conclusions

We conclude that direct access episodes, on average, are short in duration and relatively inexpensive. Potential explanations why this may be the case include lower severity of the patient's condition, overutilization of services by physicians, and underutilization of services by physical therapists. Concern that direct access will result in overutilization of services or will increase costs appears unwarranted. The fact that some direct access episodes included physician-prescribed services indicates that physical therapists are making referrals to physicians. Thus, our study offers evidence that public policy objectives for direct access to physical therapy services are being achieved.

Acknowledgments

We acknowledge the invaluable guidance provided by advisory panel members Richard Hinton, MD, Cindy Juris, MD, Annette Iglarsh, PhD, PT, Rod Schlegel, PT, and Mark Valente, PT. Insight on use of Maryland Blue Cross-Blue Shield claims data was provided by Alan Wright, MD. Chuanfa Guo provided expert computer programming in construction of episode-of-care files. Emily Tobias Shumsky assisted in the detailed inspection of final-analysis files. Comments on an earlier version of this manuscript were provided by Jack Hadley, Vivian Hamilton, and Robert Hurley.

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Submitter : **Dr. Peter Blanpied** **Date: 06/17/2004**

Organization : **University of Rhode Island**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

In-Office Ancillary Services Exception is too broad and non-specific. Physical Therapy services should be provided ONLY by individuals licensed as, or supervised by, a Physical Therapist.

Submitter : **Date: 06/17/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist in Shreveport, LA, and currently work in an outpatient clinic in close relationship with several physiatrist, orthopedic surgeons, neurosurgeons, internal medicine doctors and family prctice physicians. We have fostered these relationships because we have proven ourselves very beneficial to their patients favorable outcomes. Not only those looking to recover from surgery quicker, but also those wishing to avoid surgery at all cost. There is no question that physical therapy is a vital part of a complete medical model for getting paitents to their maximal potential. Just like Physicians refer different patients with problems that would best be seen by another specialist, physical tharapy should be viewed as the same importance. There should be no allowance for physical therapy to be billed under a physicians provider number because there is no check and balance system to regulate whether a licensed physical tharapist actually performed these specialized services. Just as you would not want a neurosurgeon performing a surgery for an abdominal aortic aneurysm, you would not want an unskilled person performing physical tharpy. The neurosurgeon would definatly be skilled enough and with time to pracitce the procedure could perform the surgery without a problem, but it is not their specialty and would not be the best choice if you were the patient. CMS has tried to keep a tight handle on over billing and watching for services that are deemed not medically necessary. I think if you continue to allow loop holes for any party, in this case physicians, to benefit from increasing referrals so they can recieve more benefit that extends beyond what is best for the patient then CMS will never get a handle on over utilization of service and will end up spending more money trying to regulate it.

Submitter : **Mr. Christopher Orecchio** **Date: 06/17/2004**

Organization : **Therapy & Wellness Solutions, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

In general, physician-owned PT practices are harming private and hospital-based practices by steering lucrative cases to themselves and sending other less lucrative clients to competition. They are reducing the competition by buying up private practices and hiring away available professionals. Those professionals who want to see the interesting post-surgical patients will gravitate toward the physician-owned practices. In particular, the private practices are at a disadvantage because insurance companies will limit the number of clinics on provider panels. Since physicians may already be on those panels, they have a distinct advantage over new start-up private PT clinics.

In our experience, the "incident to" aspect of the loophole is not being followed in these clinics. Patients are being heavily influenced to remain "under the care" of the physician and not always being informed of the financial arrangement for incentivizing referrals. They are not being told they have options to go elsewhere. In two instances, we had patients leave our clinic after initiating PT with us because the physician either demanded the patient see "their PT so we can keep a better watch on you" or they threatened the patient to discontinue the patient's care because they were going "AMA - against medical advice".

Anecdotally, a personal friend who is an orthopedic surgeon in a nearby town tells me that surgeons are being advised by financial consultants to own PT services purely because of the revenue it can bring. When one profession can violate another profession in this way, something needs to change. This kind of arrangement is not being done for the good of the patient but is motivated purely by having an additional revenue stream to make up for other difficulties physicians have endured on the reimbursement front. The sovereignty of the PT profession should be preserved for PTs. Our profession should not become a piggy bank for physicians who can control the referral relationship to their advantage. This and all loopholes need to be closed and it should be required that all physicians divest themselves of all financial arrangements by selling those practices to the PTs within 90 days as South Carolina has done.

Submitter : **Date: 06/17/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

It concerns me greatly that a physician could own services in which he controls the referrals. This could only drive health care costs up, due to over refering by the doctors. The health care system has many problems with increasing expenses and this does nothing but make things worse.
thank you.

Submitter : **Patti Schwartz** **Date: 06/17/2004**

Organization : **Patti Schwartz**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am an orthopedic manual physical therapist. I have owned my practice for over 16 years. There are 3 other PT's practicing here. The physical therapists spend 30 minutes of hands-on, one-on-one treatment with each patient. Our auxiliary staff is used ONLY in that capacity...to augment the treatment given by the PT. We generally have a ratio of 1 or 2 PT's to 1 aide / tech. Most of our patients have typically already received "physical therapy" in at least one or two other facilities and have not improved. These other facilities are almost always physician owned or corporate. Our patients consistently report that they "have never been evaluated with anywhere near" the extensive nature that they recieve here. Also, the patient does not always see the PT each visit...they are frequently seen only by the PTA or the aide / tech. They report receiving many passive treatment modalities (heat, electrical stimulation, etc.) which have limited usefulness, and little or no manual intervention from the physical therapist. They usually are taken through a generic exercise program in a gym, either with a tech, or most frequently on their own, unsupervised. They are usually resentful of this, as "I could do that on my own at home"! There is usually a high ratio of techs per PT.

This is of grave concern to me for obvious reasons...yes, I own my practice, but I am not afraid of competition on a level playing field! We absolutely provide the best care available in our area, and physicians who DO NOT own physical therapy KNOW that...they refer to us in droves. I have many family members and friends who travel from other cities to come to our facility for even a week in hopes of finding the quality of care that they can not find in their home towns! This should not be! It is my experience that physician ownership of a profession WHICH they themselves CANNOT provide has been destructive of our profession and DEFINITELY detrimental to the patients which we are supposed to serve! I am certain that there are situations where good care may exist in physician owned facilities, but the situation inherently places an ethical challenge...the patient (in the state of Texas) MUST have a referral from a physician to even access physical therapy, and that physician owns a physical therapy facility! This creates an incentive for over-referral, and often inferior treatment...we can only acquire referrals because of our exceptional care...it is too easy to become complacent if the referrals are automatic!...I speak from experience...I have worked in many facilities...hospital, physician owned, and now private practice.

In addition to less access to choice of care and often inferior quality of care for the patient, the cost to the health care system becomes problematic...when the patient is not seen by the professional (at all, or only briefly) and their care is mostly provided by a tech or PTA, the outcomes are not the same, and the patient is still in need of rehabilitation!

The "in-office ancillary services" exception has created a loophole that will expand these arrangements, to the harm of the patients and at the expense of the Medicare program. The potential for fraud and abuse is VERY GREAT, and there have been many independent studies done over the years which demonstrate this!

I have tried to be brief, but I could go on and on in great detail, with MANY, MANY situations from the personal experiences of my patients. THANK you for considering this information!

Sincerely yours,

Patti L. Schwartz, PT

Submitter : **Date: 06/17/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Every Physical Therapist knows that Physicians that own a Physical Therapy clinic refer a lot more patients to PT than do physicians that do not have a financial interest in a Physical Therapy clinic (read- 'over utilize'). What did you think would happen? Maybe we should let more physicians own thier own Labs, Pharmacies, MRI machines, and Physical Therapy clinics. Do you think that would save the CMS and the tax payers money? Sounds like a '60 Minuets' story to me!
Thanks for listening.

Submitter : Steve Joseph **Date:** 06/17/2004

Organization : Searcy Physical Therapy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

To highlight my concerns regarding physician ownership of physical therapy clinics, I have the following real world example. A prominent neurosurgeon recently opened a physical therapy office next to his own and staffed it with contract therapists. He has enterred into agreements with various DME providers, i.e. TENS, and home traction reps and requires all of his patients to receive these items. He receives kickbacks as well as the assessment and service fees billed to the patient. Were that same patient managed by an independent therapist this practise would be less likely to occur. Not having control and being dictated to provide service based on reimbursement by the physician owner is just one example of what is wrong with the current interpretation of Phase II.

Submitter : **Date: 06/17/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I have a specific example of how dramatic a difference the referral patterns of a group have changed since opening there own practice 2 months ago. Our practice has been one of three practices that this physician's group has been sending to consistently over the past 2 years (approximately 4-5 patients a month). Multiplied by three practices, you can estimate roughly 15-20 referrals per month to the three practices. They have always stated that they rotate equally among us three PT groups. We have never had any complaints and visit often with this group to discuss particular mutual patients. They are the only referral source to their own PT practice, so far. It is currently at a three week waitting list to get into to be see for PT. Both of our practices have two full-time therapists. I was told that we would still see patients from them due to the long wait. The doctor I spoke with addmitted that he didn't want his patients to wait too long to be seen. (Isn't three weeks too long when you are in pain?) What is more interesting, is that he didn't even know the one therapist's name. She happened to be there at the time of my visit. I asked to be introduced since she would be guiding the overflow patients my way. Obviously, they weren't having the conversations that we were used to to discuss changes and updates about mutual patients. The doctor's were not involved in the hiring of these two PT's, an office manager did the hiring. One of the physician's is one of the few spinal specialists in the immediate area. When I was visiting with the PT that I got introduced to (after the MD asked her her name)she admitted that she wasn't well versed in the care of spinal dysfunction! The bottom line is that this one example highlights all of the issues that are wrong with the conflict of interest of physician owned Pt practices. They are sending patients that they wouldn't normally send to physical therapy, the patients are waiting far too long to be seen, the breakdown of communication between the caregivers and the seemingly disinterest as to how good the quality of the care is for there patients. A lesser skilled therapist is also less overhead for them. Please realize the impact of your decisions on the quality and utilization of healthcare. I am yelling at the top of my lungs to stop this conflict of interest!

Submitter : **Date: 06/18/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD,PhD

Dear Dr.McClellan,
I am a physical therapist in San Diego, CA. I have practiced for the past 24 years, and been in private practice for 18 years. The purpose of this letter is to comment on the March 26 interim rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." I do have serious concerns about the interim final rule, which I hope can be addressed and corrected in the subsequent "phase III" regulations.
It is unfortunate, but well known to the physical therapy community, that physicians may drastically increase their physical therapy referrals to entities in which they have financial interest. This has been shown to often lead to overutilization of physical therapy services. It is also known to physical therapists in private practice across the nation, that as a result of physicians acquiring a financial interest in certain entities, referrals to independent physical therapy practices typically drastically diminish. It should be noted that Medicare requires a physician referral in order for beneficiaries to receive physical therapy services. This situation has occured repeatedly over the years for myself and our practice, where previously loyal physician referral sources have essentially stopped referring patients, and even told their patients to instead go to "their" own physical therapy clinic. I have even met physicians face to face, who have openly admitted that reentering the market of physical therapy service ownership, is a good opportunity for them. They have explained to me that the new regulations ("in-office ancillary services" exception) now makes it acceptable and "safe" for them to proceed with such financial arrangements. Of great concern is also that services in physicians' offices are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provision to my knowledge does nothing to prevent this practice from occuring. Medicare beneficiaries can suffer greatly from services provided by unqualified personnel. Once again, I have examples of this occuring in our community.
Physicians are the experts in medicine. Physical therapists are the experts in physical therapy rehabilitation (many have 5-6 years education strictly in the physical therapy field). Medicare patients deserve to receive the most qualified care available, and not care based on where a physician has financial interests.
I thank you for your consideration of my comments.

Submitter : **Mr. Daniel Meredith** **Date: 06/18/2004**

Organization : **Mr. Daniel Meredith**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I feel that the physician who owns a practice is a potential problem on several fronts. First it limits competition. The physicain sends patients to only "their" clinic, limiting the patient choice. This happens everyday in our service area and patients states that the physician "said I had to go there". Second, the physicain's have the ability to overutilize their services to generate additional profits. This potential for overutilization is to the detriment to all insurance plans, including CMS.

2. In-Office Ancillary Services Exception

This is a problem as non-licensed staff are performing "physical therapy" to the general public. This is a definate problem as clients think they are receiving skilled services, when in actuality, they are not.

Submitter : **Mr. William Naquin** **Date: 06/18/2004**

Organization : **Crescent City Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As related to the physician self referral, I feel that referral for profit in an establishment that the phyisian has a vested interest in is wrong.It leads to overutilization. The physicians will admit that they are opening these clinics to make up the dollars they are losing from lower reimbursement. The problem is that they are doing it on the backs of an entire profession of independant physical therapist.
The independant physical therapist are getting squeezed out of business because of the greed of the physicians. They avaliablity of most physical therapist to see patients is limited by need for a physicians referral in most states, therefore the physicians control where the patients will recieve their therapy.
Please help stop this demise of an entire profession of Independant physicial therapist.

Submitter : **Date: 06/18/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)

I am a physical therapist with 10 years of experience. I have not submitted my name for fear of retribution from local doctors if they see my name associated with this comment. I am unable to treat my patients without a referral and they hold all the referrals.

I have a private practice in Southern Louisiana and have worked very hard to ensure my practice is of the very best quality for the patients who come here. All of my staff are well educated, well trained and offer the best in care using our "hands on" approach. Our patients agree we do good work by the number of "success stories" we collect on a monthly basis.

I wish to comment on the March 26 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have

Mr comments are intended to raise concerns about the interim final rule and I respectfully ask they be addressed and corrected in the subsequent phase III regulations.

KEY POINT:The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.

As an example, a local physician opened his own physical therapy practice. Previously he had referred a number of patients to our facility, presumably because we do good work. We went from an average of 6-9 new patients per month to 0 starting on the day his doors opened to his physical therapy clinic. We did not recieve another new patient referral from this physician until he closed his physical therapy practice 18 months later (due to disagreements with his partner. He is due to re-open his physical therapy practice any day now). He referred every patient to the clinic he had financial interest in without regard to the patients location (i.e which clinic was closer) or to specialty of injury (we are known for our ability to get excellent results with back and neck pain. The Physical therapist at his facility was a new grad with very little experience and no specialty skills).

Also, due to the Medicare requirement that the patient have a physician's referral we are not even able to bypass the physician to have the patient choose our services. They have a captive market. We can't treat without a referral and we can't get the referral because the doctor owns his own clinic. That has to be an Anti-trust issue. They have a monopoly on physical therapy.

Another point is the potential for the physician's office to use non-physical therapists and bill with physical therapy codes. The practice in town that is opening any day is based on that model. I would assume that would be an abusive relationship but is possible under the current proposal. The patient is under the assumption they are getting "physical therapy" but in reality they are being treated by someone with little to no medical training. This is potentially very dangerous.

Thank you very much for reviewing my comments. I appreciate your time and attention.

Submitter : **Ms. Suzanne Willis** **Date: 06/18/2004**

Organization : **North Big Horn Hospital District**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I believe that the general public should be able to use a prescription for physical or occupational therapy at the facility of their choice & should not be told by the MD that they have to use their facility.

Submitter : **Date: 06/18/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist who owns a small outpatient clinic in Meriden, CT. I have been in practice for 6 years and love what I do. Helping people heal is a wonderful job.

I wish to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." This discussion raises concerns about about the interim final rule in the subsequent "phase III" regulations. Not only does the potential for fraud and abuse exist when physicians are able to refer to themselves, but Medicare beneficiaries may in turn recieve treatment they do not need or worse be treated by untrained staff. This situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services.

Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. In my area a large MSO has developed and has opened a physical therapy office. All of the practices that are part of that MSO are told to send their patients to their physical therapy office. This means that the patients must drive to the next town to recieve services. When asked if they could go to an office closer to their home they are given no other choice. Unfortunately, the public is not well educated regarding the choice they have in their own healthcare options. Older persons are having to drive much further than they are comfortable with to recieve care. Maybe some will forgo treatment and continue their loss of function. This is happening, as we have heard from patients who have exercised their right's to quaility care and accessible services.

The other issue in these physicians' offices is that services are often provided by non-physical therapists or worse perhaps completely untrained individuals. These services can be billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. I have spent may years in formal schooling and have taken numerous continuing education classes to learn new techniques and better my skills. It is horrifing to think that people with insufficent training may be calling what they do "physical therapy".

The "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. All I am asking for is regulations that will protect Medicare beneficiaries from fraud and abuse.

Thank you for hearing these comments. Hopefully we will be able to come to a determination that is beneficial to Medicare recipients.

Michelle

Submitter : **Date: 06/18/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I would like to add my comment . I have been a Physical Therapist for 24 years. I have worked in many different settings over the years. One of those settings was a physician owned practice. I would have to say it was one of the most enjoyable jobs I have had.
I can see why therapists who have not worked in that type of setting may think there is an increased chance of abuse. However, there is abuse going on daily in non physician based facilities at this moment.
What it comes down to is the ethics of the Physician and that of the Therapists. If the Therapist feels the Physician is referring innappropriately, then they need to speak up and challenge the MD.
The physicians I was working with were very ethical and ALWAYS gave their patients the option of where they wanted to go for therapy. They opened up their practice because of the lack of communication between out side therapy providers and their office. They felt that patient care was suffering as a result. It should also be noted that all staff were licensed therapists. This is one area I agree with. I am apposed to the practice of non licensed staff being hired by physicians to perform physical therapy procedures. It is definitely detrimental to the patient and should not be allowed.
In regards to this practice, it is being done by therapy providers in nearby clinics and is being billed out by the PT's. I feel this is also wrong.
In summary. I do not hink that physician owned practices are globally bad. But, I do believe non ethical providers both physician and therapy is.
I therefore do not feel that the ethical providers should be punished because of the unethical behavior of others.

Submitter : **Ms. Joan Schmidt** **Date: 06/18/2004**

Organization : **Ms. Joan Schmidt**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Mark B McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program: Physician's Referrals to Health Care Entities with which they have FINANCIAL REALATIONSHIPS (Phase II); Interim Final Rule with Comments

My name is Joan Schmidt, PT. I have owned my small physical therapy practice in Brentwood, California for the last 23 years. In those 23 years as you can imagine; I have seen a lot of change in healthcare and how healthcare dollars are being spent. As you know it is criterical that we continue to offer each patient the very best functional outcomes for the healthcare dollar(s).

I would like to offer you my personal opinion about the March 26 interim final rule on "physicians' Referrals to Health Care Entities with which they have FINANCIAL RELATIONSHIPS (Phase II). I have deep concerns about the interim final rule and ask that they be addressed and CORRECTED in subsequent "phase III" Regulations.

It is NO SURPRISE to realize the potential for fraud and abuse that will continue to exist when physicians are able to refer Medicare beneficiaries to entities in which they have a FINANCIAL INTEREST. This arrangement is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have INVESTED IN and to OVERUTILIZE those services for financial reasons.

It is extremely obvious that due to Medicare referral requirements; physicians have a captive referral base of physical therapy patients in their OFFICES.

I can NOT tell you how often I have received a patient from a physician owned physical therapy practice once the patient has become frustrated with the lack of results, often being treated exclusively by an aide and NOT a licenced physical therapist, modalties being the key focus of care and not individualize manual therapy techniques being offered, etc.

It is also FRAUD in my professional opinion in a physician's office that services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare Program.

It has been my observance that physical therapist that owned their own practice and therapist that work along side of physical therapist that owned the clinic; are PASSIONATE about their patients and profession and is NOT just a job with the end result being a paycheck. Our focus and outcome is our PATIENT'S PROGRESS with mutual respect on the healthcare dollar(s) being spent to reach these goals. We strive hourly to offer evidence based treatment plans in order to recieve the functional outcomes expected by the PATIENT, PAYOR, AND TREATING TEAM.

In all of my 23 years in owning my own physical therapist practice; you can not mistaken the overt difference that a patient's experience will be in a physical therapist owned practice VS a physican owned physical therapy practice with inherent financial incentives

Thank you for taking the time to read and consider my GREAT concern about patient's receiving the best physical therapy services for the healthcare dollar.

Warmest Regards,

Joan Schmidt, PT

Submitter : **Date: 06/18/2004**

Organization :

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist currently working in a private practice orthopaedic setting. I have been practicing for over 20 years and have worked in various settings including acute care hospitals, nursing homes and out patient facilities. I am concerned that there is the great potential for abuse when physicians have the ability to refer patients to physical therapy when they have a direct or indirect connection with the therapy practice. If they receive financial gain from referring patients, there is the potential to overutilize therapy. I thought this was the reason physicians are not allowed to own pharmacies?

Submitter : **Brad Zollinger** **Date: 06/18/2004**

Organization : **Brad Zollinger**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am opposed to this exception. We have an orthopedic surgeon in our area who has hired a physical therapist and refers all of his patient to his own PT clinic. Besides being an inconveniece for patients to access care near their home, it has decreased patient access to care. This therapist doen't offer some of the programs or have some of the skills necessary to effectively serve patients with certain diagnosis. There is also a question whether some of the patients being treated by the MD employed therapist really need physical therapy. I think when a financial incentive exists for an MD to benefit from referring patients, the potential for inappropriate referrals becomes an issue. This adds to the challenge of reducing the cost of health care to keep it more affordable to patients, employers, etc. This exception just doesn't seem like the right thing to do. An orthopedic surgeon makes enough money without having to hire and benefit from the practice of a physical therapist.

Submitter : **Mrs.** **Date: 06/18/2004**

Organization : **Mrs.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To: Mark B McClellan, MD,PhD
I am a Physical Therapist with approximately 18 yrs of experience. I have worked all of those years in a hospital setting. I am writing to express my concerns with the interim final rule on Physicians Referrals to Health Care Entities With Which They Have Financial Relationships. I feel that this opens up a huge potential for fraud and abuse. Physicians who own practices that provide PT services have an incentive to refer more pts for more visits and possibly overutilize the services for their own gain. I have seen examples of physicians who open PT practices and openly admit that they are only doing it for the profit. The physicians are bombarded by ads that tell them that it is easy to open up a clinic and that they don't even need to use qualified staff (physical therapists). They state in the ads that they can use any office staff to administer treatments and make even more money. THE FACT THAT MEDICARE REQUIRES THAT PATIENTS MUST HAVE A PHYSICIAN REFERRAL TO GET THERAPY CREATES AN EVEN LARGER MONOPOLY AND SETS THE STAGE FOR FRAUD AND ABUSE. I have seen very few physicians who open a practice because they want to control the quality of the practice. They can do that now by only referring to clinics that offer the best quality care. I know of one physician who sees pts regularly in his office for long series of therapy and does not use quality staff. He uses students, clerical staff etc. It is difficult to compete because he controls the referrals and he can keep his costs down by using unqualified staff. The "in-office ancillary services" exception has created this loophole that is frequently abused. It gives Physical Therapists a bad reputation because if the government finds abuse in the PT codes, they blame Physical Therapists, when in reality, anyone could be billig those codes if they work in a Physician's office. This is a waste of Medicare dollars. Thank you for considering my comments on this issue.

Submitter : **Mr. Mark Kander** **Date: 06/18/2004**

Organization : **American Speech-Language-Hearing Association**

Category : **Speech-Language Therapist**

Issue Areas/Comments

Issues 11-20

13. Definitions

The American Speech-Language-Hearing Association (ASHA) is the professional and scientific association of more than 114,000 speech-language pathologists, audiologists, and speech, language, and hearing scientists. We appreciate the opportunity to comment on the Medicare interim final rule regarding physician self-referral.

ASHA is pleased with the qualifications presented for the in-office ancillary services exception under the statute. We also appreciate the definition presented for a wholly owned entity for billing purposes.

DEFINITIONS (Preamble - Part XI)
Our comments are limited to the inappropriate deletion of CPT code 92506 from the list of designated health services (DHS). Speech-language pathology services are DHS, yet CPT 92506 ('Evaluation of speech, language, voice, communication . . .') was deleted, as explained on page 16102. The CMS rationale is that CPT 92506 'is a diagnostic audiology service.' This statement is only partially accurate, in that CPT 92506 includes the evaluation of aural rehabilitation status, but is nonetheless a major procedure code used to describe assessment services rendered by speech-language pathologists. Thus, CPT 92506 should be re-inserted into the DHS list for physical therapy services.

Thank you for the opportunity to comment on this interim final regulation. If you require further information, please contact Mark Kander at 301-897-0139 or via email at mkander@asha.org.

Submitter : **Ms. Susan Hammond** **Date: 06/18/2004**

Organization : **Tru-Care Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist in private practice in RI.I have been a practicing PT for 21 years and have been in Private practice for 7 years. Our state has a large number of private practicitioners whose livelihood is effected by the physician referrals to physical therapy practices that the physicians have ownership in.

The inherant problem with physician ownership is the increased over- use of therapy services secondary to their financial gain. The more patients referred for treatment and the longer they stay in rehab the greater gain for the referring doctor. These overuse situations are compounded by the fact that often the services are provided by the ancillary staff versus employing PTs to perform the treatments.

In my experience, I have treated many patients who have received care previously at Physician owned practices and have been totally surprised by the differances in the care recieved by my staff as compared to the treatments recieved by the doctor's staff.
Some of those comments include:
The therapists there never stretched me.
I just recieved heat and then exercised on my own.
I didn't know that PT involved so many components.

So as you can see, the care given can be quite differant at a doctor owned facility as opposed to a practice privately owned.

The in-office ancillary service exception only further exacerbates the problems of non PTs providing PT services, it faciilitates the creation of more Doctor owned practices and provides little reuglation of these services.

The more over use and inappropriate referral and treatment practices that take place the further limitations it will place on PTs in the long run. As many insurances as well as Medicare look at utilization it is important to note who is using these PT codes and who is providing needed vs. excessive treatments. My understanding is that Medicare will begin restricting use of codes and services that will in the long run hurt the beneficiaries.
These restrictions and limitations can be avoided by CMS through reviewing and actually restricting the physician self referral of medicare patients to their own practicees for profit.

Thank you for your consideration of these comments.
Susan Hammond, PT
President, Tru-Care PT
East Greenwich,RI

Submitter : **Mr. Elio D'Appollonio** **Date: 06/18/2004**

Organization : **Mr. Elio D'Appollonio**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

There is an inherent potential for abuse in this type of arrangement. Regardless of how good the services are provided, the doctor benefits finanically. This arrangement could still exist with the therapist being the sole owner of the physical therapy services. That way the doctor could still have a close look at his patients while receiving therapy.

Submitter : **Mr. James Milder** **Date: 06/18/2004**

Organization : **Milder & Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

It is unfortunate that the question of physician referral for profit should even require federal regulation. In the case of physician referral for profit to physical therapists it is a double travesty. With physical therapist referral state practice acts prohibiting fee splitting between professions and anti-kickback regulations should prohibit the practice. Those state laws have generally not been enforced.

It is the responsibility of the federal government to see that Medicare expenditures are not wasted. Clearly prohibiting payment for services provided under referral for profit scenarios is required.

Sedlow and Johnson in The New England Journal of Medicine 1999:327;1502-1506 demonstrated that referral to physical therapy happened 2.3 times as often in referral for profit situations. The authors later commented that out of $575 million worth of care referral for profit situations resulted in $233 million of that care delivered for economic rather than medical reasons.

Physician ownership of services to which they refer permeates our medical system and costs billions of dollars unnecessarily. There is no rationale for allowing this situation to continue particularly when the service being owned is a separately regulated and paid profession as is the case with physical therapists.

Submitter : Mr. **Date:** 06/18/2004

Organization : Mr.

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

What is the motivation behind physician owned physical therapy practices? MONEY... That being the case, it doesn't seem right that the referring physician controls the referrals to physical therapy. This relationship could only promote over-utilization and fraud. Physicians should not be allowed to make referrals to practices that they are financially linked to. In the Birmingham area, POP's are beginning to dominate the market, edging out privately owned practices. Until recently, the Stark laws discouraged this practice in our area. However, they are increasing in popularity due to relaxed regulations, unspecific legislation and the potential for secondary gain. Small business owners are hurt daily by the current practice. I urge you to consider increased regulation in regards to this practice. Thank you for your consideration.

Submitter : **Miss. Kristine Polak** **Date: 06/18/2004**

Organization : **APTA**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a Physical Therapist, as well as a consumer, I feel that clients have the right to choose at will where and by whom they would like to receive rehabilitative services. The general public is not always as educated as we would like them to be. If they are unaware that they have a choice between many different rehabilitation facilities, a physician can easily make a consumer feel like they should return to his or her physical therapy facility. This is unethical in my eyes and should not be allowed. The field of rehabilitation should be for the healing of the patients and not just about the money. Please do not allow physicians' referrals to health care
entities with which they have financial relationships to continue. I thank you for your time.

Submitter : **Mr. Ed Dieringer** **Date: 06/18/2004**

Organization : **Utah Chapter of the American Physical Therapy Asso**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I am pres-elect for Utah Physical Therapy Assoc. I have been PT for 14 years. I wish to raise concerns about the intereim final rule and ask taht they be addressed and corrected in the subseq "phase III" regs. The potential for fraud and abuse exists when MDs are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting PT is compounded by Medicare's requirement of a MD referral in order for beneficiaries to receive PT services. MDs who own practices that provide PT services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. I believe we have seen sufficient evidence in this and other medical areas where costs for services and utilization of services have increased significantly when owned by physician group. In addition, in MDs' offices, services are often provided by non-PTs and billed under the MD's provider number as PT services. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. Thank you for your consideration.

Submitter : **Ms. J M** **Date: 06/19/2004**

Organization : **Ms. J M**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Administrator McClellan,
As a previous practice owner, I had to recruit experienced physical therapists specialists to obtain the business of various orthopaedists in my marketplace. They were insistent in this high level of expertise as they knew it would give them the best clinical outcome. Even then, I found physicians to be very 'political' in their referrals to many different independent PT practices. When these highly experienced, previously necessary physical therapists refused to enter into employment arrangements working for physicians, the physicians hired young, minimally experienced clinicians and directed all referrals to them. Several clinics in our marketplace lost between 20-60% of thier referral base. Ironically, waiting lists were created at the physician owned clinics delaying the access to care for the consumer. Access to the preferred physicall therapist(before the physician had a financial interest) was same day.
Most healthcare providers have had to change practice patterns secondary to reimbursement changes. Physicians should not be allowed to profit off other licensed professionals to supplement their already above average income. Thank-you for accepting comments. I personally feel this is the single most threat to the physical therapy profession. Utilization will soar and outcomes will decline.

Submitter : **Mr. morey kolber** **Date: 06/19/2004**

Organization : **Physical Therapy Inst**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Physician self referral for physical therapy is a direct conflict of interest. Having been employed by physicians who owned physical therapy clinics has allowed me to become aware of the abuses such as referring patients for therapy who may not necessarily need therapy. Also physicians typically abuse the on-site physician supervision requirements of their practice act when providing such services. Physicians are well aware of the loopholes in laws governing 'incident to' physical therapy services and use unlicensed staff. Physicians have made attempts locally to monopolize the market of P.T. failing to provide prescriptions for patients who are not willing to go to their physical therapy. Many physicians own physical therapy clinics that are not under their roof despite stark 2 regulations and get away with this by usung an integrated billing address and putting their names on the door. It is imperative that CMS enforces existing stark regulations and strengthens the limitations on self referral.

Submitter : **Date: 06/19/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am very concerned about the abuse and unethical behavior already happening in my area. I have already had numerous patients who have stated the orthopedic doctors are trying to get the patients to stop seeing their current therapists and start being seen in their office. There is concern how one therapist is seeing the caseload referred by three othro surgeons. I feel these laws limit a physical therapists ability to survive as an independant clinician unless we have the ability to have direct access with patients. Please consider these if not many other potential problems with physican self-referral. Even the name sounds unethical.

Submitter : **Mr. Orieon Willhite, Jr.** **Date: 06/19/2004**

Organization : **Mangrove Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

It is vital to the public and to Physical Therapist that Physician Owned Practices in our field be eliminated ASAP!! It is more costly to Medicare and other Insurances, for one thing! More importantly it prevents the patient from getting to the treator best trained and equiped to take care of their problem! There is a Physician in our town that, before he started his P.O.P.P., sent me an average of 55 patients a year. Since the day he opened that clinic I have gotten none/zero!! Thank you!! O.D. Willhite, Jr., P.T., C.H.T.

Submitter : **Date: 06/19/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a Physical Therapist in private practice with 28 years experience, extensive knowledge in orthopaedic & neurological rehabilitation, provider of care for over 25000 out & inpatients, and attendee of hundreds of hours of post-graduate continuing education. I am an independent provider of outpatient orthopaedic Physical Therapy services in my private practice. I specialize in spinal manual therapy, industrial rehabilitation services to return injured workers to gainful employment, & treatment of injured athletes specializing in shoulder & knee rehabilitation. My point is simply this: I am permitted to provide primary care of patients by my state with or without physician referral in all aspects of my practice with the exception of Medicare patients. I must assume the rationale is that a physician possesses a higher level of knowledge than myself in Physical Therapy treatment & must provide guidance in properly caring for my patient. I believe this perception is erroneous. A physician, including an orthopaedic or neurosurgeon, is trained in many areas, however, specialized Physical Therapy rehabilitation is not among them. This also includes physiatrists, who upon completion of a three year residency course in basic general rehabilitation including speech, occupational, and Physical Therapy all within the three years, are allowed to oversee the actions of a Physical Therapist with 6, and now progressing to 7 years, of specialized Physical Therapy training. This background provides the basis for my call to repeal the 'in-office ancillary services' exception for physicians. Only Physical Therapists are properly trained & qualified to determine who does & does not require Physical Therapy services. Physicians also possess a captive referral base of patients on the basis of current Medicare referral requirements. This creates an ideal situation for abuse in the form of excessive referral for services and excessive number of visits per patient due to the financial incentive the current system creates. It has been previously established, in several studies, that Physical Therapy services in which a physician or physicians have a financial incentive refer a higher number of patients, an increased number of visits per patient occurs, and higher expenses per patient result compared with independently owned Physical Therapy practices owned by Physical Therapists. 'Physical Therapy' services provided in a physician office are seldom provided by a licensed Physical Therapist, but, rather by on-the-job trained aides with no Physical Therapy training or credentialing. A sample of this abuse is provided: an orthopaedic surgeon in our state billed the state run Workers' Compensation fund for a quarter of a million dollars in a three month period for 'Physical Therapy' services when the only office personnel were untrained aides. He was reprimanded by the Compensation fund, yet continues to this day to bill for 'Physical Therapy' & has no one but untrained aides in his office. The current 'in-office ancillary services' provision has no clause or procedure to prevent this from occuring. Physical Therapy is a highly skilled profession & should only be provided by qualified professional Physical Therapists who can provide proper & timely care under their own direction. The time has long passed when we require physician direction in the treatment of our patients. Permitting physicians to reap economic rewards in this regard is wasteful to the Medicare program & harmful to the patient. While certain physicians which are involved in these arrangements will argue this point, it would appear to be a desire to protect potential revenue streams. Physical Therapists are professional consultants. They should receive all referrals for PT directly as a primary provider or independently following the initial physician exam as is the case with any other independent medical consultant. I thank the Administrator for this forum to express my views.

Submitter : **Date: 06/19/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

To whom it may concern:

I am a physical therapist working in a small privately owned outpatient orthopedic clinic. I have been a physical therapist for six years mainly working in the general outpatient orthopedic arena. I wish to comment of "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships." I request that my comments be considered during the possible upcoming "phase III" Stark regulations.

I currently work in a privately owned clinic that is housed in the same facility as an orthopedic surgeon. There is no financial arrangement or relationship between our company and the surgeons business. We are separate entities who work with each other to provide quality, efficient rehabilitation. At this time a large group of orthopedic physicians, including the aforementioned surgeon, have begun a financial relationship with a large area hospital's outpatient sports medicine/rehabilitation facility. It is our understanding that this physician group will receive 60% of the profits made from physical therapy services at the sports medicine facility. There are also two large family practice physician groups who have begun opening physical therpy clinics within their respective facilities.

Due to the climate of the present heatlth care situation in my area, all health care providers are being reimbursed less and less. Thus it makes sense for physicians to attempt to obtain the market share for patients they refer to physical therapy. The problem occurs with the obvious potential for fraud and abuse when these physicians are able to refer Medicare patients to facilities where they have a financial interest. This will lead to over-utilization of services, including unncessessary visits and referrals of patients who are inappropriate for outpatient physical therapy. Compounding this problem is Medicare's requirement that patients obtain physician referral before reimbursing for physical therapy services. Patient's are left at the mercy of their physcian regarding advice on where to obtain PT services. The physicians are required by law to disclose their financial interest in these facilities, but it is my experience by talking to patients that this is not the case. Many are handed a PT referral with the clinic name on the referral. Now who would you call for PT if you did not know different. I believe many patients would feel differently if they felt they were being referred to a POPTS facility.

I have felt the sting of these actions firsthand over the past couple of months. I have seen our referral numbers drop dramatically since the orthopedic group began their financial relationship. My one question is "What happened to the open market and right to compete in the workplace?" The well is running dry, as the saying goes, in regards to potential referral sources. The physicians in this area are going to continue to refer patients to rehab. facilities they have financial interest in. This will enable them to make larger quantities of money at the expense of patients' dollars, private insurance dollars, Bureau of Workman's Comp. dollars, and Medicare dollars. This will have a tremendous impact on the rehab. industry, not only regarding overutilization, but also by limiting jobs and decreasing the quality of care provided. In many instances, services are provided by non-physical therapists and billed under the physician's provider number as physical therapy services. This delivery of "services" by unqualified personnel is harmful to the patient and wasteful of Medicare resources.

Please consider these comments along with any others to make a full educated decision regarding physician owned practices. Thank you for your time and attention towards this important subject. Thank you.

Submitter : **Date: 06/19/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I worked as a PT for a local home care agency that was a division of a nonprofit hospital. For several years, the majority of orthopedic referrals came from a physician practice for whom the hospital made numerous concessions re: exclusive use of operating rooms on certain days, etc. Most patients were referred to the home care agency for followup, which was a sizeable percentage of our referral base, both Medicare and HMO alike.

A relationship came to exist between the referring members of the practice and a for profit local home care agency specializing in orthopedics. One of the co-owners was also tied financially to the physician practice. It came to pass that all Medicare patients were referred to the for profit agency, while all HMO,private insurance referrals, and Medicare patients requiring abnormally large number of visits due to complications (exceeding the PPS payment to the agency) came to the agency associated with the hospital in which the surgeries were performed. Since Medicare referrals are the only ones that yield a slight margin of profit, the home care agency suffered quite a severe financial blow. The affiliation of the physician group with the for profit home care agency was incentive for that agency to limit the average number of therapy visits received by the patients, since they received a lump sum Medicare PPS payment. On the other hand, payments by HMO's, etc are made on a per visit basis with the frequency of visits determined by the insurance company. None of those payments covered the actual cost of the visit to the nonprofit agency.

Thus, financial harm was done indirectly to the hospital where the surgeries were done, and directly to its home care agency. Also, therapy staff was reduced due to a shrinking referral base. Patients referred to the for profit agency received less frequent care because they were Medicare patients. The only benefit in this arrangement was to the for profit agency and the associated orthopedic group. I no longer work for the hospital based home care agency by my choice, nor do I refer any individuals to that orthopedic practice because of perceived unethical behaviors on their part.

Submitter : **Elizabeth Hampton** **Date: 06/19/2004**

Organization : **Performance Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,

I am a physical therapist in practice since 1987 and am writing to comment on the March 26th interim rule on Physician's referrals to Health Care Entities With Which They have Financial Relationships (Phase II). I am concerned about the interims final rule and ask that these concerns be addressed and corrected in the subsequent Phase III regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own a practice 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 know of a physical therapy practice in our state that is owned by a physician. A therapist in his employ shared how frequently clients were referred for physical therapy by the physician/owner without medically justifiable goals, and the physician clearly expected the client to be treated regardless of their needs. The care of one of their clients was transferred to my clinic along with her chart notes. In reviewing her notes, I found that she was repeatedly provided the same treatment by an individual who was not a physical therapist with occasional review of her program by the physical therapist. This is such a poor representation of the physical therapy profession and the lack of progress for the client as well as financial effect is ethically disturbing.

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 practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In physicians offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The in-office ancillary services provision does nothing to prevent this practice from occurring. The delivery of so-called physical therapy services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. In order to become a physical therapist, one undergoes 6-7 years of schooling and takes a licensure exam to demonstrate knowledge required to deliver physical therapy evaluation and treatment. It is profoundly dangerous and unethical for non-physical therapists to be able to bill for services entitled physical therapy simply because they can use the physician's provider number. Washington state is amongst the poorest reimbursed of the western United States and physicians are desperate to improve their bottom line.

I know of another physician (GP) in our state who has purchased a traction machine. He places his low back pain patients on this machine and bills up to $200 per treatment for this service, as a technician observes. The physician bills this as a physical therapy code under his provider number. Physical therapy is much more than a modality such as traction. If the physicians can claim physical therapy codes, they should have taken the physical therapy licensure exam for their state. I can tell you that there is no way that they would pass the exam, as it is neither general nor basic knowledge.

There is abuse by physicians who own physical therapy practices that must be ended through this legislation.

Thank you for your consideration of my comments.
Sincerely,
Elizabeth Hampton PT

Submitter : Stephen McDavitt PT MS **Date:** 06/19/2004

Organization : Stephen McDavitt PT MS

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. Such a situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physician's 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.

As a physical therapist practicing 28 years in my community I have personally experienced blatant practicing of this leveraging by physician owned groups. It is blatant because at one time when those groups never had in-office PT services they demonstrated a practice pattern of referring patients outside their facility and upon creating their in-house self-owned services, depleted their outside referrals and kept their patient PT referrals in their owned facility. In fact, because their pattern was so entrenched to send their referrals outside, their staff initially continued to do so and upon recognizing that 'error' they would actually call the patient and tell them to cease seeing that PT and come back to be seen by only their PT. Patients referred to me from those groups in previous referrals would then call and say they wanted to come back to see me for the new problem but could not because they were told they 'must' see the in-house PT. With this practice growing in my practice area I took this information to the State of Maine Bureau of Insurance who would not act on my behalf since there was no direct complaint from patients. Leaving this up to the patient who trusts and relies on the physician to guide their care is only to allow the fox to guard the hen house. Such practices affected my practice by a reduction in 12-15% of lost business across insurance providers for only one physician group. Overall across 5-8 years I estimate closer to 20-25%. There are others in this area as well.

2. In-Office Ancillary Services Exception

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 practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In physician's offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The in-office ancillary services provision does nothing to prevent this practice from occurring. The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

It is harmful because patients believe they are receiving PT services when in fact in most circumstances, they are not. 'Supervised' personnel utilized in these circumstances in my area are exercise physiology specialists, athletic trainers, on the job trained secretaries, nurses and others such as massage therapists. Physical therapy has a unique body of knowledge and skill requiring 5-6 years of education with a Masters and /or Clinical Doctorate degree from accredited PT education colleges / universities and state licensure. Residency training, clinical specialist qualifications and specialized fellowships are also available requiring further training. The services provided by ancillary personnel in physician's offices therefore are untrained in the practice of physical therapy. The treatments provided under such circumstances without a PT are prescribed selective interventions that are only micro-components of the usual and customary PT care (Enough for the patient to 'sense' they are getting PT) and then billed under PT coding since they take place 'under the supervision' of the physician. This hurts the patient since they are not only deceived on the service provided as being physical therapy when it is not but also when such care is not performed by a PT, it lacks a PT evaluation, diagnosis, assessment, prognosis and from that unique expertise, a plan of care that measures and determines the patient outcomes based on specialized clinical expertise and best clinical evidence. Such adds cost to the care of the patient, delays or denies clinical outcomes by the utilization of unskilled services and promotes an over utilization on billing data recorded as physical therapy costs even though not performed by a physical therapist.

Submitter : **Date: 06/19/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

This next phase of the law is critical not only for the physical therapy(PT) profession, but also for the growing insurance issues. Double standards begin to arise with physicians that have an investment in PT clinics. For example with a common knee surgery that corrects torn cartilage in the knee, physicians would refer patients to PT 1 wk before the surgery and for 2weeks after. In total, they would recieve 5-7 visits of PT and there would be no issue in recovery for 98% of patients. Currently the double standard exists when there is a physician owned practice (pop) the patient (pt) suddenly needs weeks of physical therapy, and it is worth the physician's time (secondary to kickbacks) to fill out insurance paperwork. As opposed to physicians that are not involved in a pop, they will be less likely to refer their pt to PT at all due to the extensive paperwork involved and required for insurance coverage. Now instead of 2% of patients with recovery difficulty, 30% would return to the physician after 10 days to have the stitches removed and have some type of set back either with ROM, Strength or any other problem that could have been avoided with some immediate PT.

As a result, insurance companys are recieving mixed signals for the optimal amount of therapy needed and they will always err toward the side of least visits...none at all. Where ideally it would require some visits for optimal care. Too many visits(as seen in POPs)is over kill and not enough visits will cause lengthy stays in PT that could have easily been avoided by being proactive instead of reactive.

Submitter : **Mr. Michael Martinez** **Date: 06/19/2004**

Organization : **ADVANCED HEALTH**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment

Thank you in advance for taking the time to share my concern, which pertains to the March 26 interim final rule on 'Physicians Referrals to Health Care Entities in which they have financial relationships (Phase II)'.

Clearly these arrangements present a conflict of interest and evidence of this point is demonstrated by the past research that has indicated an abuse of patient referrals when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. Physicians who own practices that provide physical therapy services creates an inherent financial incentive to refer their patients to such practices hence resulting in over utilization of services.

These arrangements do not only promote over utilization, but often are downright dangerous for Medicare recipients. The delivery of so-called 'physical therapy' services within a physician's office is often delivered by unqualified personnel.

Finally these arrangements discourage quality care because the most qualified therapist will no longer treat the majority of patients. Our company has first hand experience of this fact. I am a physical therapist who has been in private-practice for 11 years. I am presently completing my advanced 'Doctor of Science' in Physical Therapy Degree, and I am one of just 2 therapists throughout Ohio who has obtained certification in 'orthopedic manipulation'. 5 of our employees are completing their advanced Doctoral degrees and we also employ Physical Therapists who have obtained postgraduate certification in: McKenzie, Lymphedema, Manual Therapy and Incontinence. We truly have a talented, educated and committed team of 62 employees who are dedicated to our profession and the welfare of patients.

Unfortunately, our commitment to clinical excellence means nothing to physicians' who has ownership in their own Physical Therapy practices. Throughout the past 18 months we have been approached by 2 chiropractors, 1 podiatrist, 1 medical center consisting of MD's and DO's and more recently an Orthopedic Group consisting of 4 orthopods and a Rheumatologist. All 4 centers wanted our company to create a 'Physician owned Physical Therapy' (POPTS) center for them and furthermore each had made it perfectly clear that if we did not proceed with such terms that they would no longer refer their patients to our centers and would find another provider to establish their facilities. In fact 1 orthopod stated 'you are lucky that we are not just hiring aids for our physical therapy center'. Also important to note is the fact that 1 of the Doctors in this group who is most committed to the POPTS also has a reputation for not utilizing therapy. In fact he had informed us in the past that 'Physical Therapy is a waste of time and does not work'. Yet this same Doctor is committed to owning his own POPTS and at that stage we are absolutely positive that his referral patterns will increase dramatically.

In closing, would you please reconsider the 'in-office ancillary services' exception which is broadly defined and has created a loophole that will promote and result in the expansion of physician-owned practices.

If you would like to discuss our first hand experiences further, please do not hesitate to call.

Professionally,

Michael Martinez, PT, COMT

Submitter : **Ken Mailly, PT** **Date: 06/19/2004**

Organization : **Mailly & Inglett Consulting, LLC**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Please find comments attached.
Sincerely,

Ken Mailly, PT
Mailly & Inglett Consulting, LLC

CMS-1810-IFC-78-Attach-1.pdf

CMS-1810-IFC-78-Attach-2.pdf

Submitter : **Mr. Kipp Dye** **Date: 06/19/2004**

Organization : **Orthosports & Aquatic Physical Therapy, PC**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

IN OFFICE ANCILLARY EXCEPTION:

I am an owner of a private PT practice in the Boston, MA area (www.orthosportspt.net) and I am deeply disturbed by physician self-referral exception for it is seriously taking business away from PTs who are out in the field trying to uphold objective practice standards.
From my research I am finding that there is quite alot of over-utilization of PT in an MDs office. I think this is negative for PT as a whole for it takes money away ultimately from people who need our services.
MDs don't know PT that well for I find myself continually teaching the MDs about what we do in PT. I would never want to work for an MD-owned PT practice for I would potentially have a boss who dosen't understand what should be done for the patient.
In the Boston area MDs are working part-time at an address location and then being incentified to refer patients to a network of MD owned PT clinics. I even had one of my patients who went to see an MD locally who tried to refer the patient to his MD owned facility. I wouldn't mind but I was seeing a great result with the patient's frozen shoulder and this is disturbing to me when an MD can undermine my profession and my ability to make a living. I also have had another MD who has taken 2 patients out of my care and never told me why. It is my understanding that the MD has some sort of financial relationship with a Healthsouth clinic in downtown Boston. It outraged me when I found out from the patients that they were referred away from me and I had to find out by calling them.
I think MDs should be kept out of PT for it will save money and it will also allow PTs to advance our profession even further without the financial constraints that MDs want to put on us by not referring directly to independently owned PT practices.

Sincerely,

Kipp Dye, MSPT
Orthosports & Aquatic PT, PC
www.orthosportspt.net
phone (617) 964-7900
fax (866) 305-1388

Submitter : **Mr. Timothy Conan** **Date: 06/19/2004**

Organization : **Costello Cooney and Fearon, PLLC**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

13. Definitions

My comments are to the 'deemed fair market value' safe harbor of the fair market value definition in 42 CFR 411.351. My first comment is that DHS entities wanting to make use of this exception will face considerable costs in obtaining the information. To obtain the physician compensation surveys, a hospital would have to join the applicable association, for example the Medical Group Management Association and then purchase the survey, which for rural or smaller hospitals is expensive. The new definition requires the hospital to join four of the associations and purchase four surveys -- that is a very expensive proposition. There are some publications such as Modern Healthcare that has an annual physician compensation survey that is published in that magazine in July of each year, which prints charts listing the average reported cash compensation by specialty as reported by each organizaiton. Since 4 of the 6 surveys are included in the Modern Healthcare Survey, and the survey charts list the average cash compensation, then I think it is reasonable for you to add 'or compilations of surveys such as Modern Healthcare which include 4 out of the 6 listed surveys'. Since Modern Healthcare is publishing in July the survey results for the proceeding year, I think it is also reasonable to adjust the compensation amount for inflation. My other comment is that the language in the definition states that the entity is to use the 'compensation level for physicians in the same physician specialty(or, if the specialty is not identified in the survey, for general practice)'. That does not make sense to me. Rather, I recommend that the regulation state that in the event that the physician's specialty is not identified, the closest applicable specialty should be used. For example if you look up in the Modern Health Care compilation, the specialty of otolaryngologists (ENT), there is no category for that, but the closest applicable specialty is general surgery, not general practice. I think that general practice or family practice should only be a default category if no other applicable specialty applies. Thank you.

Submitter : Angela Pennisi **Date:** 06/19/2004

Organization : Lakeshore Sports Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Many patients have expressed to me their confusion and dissatisfaction regarding their physical therapy choices. After I referred one patient to an orthopedist for consultation, he performed a procedure and recommended another therapy facility. The patient states she specifically requested to resume care with me, her original therapy provider, but her physician insisted on another facility with whom he likely has a financial relationship. The patient stated she did not feel she could disobey her doctor, even though she would rather return to my care.

Patients also report occasions when they are not aware of having any choices in physical therapy care--the impression that they must attend therapy in the doctor's office or recommended facility. They sometimes comment that the physician must have a financial incentive for referring to such a facility, because the quality of care was noticeably inferior. I have had patients report they think of excuses to be referred to my clinic, such as appointment time availability, to discourage their doctor from referring to their own facility or employed therapist.

In addition, some patients state that they did not even see a licensed physical therapist in their doctor's office, nor was their doctor actively directing the treatment. These patients are surprised and dismayed when they realize the difference in the standard of care when provided by a licensed physical therapists. Some doctors do hire licensed physical therapists or contract with a company to provide in-office therapy services. Before I owned my practice, I worked for a contract agency for a period. I was assigned (initially without my knowledge) to work in a physician office. I was advised that Medicare patients could only be seen on certain days, as those were the days the physician was in the office. I noticed that many patients had a significantly extended duration of care compared to other facilities for which I had worked. At no time did any physician attend a patient's physical therapy session, ask how his patient was progressing in therapy or become involved in any other way. Physical therapy is not provided in the physician office as an ancillary service -- it is provided as profit-generating service with little regard to the patient's needs, preferences or benefit.

Submitter : **Mr. Joe** **Date: 06/19/2004**

Organization : **Mr. Joe**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mark B. McClellan, MD, PhD,
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

My name is Joe and I am a physical therapist in Miami, FL. I received my masters degree in 1998 in south Florida. I worked for 4 years at a large PT corporation. In October 2002 I opened my own outpatient PT practice. I am proud to provide excellent service to everyone that enters the clinic. We have an excellent and relaxed atmosphere for the entire staff. Currently, I have one full time PT, one part time PT, one part time PTA and myself treating patients. We average 1.1 patients an hour per therapist.
I wish to comment on the March 26 interim final rule on Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). My comments are intended to raise concerns about the interim final rule and that they are addressed and corrected in the subsequent phase III regulations.
I am really concerned about the potential for fraud and abuse that exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. I am also concerned that the PT owned practices will eventually be non-existent if physicians continue to open their own PT practices. In 2 years of having my own practice I experienced 5 of my largest referring doctors open a PT practice. I am very upset to learn about the type of care some of these doctors are providing to their patients. Some doctors are providing PT in a single treatment room with equipment only consisting of one treatment table, chair, theraband, ankle weights, and an ultrasound/electric stimulation unit. The reason I am aware of their facilities is because I do my own marketing every month. I often visit their offices several times a year. I still receive patients from some of these doctors, but they are more selective to the types of patients they send to me. I only receive patients that have HMO plans (especially patients that have insurance with a low reimbursement for each visit, or with a capitation). I have experienced on 2 occasions where doctors approached me to just do evaluations for them and they would have a PTA or massage therapist perform the treatments. It is really frustrating to me that I spent 6-8 years of my life in school to become a PT and some doctors are taking advantage of lesser qualified help. Doctors are hiring lesser qualified staff or using 1 PT to treat 20-30 patients in a small evaluation room. What kind of care can a patients receive with such limited space, lesser qualified staff and a high patient to therapist ratio?
Thank you for the consideration of my comments.
Joe

Submitter : **Ms. Tamah Lettieri** **Date: 06/19/2004**

Organization : **Physical Therapist**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

I am opposed to the exceptions in the proposed Stark II law permitting MD'S to refer patients to clinics they have a financial interest in, specifically Physician Owned Physical Therapy services.

Many of these clinics are staffed by unskilled workers who purport to provide Physical Therapy services to the population at large. This violates the premise, truth in advertising as the patients are not aware the person treating them is unskilled and not a P. T. The reason for such an arrangement is clearly financial gain by the MD.

Many patients have established relationships with their own P T's and are afraid to speak up, for fear of alienating their physcian, and hence, are not afforded their right to chose their own healthcare provider.

These arrangements can lead to fraud and abuse due to improper coding and billing. Unskilled therapy treatments end up causing patients to seek additional treatment by a trained provider, thereby escalating the cost of care for that particular diagnosis.

Submitter : **Miss. Karen Giffing** **Date: 06/20/2004**

Organization : **Miss. Karen Giffing**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I believe that there are some significant opportunities for abuse and fraud under the current interpretations which define exceptions much more broadly and will most likely increase the expansion of physician owned physical therapy arrangements. Since Medicare requires a phsycian referral prior to physical therapy, any physician who receives a financial gain from ordering physical therapy can easily overutilize services but more importantly, utilize them inappropriately by having modalities administered by anyone they hire and deem trained. The protection that beneficiaries receive by attending physical therapy performed by a qualified, educated and licensed professional may very well be null and void in these cases. I would hope that under Phase III, these exceptions will be addressed and corrected.

Issues 1-10

2. In-Office Ancillary Services Exception

Having been a practicing physical therapist for 22 years, I have had the occasion to observe abuses in this area. I had a patient that came to me after a very dissatisfying and dangerous encounter with a physician owned practice where he was receiving "physical therapy." I use that term with reservation because in actuality, the patient was evaluated by the doctor and then the prescribed modalities were administered by a lay person with no medical knowledge. This patient had significant adverse affects from the modalities, including an increase of radicular signs and symptoms as well as dizziness after the administration of cervical traction. The lay person had no knowledge of the potential dangers or contraindications of the modalities they were administering and the patient did not see the physician for 3 or 4 weeks after their evaluation. Obviously, the primary concern was not the patient's well-being but continued billing of the provider for so called "physical therapy services" under the physician's name. Physical therapy is not modalities alone, it is the practice of identifying functional and biomechanical deficits and then working in conjunction with the physician as part of a health care team

Submitter : **Mr. Michael McKinnie** **Date: 06/20/2004**

Organization : **Movement Science, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist practicing in the metropolitian Atlanta area in private practice for the past year. The Stark II legislations has made it extremely difficult to access patients that would benefit from the services of license physical therapist and physical therapy assistants. Many physicians are providing "incident-to" physical therpay services in their offices with non-qualified individuals. I was in my physicians office for a check-up and a young gentleman approached me and inquiried about physical therapy school and the curriculum. He further disclosed that he was providing physical therapy in the physicians office, but he hopes to be accepted to physical therapy school after several years of rejection.

Far above and beyond the issues of finance is the issue of patients safety. Every Physical Therapist in the United States of America are required to be licensed to practice to help decrease the risk of malpractice and increase patient/client safety. The Stark II regulations undermines this protection. If CMS would only poll physicians and physical therapist to determine how physical therapy influences mueromusculoskeletal dysfunctions and functional movement there would be a vast difference in responses between disciplines. The reason for this disparity would simplybe that physicians are not physical therapists and in my argument only competent to supervise that overlying pathology that effects their patients functional impairments and limitations. In this perspective this two discipline compliment each other well in providing the best functional outcomes for patients.

Lastly, as this legislation is reviewed, I would like the fact that physician owned physical therapy practices has increased in epidemic proportions. Why? Is to provide more efficent and cost-effective healthcare? (This over-utilization case was proven prior Stark I legislation) Or to supplement physicians ridiculously rising malpractice insurance and decreased reimpbursements.

Thank you for your time & consideration

Submitter : **Dr. Erik Zamboni** **Date: 06/20/2004**

Organization : **United States Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 21-24

24. Impact

Here in the state of Oregon, there has been a marked increase in Physician owned Physical Therapy (POP) practices in the past year. Historically, studies performed in California, have clearly demonstrated that the utilization of Physical Therapy in POP practices is TWICE the typical utilization rate. This abuse can contribute to unnessary health care costs, an already signicicant burden on your national GDP.

Submitter : **Mrs. Carolyn Bloom** **Date: 06/20/2004**

Organization : **Bloom & Associates Therapy, PA**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

The patients do not benefit from physicians owning physical therapy clinics. I have a private practice PT clinic in Topeka,KS and contract rehab. services to a small rural hospital in Winchester, KS. One patient living in Winchester had a total knee replacement performed by an orthopedic MD in Topeka. He wanted her to drive the 45 minutes each way to his PT office for therapy, but she said she didn't have a driver and it hurt too much to travel. She had PT at the Winchester Hospital in the past and was very pleased and wanted therapy at the Hospital. He said those therapists didn't know his 'protocol' but he would allow PT 3 times/week for two weeks and if she wasn't better would have to come to his clinic in Topeka for therapy. My Winchester PT called the MD's office three times to get approval for more than 3 times/week therapy and no calls or faxes were ever returned, so we were stuck at only 3 times and the patient was very edemetous and painful. She had only gained about 10 degrees of motion of the knee when she returned to see the MD. He said that was unacceptable and he knew this would happen. He demanded she now drive to his clinic in Topeka daily! The patient wasn't happy and husband had to take off work to drive her. I told the patient she could file a complaint against the MD since that violated part of the KS law for MDs to practice under and I gave her the statute number. She didn't want to file a complaint against him since she needed him to complete her care and she may need the other knee replaced. These actions happen all the time and are not reported by patients who are afraid to anger their physicians. The KS State Board of Healing Arts director said if a PT (me) filed this complaint, it would not be addressed unless the patient filed it. This is why Federal mandates against physician owned clinics/services need to the made.

Submitter : Pam Palmer **Date:** 06/20/2004

Organization : Palmer Physical Therapy for Women

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a Physical Therapist who has been practicing my profession since 1985. I own a private practice, Palmer Physical Therapy for Women, in Wichita, KS.
I am very concerned about the interim final rule regarding physicians referring to health care facilities in which they have financial interests. This ruling does not appear to prevent the often fraudulent referral of patients to a physical therapist who is an employee of the physician, or referral to the PT clinic in which the physician has partial ownership. I believe that my concerns need to be addressed in Phase III regulations.
Most health care practitioners perceive that their reimbursement dollars are shrinking. Because of this, may have looked for other ways to supplement their income. What easier way for a physician to add to his or her income? Just hire a Physical Therapist and keep all patients in-house, or better yet, have your non-Physical Therapist office staff perform the "physical therapy procedures" and bill just as if the PT performed them.
What's wrong with this picture? Many, many things. Those utilizing Medicare services often don't understand they have a choice regarding their care. What I hear from patients in Wichita, KS is that their physician tells them they need PT. The patient tells the physician that they have been seeing a Physical Therapist at another PT clinic. The doctor tells the patient that they need to come to his/her Physical Therapist because if "anything goes wrong,I'm right down the hall". Or, "that Physical Therapist doesn't know my protocols". This is a scare tactic that works with many senior citizens, but certainly doesn't assure them more quality care. The Physical Therapist who works for a physician is no more qualified or skilled than I. Even worse is the physician who does not refer to PT at all. Instead, he/she has a non-skilled office worker (receptionist) perform "physical therapy". Patients believe they are receiving care from a skilled practitioner. There was an instance where the physician's office actually called the PT clinic and asked about the proper use of equipment used on patients! This is not quality health care and CMS should not be reimbursing for these "services".
Thank you for your time. I appreciate the opportunity to comment.
Pam Palmer PT

Submitter : **Dr. Mark Beissel** **Date: 06/20/2004**

Organization : **Dr. Mark Beissel**

Category : **Other Practitioner**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment.

Dear Dr. McClellan:

I am a physical therapist with 31 years experience, 24 as a Medicare Certified Supplier of physical therapy as Physical Therapist in Private Practice (PTPP). I am also the physical therapist representative on the Michigan Medicare Carrier Advisory Committee (CAC).

I have been watching with growing concern the development and rapid proliferation of physician self-referral in the Medicare program over the last several years. I am coming to believe that these arrangements will someday outnumber the legitimate PTPP?s who truly work independently, as the original program envisioned in 1972. I have attached some documents that show that there currently is a significant marketing campaign directed at physicians to employ or contract with PTPP?s, in order to circumvent the intent of the Stark laws. The ?in office ancillary services? exception has provided a blueprint for physicians to inappropriately profit form a referral, and restrict patient choice to their own office. I have personally lost 20% of my business recently to such an arrangement, as these patients are ?directed? downstairs for treatment. Very few patients know they have a choice in physical therapy providers certified by the Medicare program, so they do not question the practice. For those patients who do ask for me, sometimes they are sent to me, and sometimes the patient is told they cannot come to me. In the past I have heard that I have retired, do not take new patients, or they have heard that I am ?ill?. I have heard just about every excuse over the years, but the bottom line is that the physician makes a profit from referrals from a captive audience.

I am sure that you are aware of the many peer reviewed articles from the 1990?s which demonstrate that physician self-referral results in increased cost, over utilization and restricted patient choice. All so the physician can make some extra money without doing any work. Often the ?physical therapy? is not even done by qualified personnel.

In summary, please consider the impact of the current interpretation of the Stark rules, and thank you very much for your time.

Sincerely,

Mark D. Beissel, DPT,OCS,FAAOMPT

Please see www.empiremedicaltraining.com and click on preceptorship, physical therapy services, then on site training, for an "eye opener".

CMS-1810-IFC-89-Attach-1.txt

Submitter : **Mr. Bob** **Date: 06/20/2004**

Organization : **Mr. Bob**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Dear Sir,

I have unfortunately experienced the negative effects of physicians who own their own physical therapy services. As a society we can all hope that physicians would not send you to a therapy provider simply to increase their own revenue and that they would only send you to a physical therapist who they believe to be the most skilled at providing the services you need. This however, is not reality. A simple and real example could be that you strained your back during a round of golf. You goto your physician after a week and he sends you to his physical therapist. You do not get better and eventually go 4 months with nagging, sleep preventing pain at your low back. Through your sister you eventually discover that across the street from the physicians office is a physical therapy owned office and seek treatment there. It only takes 3 visit to get back onto the golf course pain free. You find out that because you had good insurance the physician sent you to his physical therapist and not to the low back specialist across the street. The low back physical therapy specialist is well known by the physician across the street but only sends those patients whose insurance does not pay well. This is the unfortunate reality that is not the exception, but the rule. Physician owned physical therapy services stops patients from receiving appropriate cost effective treatment by the best provider.

Thank you for you time and consideration regarding cost effective and ethical healthcare delivery. I hope you will address this issue during a Third Phase of Regulation.

Sincerly,

Bob

Submitter : **Mr. Marc Lacroix** **Date: 06/20/2004**

Organization : **APTA**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Marc Lacroix and I am the President of the New Hampshire Chapter of the American Physical Therapy Association. I am writing as I am concerned with the increasing proliferation of physicians profitting from entities they refer to.

In the state of New Hampshire, their is a disclosure regulation which requires physicians to report to the state department of Health and Human Services the number of referrals they provide to such entities they receive financial renumeration and the number of referrals to entities they do not have financial ties. Compliance is spotty at best. About 1/3 of suspected and known entities having financial ties to physicians do not report. Only about 1/3 of the physicians who are reported by entities of having financial ties report. This is disturbing that physicians can not follow a simple reporting statute. It is not a large leap to see that physicians would not follow the regulations in this proposal. We must stop or sharpely limit MD ownership of physical therapy practices they refer to so consumers are given a true choice as to where to receive their services. This is a consumer choice issue.

WE have seen several physicians grouping together for financial interest in these entities. This has created a "Walmart" effect in the geographic areas where small private clinics are being forced out of the market place. We must limit ownership to allow for fair competition. After all we are as a nation built on free trade. Our democratic system is to protect the rights of the minority. Physicians financially profitting from entities they refer to is diametrically opposite those beliefs.

The "in office" exemption has created a loop hole which helps to create more of these abusive cases. It also allows physicians to bill physical therapy services when a non physical therapist is providing them. The result is inferior care for Medicare recipients and inferior results. You should not allow this to happen.

Thank you for listening.

Sincerely,

Marc Lacroix, PT
6 Robin Road
Concord, NH 03301

Submitter : **Mr. Korre Pieper** **Date: 06/20/2004**

Organization : **Physical Rehabilitation Center**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

No relationship = no kickback = no over/underutilization. How hard is that?

6. Rural Providers Exception

As long as the therapist is independent from the physician both operationally and legally (including independent billing and renumeration).

2. In-Office Ancillary Services Exception

As long as the therapist is independent from the physician both operationally and legally (including independent billing and renumeration).

3. Group Practice Definition

As long as the therapist is independent from the physician both operationally and legally (including independent billing and renumeration).

5. Publicly-Traded Securities Exception

No Physician should be able to own and refer or own and sit on the board of directors of a PTS.

7. Space and Equipment Rental Exception

As long as the therapist is independent from the physician both operationally and legally (including independent billing and renumeration). Equipment rental should not exceed 10% in any given year of the tax value of the equipment to prevent 'back door bribes'.

4. Prepaid Plans Exception

Would you work very hard if they paid you at the beginning of the year whether you performed or not? This is just the insurance companies way of a round-about bribe.

8. Employment Relationships Exception

As long as the therapist is independent from the physician both operationally and legally (including independent billing and renumeration).

9. Personal Services Exception

As long as the therapist is independent from the physician both operationally and legally (including independent billing and renumeration).

Issues 11-20

12. Isolated Transactions Exception

Not greater than $20 in value one time per month

14. Academic Medical Centers Exception

As long as they don't charge for the services.

15. Anti-Kickback Safe Harbor Exception

Kick-backs should have no safe harbor...then you won't have to worry about how to word this.

Issues 21-24

22. Exceptions--Retention Payments in Underserved Areas

Therapists would be able to work in rural markets if rural physician practices were not monopolistic about therapy services. Independent therapy practices are often crushed by services provided by therapy practices with direct or indirect financial support for physicians.

Submitter : **Mr. Frank** **Date: 06/21/2004**

Organization : **American Physical Therapy Association**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

If a physician can not refer for profit to a PT facility they own that is located down the street why should it be different if it is in their office. The premise is the same and the resultis the same. Every pt. they recommend for PT will be a revenue source to them whether they truly need the service or not. In a revenue reducing time in health care giving physicians more freedom to put money back in their pockets by referring for possibly services a pt. (medicare or others) may not need certainly does not assist in reducing health care costs.

1. Financial Relationship-Definition

I am a PT in private practice in Ohio. I have been negatively effected by Physician ownership of PT services and the patients also have lost the choice. Physicians have a captive and at times reluctant patient population to go "against" the Physician's request to use his own PT facility. Patients need choice without feeling as though they will offend their doctor if they go outside of his services. Physician owned services open the door for excessive use of services that may not otherwise be referred. Physicians like many of the other health professions have experienced reduced reimbursement and are looking for additional revenue streams. There are a number of courses out that teach the Physicians how to make money with PT, OT, MRI, lab etc these courses are certainly not telling them how to provide a quality service but how to generate the revenue. I know of 3 Physicians in my area that do not even use licensed PT's but aides/trainers to provide the services and bill it as PT,....because they can. This is a slap in the face of the PT profession and others that have worked to gain the credentials. I am against the changes to the stark act and in fact should place more restrictions and quality assurance measures on the provision of services if they are to be performed in the physicians office.

Submitter : **Date: 06/21/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I have been a Physical Therapist in private practice for over 22 years. Physicians in my state are seeing a decline in revenues which is resulting in their seeking other ways to add to their income. Many have added ancillary services such as Physical Therapy. Because of the Medicare referral requirement, physicians have taken the unfair advantage to refer patient to their own services and not give the patient the right to choose their own Physical Therapist. The problem this presents is potential for fraud and abuse when a physician refers a patient to an entity in which they have financial interest. The Medicare beneficiaries suffer in several ways:

1. Patients lose their choice of providers and often are not able to return to the physical therapist that they have already built a relationship with.
2. The location may not be the most convenient yet the physician is no longer taking that into consideration as he is looking a his bottom line.
3. I have had patients come to me after being treated in the physician owned practice with complaints/questions regarding the financial incentive in these settings.
4. The physical therapist in the physician's office may not be the most qualified therapist for that Medicare patient as I have specialized in the geriatric patient over the last 22 years--typically the physician will hire a new graduate without experience at a lower income to reduce expenses. In my practice we have new graduates work with a master clinician (experienced physical therapist)for at least a year so that their skills can be perfected.

I my practice we must provide the best services in order to keep physicians referring their patients and in order for the patient to return until he/she accomplishes their goals. This incentive is not there in physician-owned physical therapy practices.

Thanks you for consideration of these comments.

Submitter : **Mr. Brett Eberle** **Date: 06/21/2004**

Organization : **Orthopaedic and Sports Physical Therapy Clinic, PA**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. Mark McClellan,

I am a physical therapist in private practice in Portland, Maine. I have been a physical therapist for 28 years and in private practice for 23 years. While in private practice I have been directly affected adversely by physician-ownership of a physical therapy facility. After 8 years in practice the physician group that provided the vast majority of patient referrals to my clinic informed me that they intended to own an ancillary physical therapy clinic for self referral in their new office. They wanted me to work for them. I refused, and saw my practice dwindle to half its former size. It has never recovered. My employees quit to work for the physician group since they were not busy at my clinic. Most of them worked for the physician group for a few months to a few years, then quit because they 'were not comfortable with what was going on' during their employment.

Physician self-referral in physical therapy has not been a pressing issue in Portland since the Stark Law was passed, while everybody awaited for the Stark II rules to be announced. Physical therapists are complacent because self-referral growth has slowed during the wait period for Phase II. Phase II is a disappointment. Phase II has done nothing more than define the loopholes by which physicians can resume this abusive practice.

In the coming months the physical therapy complacency will crash as we have a repeat of the late 1980's. 'Consultants' will rouse the profit motive of physicians by advertising a method to increase their revenues by starting in-office ancillary physical therapy services. The consultants will market the scheme by assuring physicians that the Stark II (Phase II) rules condone the self-referral nature of the endeavor. The consultant will point out that they already have the captive referral base to assure the project's instant success. Patients will not question their own exploitation because they trust their physician. Many of the in-office ancillary services can be provided by unlicensed personnel under Phase II, to further increase patient exploitation and the profit margin.

Stark III or Phase III is apparently necessary to close the loopholes created by Phase II. Please take the necessary steps to begin these proceedings quickly. Thank you Dr. McCellan, for the opportunity to convey my input on this very important topic.

Sincerely,
Brett L. Eberle, PT
Owner/Director
Orthopaedic and Sports Physical Therapy Clinic, P.A.
1601 Congress Street
Portland, Maine 04106

Submitter : **Mr. Patrick VanBeveren** **Date: 06/21/2004**

Organization : **APTA**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

This provision clearly allows for fee splitting or the physician obtaining fees for professional services that the physician did not provide. there is no reason that this exception should exist. Off site services are not reimburseable. Why does that chnage for on-site services. I know of no instance where a physician provides any on-site supervision. The potential for abuse is significant and has been documented ie overutilization of services, use of unlicensed personnel etc. This abusive practice costs Medicare money by paying for excessive and low quality, ineffective services. The provisions are driven by financial incentives for the physician.

Submitter : **Date: 06/21/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Physicians who abuse referral to their own clinic should be investigated. However, I work for some orthopedic physicians and the quality of our care for these patients who have undergone surgery is outstanding. I believe after the orthopedic surgeon has spent hours doing surgery on their patient they have the right to then ensure that the patient gets quality physical therapy to maximise the positive results from the surgery. For these physicians to have their own physical therapy departments is extremely beneficial to their patients. The level of communication is outstanding, the physicians protocol is very strictly followed and results are excellent. This is the best opportunity physical therapists and physicians have to work together in a true inter-disciplinary environment for the good of the patient. I beleive that the inter-disciplinary approach is the future for patient care.
As far as I can tell, over-utilization has not been defined. If a physician has 100 patients self-referring for musculo-skeletal pain, how many is he or she able to refer to another discipline before he is accused of over-utilization. When physicians and physical therapists work together there is a fostering of trust and respect. Personlly I can't see the problem of a physicain sending all of their patients to another discilpline when their skills may not fully heal the patient. As with all situations people who abuse that should be dealt with but you cannot presume all physician owned clinics are solely interested in making money. That simply is not true and many physicians are truly interested in the benefit of the patient and invest some of their resources so they can work closely with physical therapists.

Thank you.

Submitter : **Mr. Robert Swinehart** **Date: 06/21/2004**

Organization : **Ohio Physical Therapy Network, Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

The exceptions in the Stark II rule allow for the potential of physicians overutilization of services. I refer to the OIG study in 1994 where almost four out of five cases reimburtsed as physical therapy in physicians offices did not represent true physical therapy services: $47 million was inappropriately paid in 1991.

If a physician is referring patients for physical therapy, there could be incentive to schedule patients for personal gain. Physicians offices may also provide physical therapy services with the least expensive and possibly unqualified non-licensed staff and bill it as physical therapy services. There is no way to police these skilled services being administered by unskilled individuals. Not only is this wasteful of Medicare dollars but it is potentially harmful to patients.

Outpatient physical therapy clinics receive patients from all types of referral sources including patients self-choice. Physicians offices will potentially be restricted to only themselves as their referral source which as stated above creates an environment where there is potential overutilization for financial benefit.

Thank you for considering my comments.

Submitter : **Mr. Wes Priestley** **Date: 06/21/2004**

Organization : **University of Tennessee Medical Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I've been a physical therapist since for 24 years. I have witnessed the loss of choice to patients (especially Medicare pts) referred to in-office ancillary physical therapy and oppose conditions which allow physicians to refer to PT services in which they stand to gain financially. Potential for abse is high. There is no doubt that the financial gain motivates referrals, increases cost and jeapordizes care.
In physicians' offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. This is harmful to the patient and wasteful to the MC system.
Thank you for considering of my comments.

Wes Priestley

Submitter : **Mr. Kory Zimney** **Date: 06/21/2004**

Organization : **Mr. Kory Zimney**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a practicing Physical Therapist and manager of a Hospital based Physical Therapy Department for inpatient and outpatient care in Sioux City, IA. I would like to comment on the March 26 interim final rule on Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I would like to express my concerns about the interim final rule and ask that they be addressed and corrected in the subsequent phase III regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral
in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.

An example of this happens in Sioux City. There is a group of physicians that have an outpatient physical therapy clinic as part of their practice. We have heard from patients that state the reason they did not come to our clinic even though they initially wanted too, is that their physician stated that 'their therapist were much better and get better outcomes if they were to come to their facility.' When we confront the physicians with these comments for justifaction on such a statement they deny them, even though they come from patients telling us directly. It seems if ethically boundries are being crossed and the ability to gain financially can be driving force to allow this sort of practice to happen. It is unfortunate that even though currently the laws can not restrict this practice that good ethical practice can not prevail. My concern is that if the laws get even more open that this practice will continue to get worse. I feel strongly working for a non-for-profit organization that patients should be given free choice to receive care where they wish and not be denied for any reason. If a physician strongly encourages a patient against a choice that has obvious financial gain for that physician, there are ethical concerns present with that type of practice. I would be nice for the regulations to restrict this self refferal practice. I realize that it is difficult to set language in the regulations that achieve this, but I ask for continued evaluation of the current regulations to assist in this.

Thank you for your time in consideration of this very important matter.

Submitter : **Mr. Andrew Einhorn** **Date: 06/21/2004**

Organization : **LOSPT**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 18, 2004

Dr Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program: Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships

Dear Dr Mark B. McClellan,

I am a physical therapist of some 23-years. I have worked in both a physician?s office and now private practice for the past 12-years.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive 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.

The ?in-office ancillary services? exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. It?s common practice for these offices to provide services by non-physical therapists. The delivery of so-called therapy services by unqualified personnel is harmful to patient and Medicare program.

I strongly recommend that this form of abuse be stopped. This ?form? of self-referral for profit arrangement has negatively impacted patients and the costs associated with these services.
The practice of over-utilization of medial services should not be tolerated in any form of medical services.

Thank you for your consideration in this matter.

Sincerely,

Andrew R. Einhorn, MA / PT

Submitter : **Mr. Rex L. Nutt** **Date: 06/21/2004**

Organization : **APTA**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Physicians who own the service to which they refer have been shown to increase referrals (by your own studies). Personal experience with physicians and their reasons for owning physical therapy offices leads me to feel that their motives are financial rather than for the good of the patient. Having one state to me personally, "We know we can create $250,000 per year by the stroke of our pen and we are not giving it up any more!" indicate the real reason they want to own physical therapy services. Your studies in the past in Florida and New Jersey indicate increased referrals when the physical therapy service is owned by the physician.

2. In-Office Ancillary Services Exception

By bringing the service under their roof, in their offices, this only allows them protection to refer more to pay for their office building or operations. Physicians should practice medicine, referring to physical therapy when indicated and not to be sure that their bottom line is high enough to make more money for themselves. If there is a physical therapy service in their building they should rent or lease the space to a qualified physical therapist and allow that professional to practice physical therapy. Physicians should not be in the business of supplying services that can influence how much they make each month, by volume of referrals.

Submitter : **Date: 06/21/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,
I am a practicing Physical Therapist managing the Rehab & Sports Medicine Dept of an urban hospital in Florida. I would like to comment on the March 26 interim rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)".
In my fifteen years as a clinican it has become abundantly clear that our profession depends heavily on physician referral for sustained survival even as direct access to our services becomes more prevalent nationwide.
It was a breath of fresh air to learn of proposed legislation to prevent, or at least limit physicians ability to refer patients to themselves for Physical Therapy treatment and services. Not only does it impact on our professions ability to operate a self sustained business, but in many cases as I have personally seen physicians offices operating Physical Therapy clinics and have unqualified personnel delivering therapy services which is a safety concern for the patient. Physicians are reaping huge financial benefits by offering Physical Therapy services in their own offices and this is not only unfair to our profession that rely's on physician referrals but also presents the most obvious problem which is the potential for fraud and abuse. Make no mistake about it, I say potential, but it is abundantly ocurring. Physicians are able to self refer Medicare beneficiaries which is referring to an entity they have a financial interest. The current legislation is written to provide the physician a wide variety of exemptions which not only undermines the intent of the proposed law, but makes it virtually useless as far as I can see. Please carefully consider all the exeptions and make practical corrections in the phase III regulations.

Thank you sincerely for your consideration of my comments.

Submitter : **Mr. Wes Franks** **Date: 06/21/2004**

Organization : **UT med. Center**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

see attachment

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : **Ms. Lisa Simonton** **Date: 06/21/2004**

Organization : **Renal Endocrine Associates**

Category : **Physician**

Issue Areas/Comments

Issues 11-20

15. Anti-Kickback Safe Harbor Exception

I am writing as the Executive Director of an eight physician nephrology practice. We have great concern that the proposed method for establishing Medical Director fees for ESRD facilities will have a negative effect on the vulnerable ESRD populaton.

The concept of basing compensation on an hourly schedule is inappropriate due to the nature of the responsibility for activities and outcomes which are regulated by Federal and State guidelines. We do not feel that comparison to Emergency Room physicians is appropriate as the nature of activities is not comparable.

We do not feel that the use of safe harbor in the context of the Stark regulation is an unusual use of the regulation. The concept of ESRD Medical Directors is not the type of gray area that typically resultsin the use of this regulation. The use of the rule in this situation is inappropriate.

In addition we feel that the while CMS suggests "voluntary" use of the guidelines that the industry will assume these are, in fact, rules to be followed. CMS voluntary guidelines carry significant weight within the industry.

Finally,we feel the lack of the full comment and response cycle on this issue is inappropriate. Perhaps CMS does not understand the signficant impact this will have on the ESRD program and patients.

While we support CMS' efforts to ensure high quality in the ESRD program we must disagree with this approach to Medical Director compensation issue and ask for your consideration of our comments.

Submitter : **Dr. Chris Hoekstra, DPT** **Date: 06/21/2004**

Organization : **Therapeutic Associates**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am currently a practicing physical therapist treating a number of patients with Medicare insurance. I am concered that the languge in the current ruling will set up a conflict of interest on the part of the physician with regards to referral for physical therapy services.

This section is defined extremely broadly. The current language will allow for the proliferation of physician owned physical therapy clinics. These clinics provide a financial incentive for self referral and over-utilization of physical therapy services. The loss of a competitive referral system will only produce higher costs and an inferior quality of care for Medicare plan participants. The currently Medicare referral system requires recertification of need for physical therapy serviced by a physician every 30 days. The language in this section would allow a physician to refer patients to a clinic he/she owns, and then continue to certify the need for these services unchallenged. This sets up a significant conflict of interest. This current language creates an unnecessary loophole that actually serves to weaken the cost containment efforts of CMS.

Furthermore, the ancillary services performed in physician offices are often performed by non-licened personel and billed as 'physical therapy' under the physicians provider number. This sort of treatment is not allowed in a non-physician owned physical therapy clinic. Providing physical therapy servises by unlicenced personnel is dangerous to the patient and harmful to the entire Medicare program.

An analogy that illustrates my point follows: It would be absurd to allow medical assistants to perform neurosurgery in a hospital simply because they are using the physician?s provider number. From the part of CMS, there would be no way to ensure this type of procedure was performed by a qualified individual because all that is provided to CMS as an identifier is a provider number. This is the exact type of situation the current ruling would allow for with regards to ?ancillary? services. This sets a dangerous precedent that will likely lead to patient injury and increased cost to CMS.

Submitter : **Dr. Joel Anderson** **Date: 06/21/2004**

Organization : **Cascade Rehabilitation**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 11-20

13. Definitions

The definition of 'physician owned physical therapy practice' needs to be significantly narrowed. We have an MRI facility with a physical therapy clinic downstairs that is owned by a group of Proliance physicians very near our clinic in Everett. The therapists in that clinic are seeing an unreasonable number of patients per day (up to 40 patients per therapist per day) and, in my opinion, giving substandard care. The therapists are pressured by the physicians to see that high number of patients, as the need is great due to physicians ordering preoperative and postoperative treatment. One therapist recently left the clinic after only 5 months secondary to the poor working environment and continued pressure by the physicians' group to perform at levels of productivity that would not allow this therapist to give a reasonable standard of care. This is but one example of the slippery slope which we have placed ourselves. The Stark law was put into place to prevent this very thing from occurring.

Because reimbursement to healthcare providers has reached abysmal levels, physicians have been searching for ways to turn a profit in an increasingly challenging business environment. The same is true for physical therapists in private practice. In this healthcare environment, it may seem like a good idea for a physical therapist to have a consistent, exclusive referral source in the form of a physician partner or as an employee/employer relationship. In that situation the therapist would have very limited marketing responsibilities, a full caseload, and very little hassle in getting more visits approved with his promary referral source. Many difficulties we face as private practitioners would be avoided. Yes, on the surface, this seems like a good idea. Unfortunately, this creates an environment ripe for abuse. There is little internal control over physical therapy visit limits on some insurance plans (Medicare, for one), as the plan relys on the referring physician's discretion for visit limitations. What motivation remains to be frugal with the patient's healthcare dollar when the physician profits from increased utilization? Placing dollar limits per year on Medicare beneficiaries was tried in the past, but that solution limits access to care for many who need it. The best way to assure the appropriate use of therapy in each case is to develop a physician - therapist relationship that keeps the patient's care in the forefront. This cannot be achieved when there is a direct financial link established between therapy and physician profit. The definition of a Stark law violating practice needs to be very narrow, with very few exceptions. The only question legislators need to ask in determining the legality of a physician's interest in a physical therapy practice is "Is the physician profiting financially from the physician's referral of this patient?". If the answer is 'yes', it must be made illegal. Please consider these comments when entering your next session.

Submitter : **Mr. Turner Blackburn** **Date: 06/21/2004**

Organization : **Mr. Turner Blackburn**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Physicians should not be able to refer to their own employed physical therapists

1. Financial Relationship-Definition

This definition should include the physician referring to an entity that he or she has a financial relationship in but also to referring to their own employed physical therapists.

Submitter : **Mrs. Jennifer Rocco** **Date: 06/21/2004**

Organization : **Cambridge Physical Therapy Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist with 10 years experience, with the last 5 years owning my own private practice physical therapy center. I wish to comment on the March 26 interim rule on "Physicians' Referrals to Health Care Entities with which They Have Financial Relationships(Phase II)." I would like my comments to raise concerns about the interim final rule and ask you to address and correct these concerns in the subsequent "phase III" regulations. We are in a small town that has a hospital with a new outpatient PT/OT facility, a physician owned "sportsmedicine and rehabilitation" center which has no physical therapists or physical therapist assistants, and ourselves. We are very concerned about the well-being of patients who are not given the choice of facilities for their physical therapy, and/or are not being treated by licensed physical therapists or physical therapist assistants. Patients are allowed the choice of choosing their physician and if that physician has a financial interest in their own physical therapy services, of course that physician will refer to their own facility, as we've seen many times here, and not give the patient their choice of ancillary providers. Also, in the case of the physician owned practice that has no PT's or PTA's, Medicare is being billed for services performed by non-licensed personnel who are not able to service Medicare patients per Medicare guidelines. The physician in these cases is not treating the patients, as told to us by patients, yet their insurance is being billed under the physician's provider number. I've had a specific case where a patient called me to ask me how their insurance could be billed for physical therapy services when they were never treated by a physical therapist, and I told them they would have to ask that physician's office. The patient said they were afraid to as they didn't want to upset the doctor. In the situation just mentioned, patients are being treated for what they think are physical therapy services, yet they are being treated by non-licensed PT personnel. Finally, we have had people tell us that they would rather have been treated at our clinic for their physical therapy, but their doctor wanted them to go to their own facility and the patient didn't want to go against what their doctor wanted. This creates a very akward situation for the patient to express their wants against their physician whose care they are under. Made even harder for the patient and private practice physical therapist is that Medicare requires a prescription for physical therapy services from a physician, as well as documented follow-ups with a physician every so often. The patient therefore feels very obligated to that physician for their healthcare needs as opposed to feeling they have the right to choose what they feel is the best for them. Thank you for your review and consideration regarding my comments.

Submitter : **Mrs. Gloria Andrus** **Date: 06/21/2004**

Organization : **Olympic Medical Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am against physicians being able to refer and/or receiving income from their referal from entities or practices that they own. This includes pharmacies, therapy clinics and speciality clinics. Consumers need to be able to choose where they go and not feel obligated or lead there by their doctor, who in turn gain income from their referral.

Submitter : **Dr. Jill Heitzman** **Date: 06/21/2004**

Organization : **Mary greeley Medical Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

A local physician corporation in my town opened their own PT practice in their offices a few years ago and since that time, their number of PT clinics have increased while ours has decreased. The main reason is that as a physical therapist, I am required by Medicare to have a physician referral for my patients. The physicians refers his patients to his own clinics PT practice. As one physician stated 'I lose money every time I send a patient to you and not to my clinic' I am a board certified specialist in Geriatrics and in wound management with my Doctor of Physical Therapy degree. This along with 26 years of experiance should qualify me as an expert in the field of geriatrics. However, the physicians have been known to tell patients to go to their PT clinic because 'that is where the experts are'. Referring to their own practice increases their revenue without regard to patient care. Their PT clinics are allowed to have unlicensed people treating the patients. With Physical therapy being an education program of over 8 years of education, how can unlicensed people be qualified to care for the patient? I have had several people in this community tell me they wanted to come to me, but their doctor told them they had to go to the doctors PT clinic. I have also had several patients initially come to me to call me later and say the doctor's secretary called them and asked why they didn't go to the doctors' PT clinic. When they told them they wanted to come to me, the secretary said 'the doctor wanted you to go to the other PT for specific reasons and you need to follow his instruction or the care may not be what he wants'. When the entire situation is reviewed, the referral to health care entities with which physicians have financial relationships is filled with abuse, false information and poor patient care. As long as physical therapists must rely on referrals from physicians to treat Medicare patients, these physicians cannot be allowed to have ownership over any type of physical therapy clinic. Otherwise, increased financial costs to Medicare occur, decrease in quality care to the patient occurs and the private physical therapist is put out of business for not other reason than that they won't be in the physicians' pocket. Stop the abuse. Bring back quality independant care where the patient has a choice.

Submitter : **Mr. Robert Worth** **Date: 06/21/2004**

Organization : **Mr. Robert Worth**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

June 21, 2004
Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1810-IFC

Subject: Medicare Program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Dr. McClellan,

I am a physical therapist at Advanced Physical Therapy in Appleton, Wisconsin. I have been practicing outpatient orthopedic physical therapy for 12 years. I am writing to express my concern regarding the effect that the March 26 interim final rule is already having on healthcare in my area.

Prior to March 26th of this year, there were already several physician-owned physical therapy clinics in my geographic area. Consistent with data I have seen from national studies, local patients would frequently undergo extensive physical therapy ordered by the physician owning and financially benefiting from the physical therapy services provided in their office. Not only would this often result in over-utilization of physical therapy services with unnecessary costs to the insurance companies and the patients, but in addition the patients would not receive referrals to the proper specialists (physical therapists, physicians, etc.) due to financial incentives to keep the patients ?in-house?.

The current interim final rule allows for even further proliferation of such inherent financial incentives and negatively affects health care costs and quality of patient care/management. Since the March 26th rule was released, several more physician practices in my geographic have announced that they will be planning to establish physical therapy clinics in which they have direct financial gain for each patient they order to receive therapy services. I do not believe that this unnecessary conflict of interest is in the best interest of patients requiring the most appropriate care.

Thank you for taking the time to read this letter and take my comments into consideration. I sincerely hope that it will be possible to address and correct these concerns in the phase III regulations. If you should have any questions, or if I can provide any additional information, please feel free to contact me at the address below.

Sincerely,

Robert P. Worth , P.T.
3101 East Canvasback Lane
Appleton, WI 54913

e-mail:cworth@new.rr.com

Submitter : **Mrs. Christine Vezzola** **Date: 06/21/2004**

Organization : **HealthSouth PT**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

As a physical therapist in an area where every MD seems to own his own practice, I find that the patient is the one who loses with self referral by an MD. Patients are kept in therapy longer than they need to be because it benefits the business and not the patient. MDs should not be allowed to refer to themselves because it is unethical. It is not good for physical therapy as a whole as MDs control the care of patients in an area that they are not experts in. I have noticed that many patients say they would love to come for therapy where I work but their MD said they HAD to go to his place. MDs who refer to themselves DO NOT do what they are supposed to and tell pts they have a vested interest. There is too much room for scams.
Thank you
CHristine Vezzola

Submitter : **Mr. Michael Glazer** **Date: 06/21/2004**

Organization : **Ausley**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

7. Space and Equipment Rental Exception

This comment relates to the requirement in 42 CFR ?411.357(a)(6) and (b)(5) that the rental agreement be commercially reasonable even if there were no referrals made between the parties.

A busy medical practice, ambulatory surgery center, hospital or other medical business (hereafter collectively referred to as ?landlord?) may have the need for specialized services beyond its expertise for the care, treatment and convenience of its patients, such as diagnostic imaging services. If that landlord has a space or equipment rental agreement with a diagnostic imaging center, the agreement must be commercially reasonable even if there were no referrals from the landlord to that center. These parallel provisions in the referenced subsections are separate requirements from fair market value rent as contained in other subsections of this rule and appear to focus on terms of the agreement beyond just rent.

The question arises as to what is a commercially reasonable agreement when the volume of business from the landlord is so great as to dominate the services of the diagnostic imaging center (i.e. no room for referrals from outside providers or the diagnostic imaging center, which typically would not make referrals). But for the desire to have the services in close proximity for improved patient care and convenience, there would be no need for the rental agreement. That would lead to the seemingly absurd result that no agreement could ever be commercially reasonable under those circumstances. Requiring the diagnostic center to take referrals from someone other than the landlord seems artificial, particularly if the volume from the landlord is such that its patients would be displaced for the outside referrals.

Instead, it would seem that a more reasonable interpretation is that the terms (rather than the existence) of the agreement must be commercially reasonable in the market whether the landlord provides referral or not.

Can you please clarify.

Submitter : **Scott McCarty** **Date: 06/21/2004**

Organization : **MRS Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Subject: Medicare program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment.

I am a Physical Therapist and am in Private Practice. I currently have offices in Pennsylvania. I have been a Physical Therapist since 1979, and have been in private practice since 1985.

I would like to comment on the March 26 interim final rule on ?Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practice 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 issue of Physician owned Physical Therapy practices has reached a critical stage. Many Private Practice Physical Therapists have had to close their doors because of these arrangements. Physicians who were historically referring 5 patients a month to the private practice Physical Therapists are now referring 20 to 30 patients a month to their own entities from the same patient population base. Where did these patients suddenly come from?

The ?in-office ancillary services? exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. It has created a loophole that has resulted in the expansion of physician-owned? practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

In Physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The `in-office ancillary services? provision does nothing to prevent this practice from occurring. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

I thank you for your consideration of my comments regarding this very serious issue.

Sincerely,
Scott D. McCarty, M.S. P.T.

MRS PHYSICAL THERAPY
500 Market Street, Suite 103
Bridgewater, PA 15009
724.728.6365
fax 724.728.6648

Submitter : **Mr. Joshua Kinsinger** **Date: 06/21/2004**

Organization : **MRS Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a Physical Therapist and am in Private Practice. I currently have an office in Pennsylvannia. I have been a Physical Therapist since 1993, and have been in private practice since 2002. I would like to comment on the March 26 interim final rule on 'Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).' My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent 'Phase III' regulations. The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive 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. The issue of Physician owned Physical Therapy practices has reached a critical stage. Many Private Practice Physcial Therapists have had to close their doors because of these arrangements. Physicians who were historically referring 5 patients a month to the private practice Physical Therapist are now referring 20 to 30 patients a month to their own entities from the same patient population base. How did these patients suddenly need physical therapy services? The 'in-office ancillary services' exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. It has created a loophole that has resulted in the expansion of 'physician-owned' practices that provide physicial therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In physician's offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The 'in-office ancillary services' provision does nothing to prevent this practice from occurring. The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. I thank you for your consideration of my comments regarding this very serious issue.
Joshua L. Kinsinger, PT

Submitter : **Mr. John Strickland** **Date: 06/21/2004**

Organization : **Medical Rehabilitation Systems**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Subject: Medicare program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment.

I am a Physical Therapist and am in Private Practice. I currently have offices in South Carolina. I have been a Physical Therapist since 1996, and have been in private practice since 1999.

I would like to comment on the March 26 interim final rule on ?Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practice 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 issue of Physician owned Physical Therapy practices has reached a critical stage in our South Carolina locations. Many Private Practice Physical Therapists have had to close their doors because of these arrangements. Physicians who were historically referring 4-5 patients a month to the private practice Physical Therapist are now referring 20 to 30 patients a month to their own entities from the same patient population base. How did these patients suddenly need physical therapy services?

The ?in-office ancillary services? exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. It has created a loophole that has resulted in the expansion of physician-owned? practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

In Physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The `in-office ancillary services? provision does nothing to prevent this practice from occurring. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

I thank you for your consideration of my comments regarding this very serious issue.

Sincerely,
John D. Strickland, PT

Submitter : **Mrs. Kristen Mortensen** **Date: 06/21/2004**

Organization : **Medical Rehabilitation Systems**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Subject: Medicare program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment.

I am a Physical Therapist and am employed in a Private Practice setting in the State of South Carolina. I have been a Physical Therapist since 2000.

I would like to comment on the March 26 interim final rule on ?Physicians Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II).? My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practice 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 issue of Physician owned Physical Therapy practices has reached a critical stage in South Carolina. Many Private Practice Physical Therapists have had to close their doors because of these arrangements. Physicians who were historically referring 4-5 patients a month to the private practice Physical Therapist are now referring 20 to 30 patients a month to their own entities from the same patient population base. How did these patients suddenly need physical therapy services?

The ?in-office ancillary services? exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. It has created a loophole that has resulted in the expansion of physician-owned? practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

In Physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The `in-office ancillary services? provision does nothing to prevent this practice from occurring. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

I thank you for your consideration of my comments regarding this very serious issue.

Sincerely,
Kristen R. Mortensen, PT

Submitter : **Mr. Scott** **Date: 06/21/2004**

Organization : **Mr. Scott**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist working in Missouri and have been practicing for 17 years. I have had direct experience of why physician owned physical therapy practices are bad for the patients and general public. A patient of mine was referred by a local orthopedic surgeon and told only to come to our facility due to the high quality of care. He was a post op knee patient that happened to be a personal family friend of mine for many years. He was doing exceptionally well in therapy and post operatively and had several check-ups with the doctor who expressed that he was doing well and always asked how he liked his therapy. My patient expressed that he was very pleased and all was well. At one of his later follow-ups, the patient noticed that a physical therapy operation was now functioning inside the office building owned by the physician group he was attending. When the patient was asked how therapy was going, he gave his normal "great" response but was bewildered when the doctor stated that he wanted him to quit going to therapy at our facility and instead go to the one in his building. The patient asked why he wanted him to change and the doctor replied that he thought the quality of the therapy was excellent and again stated that he wanted him to change therapy locations. The patient stated that this would add twenty minutes to his drive to therapy EACH way and that he was, again, happy with his care and reminded the doctor that he highly recommended our facility initially. The doctor again stated that this new facility was better and that he wanted the patient to switch therapy facilities. My patient grew angry and stated that I was a personal friend of his and that he would not undergo the longer drive for treatment as he was getting excellent results. The physician then backed off and said the he just wanted him happy and that he could finish therapy at our office.

The above description is what is wrong with doctor owned physical therapy. The very successful, and I will assume, financially secure doctor did not need revenue from therapy, but was willing to take someone with a very positive therapy experience that he initially recommended and inconvenience the patient tremendously for his own financial gain. Being able to gain financially from therapy has already clouded the judgement of this doctor and it will do so for ohters leading to abuse of patients and higher overall costs of therapy. NOWHRERE did this doctor ever mention that he was financially tied to this physical therapy operation, as our state law requires.

Please do not weaken the ban on phsyician self referral by weakening the Stark ll laws or broadening the list of exceptions to this law. This is a good law that has the support of the Missouri Physical Therapy Association and the American Physical Therapy Assocication. Bans on financial conflicts of interest like these have even had the backing of the American Medical Association and, I believe, they still do.

Please protect the patients by refusing to let physicians enter into a conflict of interest by being able to refer to their own physical therapy clinics.

Thank you for your time and consideration,

Scott
Missouri PT

Submitter : **Mrs. Wendy Friday** **Date: 06/21/2004**

Organization : **Medical Rehabilitation Systems**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Subject: Medicare program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment.

I am a Physical Therapist and am employed in a Private Practice setting in the State of South Carolina. I have been a Physical Therapist since 1991.

I would like to comment on the March 26 interim final rule on ?Physicians Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II).? My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practice 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 issue of Physician owned Physical Therapy practices has reached a critical stage in South Carolina. Many Private Practice Physical Therapists have had to close their doors because of these arrangements. Physicians who were historically referring 4-5 patients a month to the private practice Physical Therapist are now referring 20 to 30 patients a month to their own entities from the same patient population base. How did these patients suddenly need physical therapy services?

The ?in-office ancillary services? exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. It has created a loophole that has resulted in the expansion of physician-owned? practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

In Physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The `in-office ancillary services? provision does nothing to prevent this practice from occurring. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

I thank you for your consideration of my comments regarding this very serious issue.

Sincerely,
Wendy Friday, PT

Submitter : **Mrs. Carrie Harrison** **Date: 06/21/2004**

Organization : **St.John's Mercy Medical Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist who currently oversees all outpatient services for St. John's Mercy Medical Center (an entity of the Sisters of Mercy Health System). I have been practicing for 17 years.

I wish to comment on the March 26th interum final rule on "Physician Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II)". I would appreciate consideration of my concerns in phase III.

The potential for abuse in the ability for Physicians to refer Medicare Beneficiaries to entities in which they have a financial interest is of grave concern to myself and the 50+ therapists that we employ. This inherent incentive for financial gain strongly invites abuse and overutilization - particularly in a health care environment where physicians are looking to increase their income stream to offset past reductions in their fee schedule payments. This is compounded by the requirement for therapy services to be provided only with a physician referral.

I have witnessed physician practices that have overtaken a practice or opened thier own physical therapy practices. This has resulted in lay offs, dramatic reductions in direct therapeutic contact, significant overlapping of patients, shorter visits and reduced quality of care.

As a leader in a hospital organization, I see the continued trend of hospitals being squeezed by the physician community as they open their own outpatient venues. This reduces our referral base while we continue to provide the high cost or poorly reimbursed services within the confines of the hospital envirnment.

I appreciate your time and attention to this matter. Please do not interpret my comments as negative towards the physician community in any way. I work with a tremendous medical staff here at St. John's Mercy. I truly believe that most all health care providers, physicians certainly included, have the patient's best interest at heart. I just am opposed to establishing loopholes that provide an avenue (intentional or unintentional) to increase costs, promote overutilization and reduce quality to our seniors.

Submitter : **Mr. Seth Kaplan** **Date: 06/21/2004**

Organization : **BRPT-LAKE Rehabilitation Ctrs**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist from Baton Rouge, Louisiana. I have been in private practice for over 15 years. I am the Vice President of a large outpatient private practice that provides physical, occupational and speech therapy for a wide range of patients. My company has over 25 therapists with a support staff numbering up to 65.

I am writing to express my extreme concern over the Stark Legislation debate. I wish to comment on the March 26 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? I would like to make clear my concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. The physicians control the referral and now are controlling the entity to which they refer. This is a huge conflict of interest. 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 gain. Previous studies have proven this fact.

I regret that this practice is rampant in Baton Rouge and in fact all over Louisiana. The physicians in these financial arrangements make no qualms about the fact they are doing this for financial gain. There was a time when they were more discreet, but now their comments are that they are getting into the physical therapy business to ?recoup lost revenue from the ratcheting down of their reimbursement.?

My concern has always been for my patients and my profession. The ?in-office ancillary services? exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical, occupational and speech therapy services.

Please understand that I know this is a daunting task for your organization to look at this problem. However, if you truly analyze what is happening in the Medicare arena, you will find the potential for cost savings if you identify these arrangements for what they are - purely financial arrangements to gain wealth.

Thank you for the opportunity to make our concerns known.

Submitter : **Mr. Theodore Kepros** **Date: 06/21/2004**

Organization : **Midwest Athletic Club Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed Stark II changes are counter-productive to health care costs savings, and the ability of the patient to seek the best clinician available. Allowing physician's to have ownership or financial relationships with referral sources will lend to further abuses which we have already seen by one such model (Health South). It would be my hope that we learn from such mistakes rather than promote them through our regulations.
We need to take a clear look at the goals of the regulations we implement and ask ourselves, are we truly addressing them?

Submitter : **Mr. Steve Harada** **Date: 06/21/2004**

Organization : **American Physical Therapy Association**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist in the State of Washington and am concerned about physicians owing and referring patients to their own physical therapists. If a physicain owns the physical therapy practice, the more they refer to the therapists, the more they make in profits. I realize not everyone would do this but I believe the patient's best interest will not always be first. As a private physical therapist in private practice and one who had been working for a hospital, I can decide if the patient needs more or less treatments and confer with the physician. Patients can go to whomever they wish and know their care is for them and not for the profit of the physician who referred them. Thank you for your attention to this matter. Sincerely, Steve N. Harada, PT

Submitter : **Mr. charles disanto** **Date: 06/21/2004**

Organization : **apta**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

As Physical Therapists, My wife And I feel that Physician owned and self refering pactices are unethical and are not in the best intrest of the patients or the healthcare system.

Submitter : **Date: 06/21/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 21, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Dr. McClellan:

I have been a physical therapist in solo private practice for three years in Oklahoma City, Oklahoma. My specialty is in the treatment of spinal derangement, and I attend approximately 75 hours of continuing education per year to gain more knowledge of the evaluation and treatment of these disorders. I have seen a great impact on my practice by physician owned physical therapy clinics and am writing this letter in favor of the abolishment of these practices. I can cite a few examples:

1) Approximately 60% of my referrals used to come from four physicians who now own their own physical therapy clinic with a large group of physicians. Prior to that clinic opening, I was 'the best physical therapist' and achieved 'the best results'. Once their doors opened approximately four years ago (I was building my practice at that time with a group of other PTs), their referrals stopped. Did I all of a sudden become an incompetent therapist? Or did they decide that a therapist at a lower skill level would be worth the financial gains they would receive from their self-referrals? My practice has been successful in spite of this experience; more of my referrals now come from word of mouth.

2) The reputation of the clinic cited above is poor: no therapist continuity because the therapists' caseloads are too high, limited one-on-one time between the therapist and patient, limited manual therapy because of time constraints, patients complaining that they feel they are in a 'patient mill' because of so much congestion with little privacy.

3) I was treating a particular patient for a shoulder injury. During the course of his treatment, he went to see a physician for his low back. (This was a physician that used to refer consistently before he opened his own clinic.) The patient asked if he could see me for treatment of both his shoulder and low back; the physician 'ordered' him to go to the clinic he owned. I told the patient that it is the patient's choice where he attends therapy; however, the patient did not want to offend the physician. Therefore, the patient chose to drive 20 miles out of his way to attend PT at another location.

To summarize, I feel that physician owned physical therapy clinics are an ethical violation for the simple reason that there is a financial connection to every referral made by the physician, including the number of visits that the patient is seen, leading to a waste in health care dollars and promoting abuse to the health care system. I greatly appreciate your consideration of the points I have made.

Sincerely,

A Very Concerned Physical Therapist in Oklahoma City

Submitter : **Date: 06/21/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist. I have been in practice for 21 years and owner of a physical therapy outpatient office for 15 years. I wish to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I have concerns about the interim final rule and ask that they be addressed and corrected in the subsequent "phase III" regulations.
The single most effective way to reduce healthcare costs, fraud and abuse is to eliminate conflicts of interest. Physicians that have a financial interest in physical therapy services are in a conflict of interest. A physicians prescription is required by Medicare for reimbursement. The physician is in control of the referral. Physicians that refer physical therapy services that they own tend to over-utilize those services and provide a lower quality service. Physical Therapists in independent practice must provide the highest quality care in order to compete in the market place. The physicianed owned PT office has no competition. I urge you to take conflict of interest arrangements, and with it, the greed, out of Physical Therapy. You must clearly and permanently ban any and all situations where a physician profits by their referral to Physical Therapy.
Thank you for consideration of my comments.

Submitter : **Date: 06/21/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist and have been practicing in outpatient orthopedics for over 6 years. I have spent the majority of that time in the Virginia area. I am concerned about situations in which physicians are referring Medicare beneficiaries to entities in which they have a financial interest.
I have a unique background where I used to work for a physician owned practice. It was early in my career and I was not fully aware of what was going on. Looking back on our treatment and the way patients were directed our way worries me if it is happening throughout the country. I saw on numerous occassions where patients were referred to physical therapy with questionable need for such services. Therapy was prescribed for a frequency and duration that the therapist thought was excessive, but that the physician had told the patient they needed. Since that was my livelyhood, I would not force this issue with the doctor that owned the practice. While he generally offered excellent care and had only the patient's best interest in mind, there were times when it seemed there was an inherent financial incentive to refer patients to the practice they were invested in. There were no "options" for physical therapy given to the patient, simply when they wrote for PT, they said - "go and see one of our therapists".
Since leaving that practice, I look back and see the abuse that was occurring there. While the care we gave was excellent, the incentive to see and keep patients there for longer than necessary was overwhelming.
I am now on the other side of this issue and have tried to market to physician owned practices and to those that have a financial stake in a practice (ie. doctor owns the building that PT is in or is a "medical advisor" getting paid to advise the clinic in some way). They make no effort to give the patient options for PT and direct all of their patients to that one place so that they can keep getting paid either directly or indirectly for PT that the doctor prescribed.

The "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. It has also created a loophole that has resulted in the expansion of physician-owned practices that provide PT services. Often times services are provided by non-PT's and billed under the physician's provider number as PT services. These services are wasteful to the medicare program and could be harmful to the patient if given poor advice or treatment by an unqualified individual. Most medicare patients believe that if someone works in a medical enviornment, they must know what they are talking about, even if they have no training or licensure.
Please take my comments into consideration when deciding on the interim final rule and addressed and corrected in the subsequent "phase III" regulations.
Thank you for your consideration of these comments.

Submitter : **Voree Smith** **Date: 06/21/2004**

Organization : **Anacortes Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I believe it is inappropriate and unethical for a medical doctor to have the wholesale rights to another profession's livelihood, thereby eliminating the concept of independent and private practice. As long as we are on an unequal playing field with our referral sources being medical doctors, we are bound to them for our careers. We are a Master's level and soon to be Doctoral level profession and need to be viewed as a team member, rather than ancillary services. We also need to have the right to be NOT reliant on MD's to furnish our patient's for us. We need direct access to these patients which would make the POPs less lethal to our livelihood and make the competition approximately fair. This would not make the Stark laws antiquated, but would make their interpretation less of an issue. What is a private practice to do when they lose their referral source to a POP? There is no alternative at this point other than to branch out into other areas of PT, which may be less profitable, which would bring about less desire for the MD to come in and take over the practice. That is, make your income potential so small that no one would take the time to take it from you.

Sincerely,

Voree Smith, MPT
Anacortes PT

Submitter : **Mr. James Doeberling** **Date: 06/22/2004**

Organization : **Doeberling-Muccio Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Previous Physical Therapy patients are told to now only go to the Physician owned Physical Therapy in spite of their request to return to our PT owned practice. A patient has lost his ability to go to his choice of facilities, geographical area or individual therapist due the monopolistic control a Physician has. One patient followed the Physicans request rather than face losing workers comp. An Orthopedist Physician boasted to my employee that all his patients will be seen in his clinic and did not know how PT clinics could compete. There are no longer contols of the patient getting the best care at the patient choice but at the demand of the Physician for his Monetary gain.Suddenly with the opening of the Dr. PT clinic all referrals are funneled to that clinic with less than 5% elsewhere. these are the rare patients who demand it. All others do not want to offend the Dr. The likehood of overutilization of PT services has begun as the reason stated by Pysicians is to enhance their revenue lost by high malpractice premiums and insurance adjustments.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

This issue allows a physician to set-up a physical therapy practice that they have a direct financial gain in, allowing for the potential for overutilization of physical therapy services. In fact, often-times, these practices are staffed with un-qualified rehab aides that do not have a license to practice physical therapy. The patients are then billed under the physicians provider number. The medicare beneficiary is then receiving sub-standard care, and is at risk for further injury. On behalf of the patients, and the profession of physical therapy, do not allow this arrangement of physician owned physical therapy practices to continue. Strengthen the Stark II law....don't weaken it! If the ethical reasons for a physician not owning physical therapy services is not enough, then why don't we allow physicians to own pharmacies? Same reason.

Submitter : **Mr. Paul Slocum** **Date: 06/22/2004**

Organization : **Greater Hazleton Health Alliance**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment

Dr.McClellan, I am Paul Slocum PT MS, Director of Physical Medicine & Rehabilitation for the Greater Hazleton Health Alliance in Hazleton, Pennsylvania. I am a physical therapist with over 30 years experience, currently rehab director for hospital based programs that service one of the top Metropolitan Statistical Areas with Medicare beneficiaries in the country.

I am commenting on the March 26 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I am contacting CMS in order to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations. My concern is the potential for fraud and abuse that exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive 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. The issue of economic inroads by managed care, decreased reimbursement by the Medicare Physician Fee Schedule and other repayment drawbacks by insurance has affected physician income. Physicians have therefore sought other income avenues within the pressured health care sector. I am concerned that fiduciary abuse can occur due to these economic forces

Medicare beneficiaries should have the right to chose where they get their health care and who the provider of health care will be, including physical therapy. Unfortunately in my community I have learned situations where the patient?s freedom of choice is curtailed. In offices where physicians who own practices that provide physical therapy services, the Medicare patient is directed to the practice that the physician has invested in. I am aware of situations where the physician and/or office staff has walked the patient over to schedule the initial appointment. This is certainly a travesty with the practice of patient?s freedom of choice. This is a clear example of where ?in-office ancillary services? exception has created a loophole where physicians have a captive referral base of physical therapy patients in their offices, and freedom of choice to the patient is denied.

As a hospital based physical therapist and rehab director, I have another concern on the likelihood that physicians who own practices that provide physical therapy services will ?cherry pick? patients. And therefore sending patients to hospital departments who are uninsured or otherwise do not have financial resources for their rehabilitation care.

Dr, McClellan, I urge you to take a close look at the situation where physicians own or have a fiduciary interest in their physical therapy service. Please review this issue carefully and reject an environment where physician ownership can create economic conflict of interest and tainting physical therapy referrals.

Thank you Dr. McClellan for your consideration to my comments, and the opportunity to express my views on this subject

Sincerely
Paul Slocum, PT, MS

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist who currently provides care for patients in a physician owned practice on a per diem basis. Upon interviewing, I was told that the practice was "ethical" and that self referral is not abused and that patients are offered many choices for receiving therapiy services. I have found that the physicians often refer patients to their own physical therapy practice without giving the patient a choice. This is despite the fact that there are multiple providers in the area and many of them have specializations and experience well above and beyond those available at the physician owned practice. One specific example includes a patient who credits a therapist down the road for her ability to be able to walk after an ankle fracture. This patient started having pain 3 years later and requested to return to that therapist (who still works down the road). Her physician (an owner of the practice) instructed her that she had to come to our facility to receive therapy. The patient did not want to anger her family physician, so she came to our facility. Despite educating the patient that she had the choice to go see her previous therapist, the patient chose not to, so she wouldn't anger her physician. This is only one example of many in which I am aware that patients were not even told that they have a choice. Not allowing patients to have choice of provider can absolutely lead to abuse. I believe that this type of practice is unethical and will not be working in this situation much longer. Unfortunately, younger therapists (like those working in this clinic) tend to be naive and not understand the implications of self referral.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist with 17 years experience and I have strong reservations regarding the 'physicians' referrals to health care entities with which they have a financial interest.' Exceptions to the ban are defined too broadly. There is tremendous potential for fraud and abuse, especially because Medicare requires a physician referral for physical therapy. I am aware of situations in which patients (who have been treated or had surgery performed by a physician who owns a physical therapy clind) have been 'strong-armed' into having physical therapy at his clinic. This severely restricts the patient base for the other physical therapists in the area and is in my opinion a restriction of free trade. It is also a common occurence in these types of clinics for one therapist to see more than 20 patients in an 8 hour day. Where is the quality in that type of caseload. I had planned to open my own practice as the only certified physical therapy specialist in the area, when I learned from an office manager in a local physician's office, that he was planning to open his own physical therapy clinic to help offset the cost of his malpractice insurance and he was planning to refer all of his patients to his clinic. Isn't that 'double-dipping' Medicare? I also strongly oppose the 'in-office ancillary services exception because it does nothing to assure that the provider of the services is a licensed physical therapist and not a secretary. Does CMS really want to pay a non-licensed person to provide skilled services? What harm could arise from a non-educated, non-licensed individual performing ultrasound in the area of a malignancy, or giving a patient with severe osteoporosis a flexion exercise program for back pain? The first instance could lead to metastasis, and the second could cause compression fractures and additional pain, possibly requiring surgical intervention. Thank you for considering these comments. Please think about how you would like your parent to be cared for when they have Medicare as their primary insurance. I would like to see these concerns addressed and corrected in 'phase III' regulations.

Submitter : **Ms.** **Date: 06/22/2004**

Organization : **Ms.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To: Mark B. McClellan, MD, PHD, Administrator for Centers for Medicare and Medicaid

This electronic communication is to express my concerns regarding physical referral to health care = PT practices in which they have a financial relationship and from which they will benefit monetarily.
1. MDs are no longer allowed to own a financial interest in pharmacies from which they would benefit financially. The very same problems are of great concern if MDs are allowed to refer to a PT Clinic from which they receive financial gain.

2. I live and work 35 miles from Reno, Nevada. Occassionally our patients require medical attention and surgery, especially spinal surgery as it is not done locally, from a Reno MD/surgeon. When the MD asks the patient,who just had back surgery and also lives in Truckee, to drive to Reno to see "their" PT, one has to wonder. The patient has an established, positive relationship with a local and convenient PT (competent with extensive credentials and 20+ years of experience); when driving and sitting are contraindicated and the MD still requests the patient to drive to see "their" PT one has to wonder what the motivation could be. When I called and asked I was told it was a physician owned PT clinic. Given the above information, referral for profit at the patient's expense for time, costs and well-being was the motive.

3. Given human nature as it is, given the opportunity for referral for profit, it is unfortunate to expect at least some level of abuse. If CMS is looking to decrease their costs, then closing these loop holes would be in their best interests.

4. As monetary reimbursement is cut from MDs they are looking for other sources of revenue. Hence the increase in MD owned surgical centers and physician owned PT clinics. If money is the primary motivator what will be the outcome?

5. In MD owned clinics it is not required by law that a PT perform the ultrasounds or provide the services. Yet in an outpatient clinic it must be a PT. Where is the equity or quality of service that CMS expects.

6. As a private practice PT my continued existence depends on the quality of care that we as PTs provide both to the patients and the doctors. Lousy service and care equals no more patients in a small town. Surgeons wont tolerate poor care to their post-op patients. However, the same is not true in a physician owned clinic. The docs can just write the prescription to his/her own clinic. Quality is not the issue, reimbursement and financial gain become the goal.

7. If you don't believe this, then just take a close look at the number of visits, the outcomes and the costs of a private practice PT owned physical therapy clinic versus a physician owned PT clinic. I am sure the APTA would be happy to provide you with more information that you care to peruse.

I went in to physical therapy to help patients with musculoskeletal problems. All totalled I spent 7 years in college and post-graduate programs. I have extensive skill, experience and training in orthopedic problems. When I treat a patient it is to improve their quality of life as quickly and thoroughly as possible. After 20+ years I can do this effectively. An MD can have an office staff doing ultrasounds and new PT graduates working for pennies and make a tidy profit. The patients suffers.

Thank you for your time and attention to these comments. I trust you and your staff will make your final decisions based on the good of the patients, the good of CMS and the good of the overall health care system for our seniors. No doubt you have no choice but to close the loops holes that allow MD owned clinics and stop such practice. Thank you.

Submitter : **Dr. Troy Bourgeois** **Date: 06/22/2004**

Organization : **The Movement Science Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist in New Orleans, LA and have started a new practice three years ago. Besides the difficulty in buisness concerns, I have personally witnessed the truly unethical nature of physician ownership in PT practices within my city. This started with a new clinic opening down the street from my clinic offering 5 - 10% ownership to orthopedic surgeons who would refer patients. When they did this and prospered greatly while providing poor services and not disclosing that the doctors referring owned the facility, other clinics in my area began selling MDs ownership in their practices. Basically, there is no referal to the spcialist in the area for women's health, foot/ankle specialist, aquatics, etc...
The decission to refer is solely based on how much money one can make off of the referral. This is damaging to the patient who is looking for the best therapist within a specialty area and even more damaging to the profession as a whole.
I wish to comment on the March 26 interim final rule on
: ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

KEY POINT: The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.

? 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 practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

? In physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The ?in-office ancillary services? provision does nothing to prevent this practice from occurring. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

Closing: Thank you for your consideration of my comments.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a PT who has been in practice full time for 19 years; I have been a partner in a physical-therapist owned facility for 11 years. I am concerned about the current status of the Stark II regulations and I hope that you reconsider these regulations to protect patients' interests, abilities to choose providers, and avoid abuse of my profession.

In my current setting, I realize that my daily decisions are also molding the PT profession. Allowing physicans to own a PT practice allows them to control another discipline and this has the strong potential to and already has lead to overutilization and abuse of services.

One of the requirements that Medicare currently abides by, regarding the need for a physician referral to attend physical therapy, gives the physicians a much stronger advantage in referring to their own practice for financial gain.

In our clinic we have seen a woman who was told she had to attend PT at the orthopedic surgeon's PT office immediately after surgery. This required a 50 minute commute in each direction when other clinics were available to her, at 0.25 miles from work and 10 minutes from home. In this instance, the insurance type was worker's compensation, so the insurance company was also reimbursing for mileage. This demonstrates the physician's stronghold over ordering the patient on where to attend PT, irrelevant of cost to the patient or insurance company or convenience to the patient after surgery. I realize this instance in insurance type is not directly related to you, but bottom line - it was profitable to the physician.

In another instance of abuse, the physician ordered PT for a patient but ordered her to attend at his PT clinic only. When the patient complained that the hours were not conducive for her & another facility was closer to her home, the physician discontinued her physical therapy. When she complained of continued pain, he stated he couldn't do anything else for her. This was a blatent referral for financial gain and the physician has lost all objective measures in his ability to treat his patients by doing so.

Patients have come into our clinic expressing disgust at being strong-armed to attend the physician-owned PT clinic. Patients are looking for appropriate, objective care when seeking medical help and they are not finding it in offices that also have physician-owned PT services.

The longer I practice, the more I feel that the best & least expensive care is always the best quality care, as it's always cheaper to do it right the first time than to have to fix mistakes. I feel that the best qualityin physical therapy will come from physical therapists, and physical therapists alone, who have a financial interest in their clinic as they also have a financial interest in their future and their profession.

I thank you for re-considering the Stark regulations and I do hope that you can see that physical therapists, and NOT physicians, should be the owners of physical therapy practices. Not mandating physician referrals for physical therapy would also help to lessen the current potential for abuse.

Submitter : **Dr. Chaim Charytan** **Date: 06/22/2004**

Organization : **Renal Division, NYHQ**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : tim kelly **Date:** 06/22/2004

Organization : physical therapist

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

As a physical therapist, in private practice for nearly 30 years, I believe it is time to permit physicians and physical therapists to own and operate a private rehabilitation facility that directly incorporates their specialities. Ex. (1)orthopedics or sports medicine and physical therapy services (2) pain management and physical therapy modalities and exercise protocols.
Referral to a self owned business is common sense, esp when treatment protocols can be followed and adjusted according to the patient's response.

Submitter : **Mary Allen** **Date: 06/22/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

As a physical therapist, it is very concerning to read the alterations to the Stark II law that define broader exceptions to the ban on physician referral to physical therapy clinics in which they have a finacial interest. With the finacial state of Medicare and Medicaid being a national concern, it is not finacially responsible to support changes in a law that opens the door for potential fraud and abuse. Ethically, the practice of physician owned ancillary services is very suspect, both from the potential profit aspect which could lead to overutilization and increased costs to the system, as well as the potential for patients receiving less that optimal treatment. In our clinic, Medicare and Medicaid patients are treated only by a physical therapist or a physical therapy assistant. In physician's offices, these services are often provided by non-physical therapists, yet are billed as physical therapy. Practicing in a non-physician owned clinic allows me to make clinical judgements that are solely in the interest of my patients, not what is best for the pocket book of the physician that referred that patient to me.

I am aware of the growing number of physician owned physical therapy sevices in the United States and the negative impact it has had on ethical physical therapists who will not work under such an arrangement. Locally, physicians are expressing an interest in developing their own clinics soley because of the extra revenue it would mean to their practices, not because it would improve the quality of care. Physical therapy health care costs have been shown to be lower when patients can self-refer to physical therapy as opposed to going through a referral source; imagine what will happen to costs if large numbers of physicians own the ancillary services they refer to.

I urge you to consider carefully the modifications to the Stark II law and maintain a fiscal and ethical separation of physicians from ownership of ancillary services. The exceptions to the ban should be very limited in scope, not broaden as has happened with the interim rule.

Thank you for your time and attention to these concerns.

Submitter : **Mr. Brian Hoke** **Date: 06/22/2004**

Organization : **Mr. Brian Hoke**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

The in office exemption has been exploited by local physicians and group practices looking to increase their practice revenues in areas of ancillary services. Because physical therapists must have a physician referral for provision of PT services to Medicare beneficiaries, these physicians are using the in-office exemption to "capture" the PT referrals from their medical practice. This avoidable conflict of interest inhibits free market competition and necessarily limits choice of PT providers for the patient. I believe that elimination of this exemption would greatly improve the choices fro Medicare beneficiaries and reduce unnecessary expense to the Medicare program.

Submitter : **Mr. Michael Supler** **Date: 06/22/2004**

Organization : **Michael M. Supler and Assoc.**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

When a physician has a vested financial interest in a physical therapy practice, the quality of care in such facilities is hindered as the therapist is often required to perform routines which are billable but not necessary for the good of the patient. The possibility of the physican referring for monatary gains is greatly increased and the overall effects on the profession of Physical Therapy and health care in general is undermined.
Please consider the effect this will have if physican owned physical therapy practicies are allowed.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

I am writing this letter in reference to the Medicare Program; Physician?s Referral to Health Care Entities with which they have a financial relationship (phase II); Interim final rule with comment. My comment are intended to raise concerns about the interim rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

I am a physical therapist in private practice for the past 8 years. I practice in a region of Florida where I have 17 competitors; 2 hospitals, 5 private practices and 10 physician owned or financially interested practice, which makes up 59% of the physical therapy practices in the region.

Physician owner or financially interest in physical therapy practices is an appalling broche of ethics and undermines the legitimacy of the physical therapy profession. The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive 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.

I have witnessed abuses such as physicians refusing to give a patient a referral for physical therapy in they did not go to a practice that they were referring them too; incidentally the practice that the physician had a financial interest in. Treatment preformed and billed for by non-licensed personnel. Treatment care decisions being made by financially interested parties not involved in patient care such as chiropractors, attorneys and private investors.

Thank you for your consideration for my comments.

Sincerely
Florida 33414

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a physical therapist, I have many concerns about the clarifications of the Stark II law. My practice strives to bring the best value for services to the public. As such, I feel compelled to comment about the possible abuse of the vagaries of this proposed legislation.

The language used gives physician practices the opportunity to bill for physical therapy services not rendered by a licensed physical therapist. This can certainly increase costs to CMS. Physicians may feel they are providing a needed service to their patients, but I contend that anyone who requires those services can easily find them elsewhere and avoid the self-referral conflict. As a consumer, I am concerned about the sky-rocketing cost of health care. To avoid potential overuse, I suggest that only those licensed in the States of our country be allowed to provide physical therapy services in a free standing and unfettered place of business. I believe that previous studies have indicated higher usage of physical therapy services in physician owned practices. This is what made the Stark II legislation neccessary. Let's not move backwards on this issue. Thank you for the opportunity to share my views.

Submitter : **Ms. Melissa Fox** **Date: 06/22/2004**

Organization : **University of Virginia Health Sciences Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have been a physical therapist for 10 years, and strongly feel that we need to end the ability of physicians to self-refer to facilities in which they have a financial interest. There is a huge potential for fraud - we've seen over-utilization of physical therapy (PT)services when physicians own the PT practice to which they refer their patients. Even worse, we are seeing that physicians are billing Medicare for 'physical therapy' under their provider number, when the services are provided by office staff who have not undergone physical therapy training. This loophole is created by the 'in-office ancillary services' exception. Medicare should only be paying for physical therapy that is provided by a licensed physical therapist or a licensed physical therapy assistant! Thanks for listening.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

If a physician is allowed to have a vested interest in a facility there is a potential for unnecessary referrals. This is a critical factor especially with the decline in medical reimbursements for services. Physicians are seeking other means to suppliment this decline. This will be at the cost of proper care by a skilled therapist for the patient along with a greater cost to Medicare. Several published studies have documented the overutilization of services in which physicians have a vested interest. The studies have demonstrated an increase in cost of services for the patient and insurance companies along with a decline in availability of services. Allowing physicians to own physical therapy clinics will also result in many privately owned clinics going out of bussiness. Many states do not have direct access and are dependent upon physician's referrals. Physicians can then control the market. Patients do not know they have the right to choose where they receive their care. They depend upon the physician to make an unbiased assessment of their condition and recommend the appropriate care based on the patient's needs rather than the MD financial. If a physician has a vested interest, it would seem obvious that they would be more inclined to recommend questionable services in which they would profit. Thank you for considering my objections to this issue.

Submitter : **Mrs. Gretchen Seif** **Date: 06/22/2004**

Organization : **Mrs. Gretchen Seif**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Dr. McClellen,
I am a physical therapist in South Carolina specializing in outpatient orthopedics. I have been licensed in the state for eleven years. I earned my Bachelor?s degree from The Ohio State University and my Master?s degree from The Medical University of South Carolina.
I wish to comment on the March 26, 2004 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They have Financial Relationships (Phase II).? There is a potential for fraud and abuse when physicians are able to refer Medicare beneficiaries to entities in which they have a financial relationship. This is the case with physical therapy since there is still a requirement for a referral from a physician for Medicare recipients regardless of state statutes. If a physician is allowed to have a financial interest in a physical therapy practice, and because of the continuing requirement for physician referrals, there exists an incentive to refer to their PT clinic with the potential for over-utilization. This has been demonstrated in The Mitchell Study and in a study by Swedlow. (1,2)
In addition, the ?in-office ancillary services? exception is defined too broadly and it can also lead to abuses in the referral system. This loop-hole has created in the expansion of physician practices that provide physical therapy services. In South Carolina there is tremendous anecdotal evidence that these practices are proliferating. In some of these offices, because the physical therapy services are billed under the physician provider number untrained non-physical therapists personnel are providing these services. The delivery of physical therapy services by unqualified individuals will be harmful to the patient. I have had several patients from various physician owned practices who stated their ?physical therapy? was provided by the unlicensed medical assistant or the front office personnel. One orthopedic physician practice manager stated specifically to me that if South Carolina prevented physician ownership of physical therapy practices the physicians would just fire the physical therapists who were currently working for them and hire untrained individuals and file under the physician provider number. These statements are of great concern to me. These patients will not (did not) receive the care that is appropriate for their specific functional limitations. Patients have increased risk of injury from treatment by unqualified individuals. Patients receive care that can be harmful for their conditions because of the lack of skill and knowledge of the caregiver. For instance, a patient may receive treatments that are contraindicated for their specific condition or their co-morbidities. Patients will not have the benefit of a highly educated professional knowledge base for the patient education that is required for appropriate care if unqualified personnel deliver this care. Finally, unqualified and unlicensed personnel providing physical therapy are not bound by a practice act and a legal system to protect the patient and are therefore not held accountable for their actions in the practice setting.
These comments are intended to raise my concerns about the interim final rule and I hope that they will be addressed and corrected in the subsequent ?phase III? regulations.

Thank you for your consideration,
Gretchen Seif, PT, MHS, MTC
1. Mitchell JM, Scott E. Physician ownership of physical therapy services: effects on charges, utilization, profits, and service characteristics. JAMA. 1992; 268: 19-23.
2. Swedlow A, Johnson G, Smithline N, Milstein A. Increased costs and rates of use in the California Workers? Compensation System as a result of self-referral by physicians. N Engl J Med. 1992; 327: 1502-1506.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan MD, PhD
Adimistrator
Ceneters for Medicare and Medicaid Services
UD Dept. of Health and Human Services

Dear Admistrator McClellan,

I am a physical therapist who has been in private practice for 17 years. The recent proliferation of Physician owned Physical Therapy practices (referral for physician profit)has dramatically impacted my business and tilted the "playing field" of free enterprise unfairly.

The same physician groups who have publicly and privately praised us for quality of care are now only concerned with keeping their patients within their own four walls. They attempt to discourage patients who would like to come to our facility and attempt to persuade patients to leave our facility and come to theirs (if they were referred by another physician previously). We are now starting to see patients who are unhappy with their care at these facilities, seeking us out.

I have seen a 20% decrease in referals in one facilitity and an aggregate loss in over 500 referals in a years time in several others. I am not an expert in law but it seems inherently wrong and smacks of anti-trust that there is such a broad interpretation of "in-office ancillary services" exceptions that allows physician to refer to themselves for profit and allows the hiring of unlicensed "physical therapists".

There are now websites setup for physicians that encourages them to "capture lost revenue" by opening their own Physical therapy office and giving them a step by step map in how to do it. The prevailing advice is that the physician can legally exploit the loophole by hiring unlicensed people to perform "physical therapy" so they can increase their income. This loophole eliminates the protection of the consumer to receive physical therapy from a person who is licensed by thier state's allied health or medical board!!!!

I believe that the philosophy of maximizing revenue first, can only put patients best intersets and responsible spending of healthcare dollars last. The healthcare crsis in our country is well documented. Watering down the original Stark legislation and allowing such broad excepetions will certainly increase spending (more than likely compromise care) and over utilization.

I have built my reputation on provided best outcome, cost-effective care. Please close the exception loopholes and level the playing field for not only the independent practitioner and hospitals, but for the citizens of our country as well.

Thank you for the opportunity to give my comment. I urge you to close these loopholes in the "phase III" regulations.

Submitter : David Escobar **Date:** 06/22/2004

Organization : Blue Grass Physiotherapy PLLC

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Physicians are not physical therapist and should not be allowed to refferr patients to any physical therapy, speach therapy, or occupational therapy, that they themselves or their practice, or family members stand to profit from.

Submitter : **Mr. Mike Andrews** **Date: 06/22/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I would like to voice my concern in regards to the Stark II amendment regarding physician referral to physician-owned physical therapy organizations. I feel this creates a potential conflict of interest due to the fact that the referring physician would have a vested interest in assuring the PT facility is successful. This may result in overutilization as the business must be profitable to survive. I personally feel that physical therapy treatment should be based on convenience for the patient, with the referral placed to the clinic closest to the patient's home or work. Currently, most physicians refer to clinics who have provided excellent care for their patients in the past and usually will take into consideration where the patient lives when suggesting a clinc. Selfishly, this amendment does pose a threat to many non-physician owned physical therapy clincs, including mine. In conclusion, I believe one of the problems with healthcare in general today is that it's become more of a business than a service, and this amendment only encourages this to continue. Please reconsider this amendment to prevent PT patient's from being viewed as $'s instead of people.

Sincerely,

Mike Andrews, LPTA
Clinic Director
Physiotherapy Associates, Inc.
Strawberry Plains

Submitter : **Mr. Craig Bertsch** **Date: 06/22/2004**

Organization : **Progressive Rehabilitation**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have worked in the field of physical therapy for 6 years, receiving referrals from numerus MD's in the tri-state. The range of MD's that refer to our clinic has recently declined, and I relate this to the fact that many now have a financial interest in where they refer. The idea of MD's now referring to specific clinics where they have a finacial interest creates serious issues. I have had people I know state they would have come to me for treatment, however their MD said, 'no, you need to go here for treatment (to a clinic they have a financial interest).' MD's not allowing patients to go where they want for PT is actually illegal. Another fact - studies have shown that the case cost for individuals referred to a PT clinic where MD's have financial interest are signficantly higher than those referred to an entity without the MD's financial interest. Basically, if MD's have a financial interest, overutilization will occur. I believe the interim final rule must not allow MD's to have a financial interest in P.T. clinics, to avoid illegal actions and to prevent overutilization of services.

Submitter : **Dr. Robert Bucholz** **Date: 06/22/2004**

Organization : **American Academy of Orthopaedic Surgeons**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Definition of Referral:

In our previous comments to the Proposed Rule issued in January 2001, we urged CMS create a definition of referral that is appropriately limited so that technical violations of the Stark provisions would not impede the practice of medicine and proper care of Medicare beneficiaries. In particular, we encouraged you to exclude from the definition of referral services that are performed 'incident to' a physician's personally performed services or that are carried out by a physician's employees. The AAOS is disappointed that CMS declined to adopt our recommendation to exclude such services from the definition of referral because these services are integral to many orthopaedic practices.

2. In-Office Ancillary Services Exception

In-Office Ancillary Services Exception-The 'Building' Requirement

In our 2001 comments, the AAOS argued that the single building/single address and 'centralized building' requirements were arbitrary, and urged CMS to create a better, more common sense definition. Although in this current interim final rule, CMS declined to make any substantial changes to the definition of 'centralized building,' or to develop a more flexible definition of 'same building,' it did introduce three new alternative tests to determine whether services are furnished in the 'same building.'

Although the AAOS appreciates the added flexibility CMS incorporated in the rule by including these three alternative tests, we are concerned that requiring physician presence, either by the referring physician when ordering or a member of the physician group when furnished, in connection with the provision of DHS, may be too onerous for some group practices. It may be difficult for a group practice to be able to distinguish its operations as clearly meeting one test or the other, as well as to track and document its compliance with this assortment of practice variations. Therefore, the utility of the three tests, and, in particular, the second and third tests, for purposes of satisfying the same building requirement remains uncertain. Furthermore, the administrative burden of documenting compliance at all group offices could be substantial.

Under the first test, the same building component will be satisfied if the referring physician or his/her group practice has an office that is normally open to the physician's or group's patients for at least 35 hours per week, and the referring physician's or one or more members of the referring physician's group practice regularly practice medicine at least 30 hours per week at that location. The 30 hours must include at least 'some' physician services that are unrelated to DHS payable by any payor (Medicare or private pay) even if the services ultimately lead to the ordering of DHS. Unfortunately, CMS does not define what constitutes 'some' physician services except to state that the term will be interpreted by CMS in 'its common meaning.' Further clarification of these terms by CMS is needed to help avoid any unnecessary ambiguity associated with these otherwise subjective standards.

3. Group Practice Definition

Distribution of Profits in Multi-Specialty Group Practices:

In Phase I, CMS expanded the permissible methods by which a group practice's profits may be distributed to its members, concluding that differing methodologies for distributing profits to sub-groups of five or more physicians may be employed by the group. While CMS considered permitting a grouping of only three physicians and rejected this suggestion, we would like to encourage CMS to reconsider this conclusion in certain limited instances where the grouping of less than five constitutes an identifiable specialty or practice focus within the group.

According to AAOS census data, one out of every four orthopaedic groups have only two to three surgeons. Within many single-specialty group practices of two to ten orthopaedic surgeons, there are smaller sub-groupings with two to four physicians with entirely different clinical practice focus (e.g., orthopaedic oncology, pediatric orthopaedics, etc.).

Within these single-specialty practices, the most equitable distribution and the preferred manner of distributing profits within the group would be based on the subgroups of different practice concentrations. While CMS will permit this if the practice scope subgroup reaches five physicians, it is not permitted in the more common orthopaedic group in which only two or three physicians make up a practice subgroup or specialty focus. However, CMS permits solo practitioners and group practices of less than five to be compensated in this method under Phase II. This inequity is not justifiable and contrary to the stated intent of the provision in Phase I to permit groupings based on location or specialty. Thus, the AAOS urges CMS to reconsider whether groupings of less than five physicians should be permitted when the group practice can reasonably justify such grouping on the basis of some identifiable practice focus or specialty.

Issues 11-20

13. Definitions

Percentage Compensation 'Set In Advance':

In a significant change from Phase I, the Phase II regulations allow certain percentage compensation arrangements to satisfy the 'set in advance' requirement contained in several of the Stark compensation exceptions. Under Phase II, percentage compensation must be established with specificity prospectively, must be objectively verifiable, and may not be changed over the course of the agreement between the parties based on the volume or value of referrals or other business generated by the referring physician. Although the AAOS welcomes the additional direction on this issue, uncertainty remains as to whether a percentage compensation arrangement will satisfy the 'volume or value' standard found in many Stark provisions. Unless CMS provides further guidance on this point,

percentage fee arrangements not tied entirely to a physician's personal service (which are not considered referrals) could still create a compliance issue under the Stark Law. For instance, it is unclear whether a physician in a management position could receive an incentive based on a percentage of revenue of the business unit for which he or she is responsible. The AAOS requests that CMS address more than the narrow issue of percentage compensation for personally performed services, and instead fully confront the entire issue of percentage compensation.

11. Physician Recruitment Exception

Physician Recruitment Exception:

Many physicians and/or practice groups have entered into recruitment arrangements with hospitals that provide for payments and/or forgiveness of obligations over extended periods of time. Because the new regulations impose specific limitations on permitted recruitment arrangements, benefits provided after the July 26 effective date of the rule could result in a non-compliant financial arrangement under the Stark Law. These specific limitations were not defined in previous guidance, and many parties entered into these arrangements in good faith, relying on the guidance available to them at the time. We urge CMS to provide relief in the form of a grace period for physicians and hospitals in this situation, in order to avoid disruption of contractual arrangements that may ultimately lead to a limitation in access of care to Medicare beneficiaries.

CMS also created a 'narrowly tailored accommodation' that allows hospitals to financially support the recruitment of a physician into a group practice under limited circumstances. The recruitment payment must be passed directly to the recruited physician, except for actual recruitment costs. If an income guarantee is used, any costs recovered by the group practice are limited to the actual additional incremental costs attributable to the recruited physician (e.g., overhead). In addition, the group practice may not impose any restrictions other than conditions related to quality of care on the recruit (e.g., a non-compete clause).

These restrictions on group practice recruitment may pose problems. For hospitals and physician groups with existing agreements that do not meet the conditions of the rule, trying to unwind the arrangement will be daunting. Permitting the group practices to recover only incremental costs related to the recruited physician will be difficult to calculate and will likely understate the actual costs. The prohibition on non-compete clauses may limit the ability of hospitals to bring non-employed physicians into the community.

Issues 21-24

21. Exceptions-Temporary Noncompliance

Compliance Lapse Provision:

Phase II creates a limited exception that would permit, in narrowly defined circumstances, an entity to bill the Medicare program for a designated health service (DHS) provided during a period of temporary noncompliance with the Stark Law. In particular, the compliance lapse provision would only apply if the lapse arises for reasons beyond the control of the provider of designated health services, is limited to a period of 90 days, and is unavailable more than one time every three years.

The AAOS believes that the many limitations and restrictions contained in this exception will render it of little practical use in most circumstances. Compliance lapses that are truly 'beyond the control' of a provider are likely to be quite limited. As a practical matter, temporary compliance lapses result more often from inadvertence, which, although understandable for a busy provider with many physician relationships, may not be found to be beyond the provider's control. Furthermore, the exception's protection period extends only 90 days from the initial date of noncompliance, not from the date the noncompliance was discovered. Thus, an already brief period will likely be further shortened because discovery of the problem may take a period of weeks or months, effectively eliminating the use of the exception in such cases. The AAOS believes that this narrow approach to temporary lapses may make matters worse for providers having unintended noncompliant relationships that do not fit within the tight parameters of the exception.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

I have been a healthcare practitioner for over 20 years. In that time, I have seen physician owned practices expand and contract and now expand again. During that time, there is a direct correlation to the Stark amendment interpretations. Physicians who own physical therapy practices benefit financially from their use of physical therapy. Physicians control the referral to physical therapy and benefit financially from each of those referrals. It has clearly expanded beyond the intent of "extension of the physician's practice." This arrangement is pure profit and financially driven. The physician groups and the broad interpretation of what a group is had led to the ability of multiple groups made up of specialists including orthopedists as well as primary care physicians to partner to own physical therapy services. This partnership has led to increased profits by physicians in an environment in which they uniquely control the referral. This practice should be tightened and not BROADENED!

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a partner in a physical therapy private practice. I have dedicated my professional career to helping others in need. I am very concerned about the potential fraud, misuse, and referral for profit with physician owned physical therapy services.

I have a unique perspective in that I used to work for a POPTS clinic as a physical therapy aide in the early 1990's. Only after I attended PT school did I learn of the facts surrounding POPTS clinics. Back then, physicians argued that ownership of a practice improved continuity of care, 'it is better for the patient if they go to my clinic.' Yet I never recall a physician coming down to the physical therapy office to conference with one of our physical therapists.

Now the physicians in the area openly tell us and some of my other physical therapy colleagues that they are opening their POPTS clinics for the money. Moreover, there are businesses that are soliciting the orthopedic groups to assist them in opening their own POPTS.

I am very concerned that patients will not have the choice to receive physical therapy when or where it is most appropriate for them. With physicians directing them to their own clinics, patients may be over treated for profit; long distance commutes to physician-owned clinics will be financial taxing on patients, not to mention inappropriate for their diagnosis. I have had patients with the diagnosis of a herniated disc drive 45 minutes to get to a physician-owned clinic. Physical therapists know that driving is often the worst thing a back patient can do.

Quality of care and cost are the major issues. Previous studies like the Mitchell study demonstrate that visits per patient were 39% to 45% higher in joint ventures (POPTS) and both gross and net revenue per patient were 30% to 40% higher in facilities owned by referring physicians. Physical therapy was initiated 2.3 times more often by physicians in self-referral groups than by those in independent referral groups (68% versus 30%) according to the Swedlow study. Finally, patient care may also suffer in POPTS. Both licensed therapy workers and non-licensed workers spent less time with each patient, indicating that a lower level of care is provided, according to a study by the Florida Health Care Cost Containment Board, which also found that assistants are substituted for licensed therapists in POPTS facilities.

In this day and age, where cost is a major issue, physicians and management groups are openly stating that they are opening POPTS to increase revenues, and past studies already document the inefficiency, it makes no sense that we allow POPTS to proliferate in the market to further tax an overburdened medical system.

Will special interests win again? Will physical therapy professionals that provide a better quality of care at a lower cost be excluded from the market by self-referring physicians? Will patient care be compromised in the name of profit? Will physicians profit from the work of another medical professional?

I urge CMS to prohibit physician ownership of physical therapy practices! It makes no sense at all.

Submitter : **Mr. Vincent Smolczynski PT,CHT** **Date: 06/22/2004**

Organization : **Smolczynski P.T. Associates**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist who has been in private practice for 27 years. I have been practicing in the greater Allentown Pa. area for all those years. I have personally witnessed the progressive deterioration of the practice of physical therapy due to greed and unfair control of patient referrals.

Within a 25 mile radius of our office, virtually all but two orthopedists now provide "in office P.T services. This has devastated our practice. It has also tragically served to minimalize the P.T. profession. I have personally interacted with numerous physicians, marketing our services etc. In the past if you provided a good service you were rewarded by more referrals. Competition is healthy- its keeps you on your toes as a professional. It was a level playing field.

Now, all that has changed. Physician groups have danced around the laws regarding self referral, made a mockery of the Stark rulings and fraudulantly misrepresent the practice of physical therapy. I have continued to market our practice only to be further shocked by the outright greed, disregard for patient choice and the extreme strangle hold orthopedists and other entities (hospital networks etc.) exert on their patients.
Recently, I was approached by a group of six orthopedists to manage their P.T. practice. Their conceren was that their patients are waiting two to three weeks to get evaluated by their own P.T.s. They flatly refused to refer any of these patients to my practice or any other entity despite the acuteness of their condition or need for therapy because they would not financially benefit.

Usually the feedback I get from patients who end up in our facillity after they have been to other POPTs is alarming. They see the P.T for the eval, they are followed(if they are lucky) by the PTA, or some other less trained employee until their insurance benefits are exhausted, then discharged. These patients are shocked after a few visits with us. They actually get to interact with a therapist, have someone actually touch them, modify their programs accordingly and most importantly work with them to achieve their goals and reach an appropriate outcome.

A few years ago I needed therapy myself following a shoulder surgery. I elected to go to a friend who I worked with a few years before and was personally responsible for some of his clinical training. He was in my mind a great P.T. He had taken a job with a physicin group as manager of their practice. Despite this connection I sought his help. Much to my dismay, my therapy was a sham. Because he and his staff were overbooked and forced into physician determined efficiency quotas, my therapy barely resembled anything I understood to be effective quality care. I was in and out of the facillity in a half hour. My bill reflected 15 to 30 miniutes of therepeutic exercise, 15 minutes of manual therapy, an ultrasoud treatment and 15 minutes of moist heat. The reality was that an excellent P.T was being reduced to abbreviated and slipshod practices due to physician ownership of the practice. I am quite sure that I was not the only patient this was happening to.

As a profession, we have made every effort to grow and become more efficient in the delivery of therapy. The academic entry level has consistently been progressed to graduate better educated and clinically adept practicioners. Concurrently, the practice has been degraded by physician intervention into our profession. More therapy is provided by ancillary personnel and P.T.s are used minimally to legitimize these practices. I have a deep concern about my profession and the future of the newly graduated P.T.s. I urge you to consider these thoughts and legislate to stop this practice of physician self referral.

Respectfully,

Vince Smolczynski PT,CHT

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

From information I have read, this ?in-office ancillary services? exception has created a loophole resulting in the expansion of physician-owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. This type of arrangement violates principles of open market commerce upon which this nation was founded. The playing field is not level for physical therapists who earnestly gain their degrees, establish a private or group practice and then attempt to compete with physician owned practices. Also, the way Medicare regulations currently read, therapy services provided in the physician?s office do not require the services be provided by a licensed physical therapist. Physicians have financial incentive to hire the least costly personnel, non-therapists, to provide ?physical therapy? to Medicare beneficiaries. This situation has the potential to be harmful to the patient, and is wasteful to the Medicare program as well.

Dr. McClellan, I?m sure you will agree the most important part of providing any form of health care to Medicare beneficiaries is the decision-making process. Physical therapists are the most qualified to make decisions regarding the provision of therapy services to Medicare beneficiaries. A level playing field where physicians have no financial incentive to refer their patients for therapy services will keep downward pressure on rising health care costs, and will also allow the most qualified practitioners to be the ones who provide the care to the patients.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Comments re: Medicare Program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Dr. McClellan,

I am a physical therapist in the great State of Utah. I have practiced physical therapy for 16 years now having enjoyed the many opportunities in working to help individuals to recover from devastating neurologic injury, as well as helping those who suffer pain with arthritis and other ailments more common in the geriatric population. Over these 16 years I have seen tremendous evolution in the provision of physical therapy. As part of this evolution I have seen advances in therapy regimens that have significantly reduced the volume of therapy service provided per a given diagnosis. Also contributing to these reduced provision of therapy services is a better understanding by therapists of principles of teaching and learning that have allowed us to more efficiently instruct and motivate individuals to accept more responsibility for their own care, not only during the time therapy services are being provided, but also post discharge to encourage individuals to modify any behavior that may contribute to successive needs for therapy. Given these positive changes I have viewed, I would like to comment on the March 26 interim final rule on the Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Stark Phase II).

Based on Medicare requirements, physical therapy cannot be provided to Medicare beneficiaries without a physician?s referral. I appreciate the collaborative relationship this fosters with the physician in caring for the patient. Physicians with whom I work appreciate the input I provide in care management for appropriate patient conditions. I understand the limits of my expertise, the parameters of improvement to be expected in rendering therapy for a given condition, and when not met I refer the patients back to the physician to pursue additional diagnostic testing, or other physician care to benefit the patient most efficiently and effectively. Given the parameters expressed in the aforementioned Phase II rule, I do not see any incentive for the physician to look for efficiencies of care; rather, it seems to me the potential for fraud and abuse is readily present when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. Physicians who provide therapy services in their offices, or who own practices that provide physical therapy services, have an inherent financial incentive to refer their patients to these practices, and to over-utilize those services for financial reasons.

Thank you for the opportunity to comment.

Submitter : **Mr. Bill Powers** **Date: 06/22/2004**

Organization : **Mr. Bill Powers**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I feel that as long as a physician dicloses his interest in the entity to which the referral is made and the patient has the right to choose which entity he would like to attend, then the physician has done all he can to allow freedom of choice. I do not believe government should have the right to limit these actions as long as disclosure is made and patients have choosen to attend a clinic even if it is owned by a physician group.

Thank you

Submitter : Ann Heiman **Date:** 06/22/2004

Organization : Spencer Hospital/ APTA

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I work in what is considered a Rural Area. However, we really aren't. We have a community hospital that the area is VERY proud of. I am the director of the rehab services that include 6 PT's; 4 OT's; and 2 ST's. We have 12 general practice physicians, 4 Orthopedic Surgeons; 5 general surgeons among others that support Spencer Hospital. PROBLEM--The ortho's now have a PT in their facility. They utilize "incident to" billing to get away from any Stark regulations. This has dropped our outpatient revenue by 50%. We may be required to cut staff. The problem is we need the staff to provide service to our community in home health, outreach clinics, inpatient, and for the remaining outpatients. Patients ARE NOT given a choice. They are told to go to the PT in their office as it is "convenient". This is unethical to say the least, and I would question the appropriateness of services.
Look at the Research--Utilization is up; financial gains up when the MD refers to his own practice!!!
Do SOMETHING!!! This is a PROBLEM everywhere in REHAB!!!

Submitter : **Mr. William Melchione** **Date: 06/22/2004**

Organization : **Blue Ridge Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

7. Space and Equipment Rental Exception

Hello,
I am a practicing Physical Therapist and have been practicing for 16 years. I have seen the benefit to our patients, and the medical system in general when physician self referral was eliminated with the Stark laws. It is now back in full force due to the recent interpretation of the Stark II laws allowing physicians to own a physical therapy center that they refer to. We have seen a proliferation in Virginia of physician owned therapy centers. There is a body of data that clearly demonstrates what happens when physicians are allowed to refer to a service that they own. This has been demonstrated in the studies carried out in Florida and California in the 1990's. William Mercer concluded in his study in 1992 that "this phenomenon generates approximately $233 million in services delivered for economic rather than clinical reasons." That it $233 million dollars in 1992 dollars. Ther eis certainly more of a financial motive for physicians to self refer now then in 1992. Their malpractice insurance premiums are rising and their insurance company re-imbursements are decreasing. Owning a physical therapy service is a convenient way to offset those losses. Studies in Florida have demonstrated that in phsician owned therapy centers patients recieve 43% more visits per patient which resulted in a 31% higher revenue per patient then in PT owned facilities. Therapists working in a physician owned clinic treated 62% more patients then in a PT owned clinic. This study concluded that physician owned clinics provided a lower quality of care becuase both licensed therapy workers and non-licensed workers spend less tiem with patients. The California workers compensation study demonstrated the abuse of referal as 66% of the time a workers compensation patient was treated by a physician who owned a therapy clinic a referral was made to PT versus only 32% of the time when the treating physician did not own the therapy center. The Stark II loopholes need to be closed. When the Stark laws were written it was to prevent this kind of abuse. Abuse of any kind has no place in our healthcare system. You have an opportunity to eliminate this practice of self referral which has clearly been demonstrated to be abused. I ask you as a healthcare provider, and as a taxpayer to please eliminate the opportunity of any kind for a physician to self refer. Thank you.

Bill Melchione, PT, MS
Blue Ridge Physical Therapy
Lexington, VA

Submitter : **Mrs. Jocelyn Bohnet** **Date: 06/22/2004**

Organization : **In Touch Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. McClellan:

I have been a Physical Therapist for 5 1/2 years primarily working in independently owned private practice clinics in both Ohio and Oregon where providing high quality care has been our primary objective. For the past 2 1/2 yrs I have been working at In Touch Physical Therapy in Tualatin, OR.

In Touch Physical Therapy has been directly impacted by Physician Owned Physical Therapy Services (POPTS) on two separate occasions. In both circumstances some of the physicians in these practices were large referral sources as they appreciated the excellent care and outcomes their patients recieved under our care. When their clinics started their own physical therapy services there was pressure from the heads of their clinics to refer internally. In both situations the doctors spoke with us and said, in essence, although they would prefer to continue to refer their patients to us they felt pressure from their employers to refer to their POPTS.

This presents a problem on at least two accounts. Physician owned physical therapy services may be over utilized for financial gain by referring patients unnecessarily - the physician's financial interest, not medical need, becomes the primary reason for referral. In addition, this takes away a patient's right to choose where to obtain PT services as they are being offered only one choice in most situations where POPTS are concerned.

Regarding the "in-office ancillary services" loophole, non-physical therapists are providing care for patients which are billed under the physician's provider number as physical therapy services. This presents a problem for patients as their insurance benefits for physical therapy are being exhausted without receiving appropriate care from a trained physical therapist - an occupation that requires 5-7 years of undergraduate and graduate education. This is harmful to the patient as untrained staff are not attuned to the possible systemic diseases that may also be causing the patient's symptoms, they may not know when to refer the patient back to the physician for further testing, they are not trained in all the precautions for utilizing physical therapy modalities and they are unaware of protective techniques to progress patient's treatment without harm. Non-physical therapist treatments being billed as physical therapy service is also very wasteful to the Medicare porogram for the same reasons as stated above.

I highly urge you to consider my comments to make the final decision to restrict the ability of physicians to own and refer to physical therapy services in which they have a financial interest.

Respectfully,

Jocelyn Bohnet, MPT

Submitter : CLAUDIA MILLER **Date:** 06/22/2004

Organization : STO-KENT PHYSICAL THERAPY INC

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2004

Subject: Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Mr. McClellan:

I have been a physical therapist for 23 years, and have owned an outpatient private practice for 15 years. My typical patient comes with an orthopedic condition or injury. However, I have also served the home health and long term acute care populations. I am eager to provide wellness care and consultation now that Ohio has become a "Direct Access" state.

I wish to comment on the March 26 Interim Final Rule on "Physician's Referrals...." I am concerned that the Interim Final Rule interprets the statutory prohibition of physician self-referral too narrowly and defines the exceptions to allow physician ownership too broadly, rendering the self-referral ban purposeless. The prohibition on self-referral should be strengthened in order to minimize the potential for abuse when physicians are able to refer Medicare beneficiaries to entities in which they hold a financial interest. In the case of physical therapy services, currently, a physician's referral is required. Physicians who own practices that provide physical therapy services have in inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. The "in-office ancillary services" exception has increased opportunities for physician-owned practices that provide PT services: physicians have a captive referral base of physical therapy patients in their offices. These services are often provided by non-physical therapists, builled under the physician's provider number as physical therapy services. The so-called "physical therapy" provided by unqualified personnel is not the standard of care that the term "physical therapy" implies; it may be ineffective, harmful for the patient, and wasteful to the Medicare program. Patients may not be aware of the qualifications of such providers and, it aware, may not want to oppose their physician's action in the self-referral situation.

I am aware of several physician-owned physical therapy services in my geographical area that have appeared in the past few years. Co-incidentally, my volume of patients has decreased significantly. One physician-owned service employs a grandfathered Physical Therapist Assistant that supplies the "in-office ancillary services" to their patients. I am not merely complaining about the loss of business, rather, I am suggesting that the patient's ability to choose a more skilled practitioner (myself, a Board Certified Orthopedic physical Therapist) is restricted unless the patient has broad knowledge of the existing situation.

Thank you for listening to my concerns. I would really appreciate it if you would work to remedy this anti-competitive situation by strengthening the prohibition against physician self-referral as it was originally intended.

Sincerely,
Claudia L. Miller, PT, OCS

Submitter : **Mrs. Dana Kwong** **Date: 06/22/2004**

Organization : **In Touch Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To: Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II);
Interim Final Rule with Comment

Dear Mr. McClellan:
I have been a physical therapist for 11 years primarily working in privately owned outpatient orthopedic clinics in the Portland Metro region. My work history also includes a year of on-call physical therapy where I was able to visit a variety of settings which gave insight to how many clinics operate and thrive. I am currently working at In Touch Physical Therapy in Tualatin, Oregon and have been at this setting for the last 3 years.

I am writing because of my concern regarding the March 26 interim final rule on Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). In the past year Physician Owned Physical Therapy Services (POPTS) have negatively affected In Touch Physical Therapy. In two separate instances physicians that we closely work with informed us that they could no longer refer to our clinic as they were now required to refer to a designated P.T. clinic. In each instance we lost potential business and the opportunity to treat and rehabilitate patients from those medical clinics. But, most importantly, the patient lost the opportunity to choose their place of treatment as they were only offered one option. There is a difference between physicians referring solely to a clinic based on receiving excellent care of their patients and one where referrals are made based on monitary gain: the physician's financial interest-not medical need-becomes the primary reason for referral.

If any form of POPTS is allowed,including the allowance of in-office ancillary services,the system will be abused. Physician's will over refer, small privately-owned businesses (that aren't physician owned) will eventually fail and the quality of care for patients will be lost. In the long run, this becomes wasteful to the Medicare program. If a clinic knows they will make money because of having a 'for-sure' referral base physical therapists will not have the motivation to give the best quality of care available. Instead therapy will turn into a treatment mill,rushing patients through to make the most money. Many patients do not know they have an option to pick a P.T. clinic different from the one that their physician referred them to. However, like any other service, people should have the right to choose.

I highly urge you to restrict the ability of physicians to own and refer to physical therapy services that they have a financial interest in. Thank you for consideration of my comments and concern.

Sincerely,

Dana Kwong, PT

Submitter : **Mr. William Melchione** **Date: 06/22/2004**

Organization : **Blue Ridge Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Hello, I am a practicing physical therapist and have been practicing for 16 years. I have seen the benefit to our patients, and the medical system in general when physician self referral was eliminated with the Stark laws. It is now back in full force due to the recent interpretation of the Stark II laws allowing physicians to own a physical therapy center that they refer to. We have seen a proliferation in Virginia of physician owned therapy centers. There is a body of data that clearly demonstrates what happens when physicians are allowed to refer to a service they own. This has been demonstrated in the studies carried out in Florida and California in the 1990's. Willam Mercer concluded in his study in 1992 that "this phenomenon generates approximately $233 million in services delivered for economic rather than clinical reasons." That is $233 million dollars in 1992 dollars. There is certainly more of a financial motive for physicians to self refer now then in 1992. Their mal-practice insurance premiums are rising and their insurance company re-imbursements are decreasing. Owning a physical therapy sercice is a convenient way to offset those losses. Studies in Florida have demonstrated that in physician owned therapy centers patients receive 43% more visits per patient which resulted in a 31% higher revenue per patient than in PT owned facilities. Therapists working in a physician owned clinic treated 62% more patients than in a PT owned clinic. This study concluded that physician owned clinics provided a lower quality of care because both licensed therapy workers and non-liscened therapy workers spend less time with patients. The California workers compensation study demonstrated the abuse of referal as 66% of the time a workers compensation patient was treated by a physician who owned a therapy clinic, and referral was made to PT versus only 32% of the time when the treating physician did not own the therapy center. The Stark II loopholes need to be closed. When the Stark laws were written it was to prevent this kind of abuse. Abuse of any kind has no place in our healthcare system. you have an opportunity to eliminate this practice of self referral which has clearly been demonstrated to be abused. I ask you as healthcare provider, and as a taxpayer to please eliminate the opportunity of any kind for a physician to self refer. Thank you, Bill Melchione, PT, MS. Blue Ridge Physical Therapy, Lexington, Virginia.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

June 20, 2004

To: Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid
U.S. Department of Health and Human

Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program, Physicians? Referrals to Health Care Entities with which they have financial relationships (Phase II).

Dear Dr. McClellan,

I am a physical therapist and have been practicing for nine years. During that time I have become certified as a hand specialist. I currently practice in an outpatient rehabilitation and fitness center owned and operated by a physical therapist.

I would like to comment on the March 26th interim final rule on ?Physicians? Referrals to Health Care Entities with which they have financial relationships (Phase II).? I have concerns about the interim final and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive 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.

In a progress report that I sent to a physician regarding his patient, I included some other pertinent musculoskeletal findings from my evaluation. The physician faxed the note back with a comment ??don?t try to play doctor.? I only put in things that I had learned in physical therapy school. I was trying to be a thorough physical therapist. My point is, the physician resented me doing what he thought was his territory. As a physical therapist I resent physicians doing what is clearly my territory as a physical therapist. I went to a university to get my degree in physical therapy which took several years. How much education do physicians get to practice physical therapy? I would venture to say, maybe one day in medical school if they are lucky.
I have had numerous patients tell me that they did not get the kind of care from physician owned physical therapy clinics that they receive at our clinic. They have reported less time spent with them as well as they didn?t get in better. Furthermore, they felt like they wasted their time and money.

The ?in-office ancillary services? exception is defined so broadly in the regulations that it facilitates the creations of abusive referral arrangements. It has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

In physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The ?in-office ancillary services? provision does nothing to prevent this practice from occurring. The deliver of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. There are indications and contraindications for all modalities and procedures administered by physical therapists. Without the proper knowledge these can cause harm by delaying the healing or make matters worse. Exercise, as simple as it seems, can be prescribed incorrectly and often has been by physicians.

Thank you Dr. McClellan for your consideration.

Sincerely,

Johanna Deckert, MPT, CHT

Submitter : **Mr. Howard Bogard** **Date: 06/22/2004**

Organization : **Burr**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

This comment is submitted in regard to the Phase II, Stark Law published March 26, 2004.

On page 16076 the following statement appears:

"Billing by a physical therapist under his or her own billing number does not satisfy the billing requirement of section 1877(b)(2)(B) of the Act, which requires that the service be billed by the performing physician, the supervising physician, the group practice using a number assigned to the group, or an entity wholly owned by the performing or supervising physician or the group practice. However, if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist's number indicated on the bill), then the billing requirement would be met."

In the State of Alabama, Blue Cross Blue Shield of Alabama, the Medicare carrier for Alabama, will not issue a "group" Medicare number to a physician group. Rather, each individual physician has a separate Medicare number. Consequently, it is not feasible for the group to bill for physical therapy services under the group's billing number (since there is no number). Rather, the physical therapist can bill under his or her own number and reassign his or her right to payment to the group. If this arrangement is not permitted, a physician in the group would need to bill for the physical therapy services under the "incident to" rules, and would need to provide direct supervision to satisfy the incident to billing requirements. To require incident to billing would impose additional supervision restrictions on a physician group simply because the carrier will not issue a group number.

I ask that you clarify the above issue. In those states in which a physician group is not able to obtain a group Medicare number, would the group need to enroll as a "physical therapy group" even though the group is a physician practice? Would the physician group need to form a wholly owned subsidiary to serve as a rehabilitation agency? If not, I ask that you allow under the in-office ancillary exception for a physical therapist to bill under his or her number and reassign the payments to a group practice; provided, however, that the group practice operates in a state in which it is not able to obtain a physician group Medicare number.

Thank you for your attention to this matter.

Submitter : **Mr. Paul Hughes** **Date: 06/22/2004**

Organization : **Mr. Paul Hughes**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

As a Practicing Physical Therapist for over 30 years, I have personally observed the continuious growth of in-office provision of ancillary services by physicians, including the dramatic increase of physical therapy for the sole purpose of increasing physician's practice revenue stream. What I find so amazing is the broadening base of physician type offering services. At one time, it was only orthopedic surgeons. That has changed to neurologists, anesthesiologists, internists and family physicians. Many will admit, privately that is, that providing increasing levels of these services is necessary to compensate for the loss in physician fee schedule rates. With or without the use of licensed physical therapists, this can not be beneficial to the public. Congress has opened the door and allowed it to stay open for abuse. Additionally, without regulation of these in-house services, the abuse has just continued to grow. I am a tax payer and this is not where I chose to spend my money.

Submitter : **Mrs. Melissa Martin** **Date: 06/22/2004**

Organization : **M & M Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a PT who owns a private practice and am surprised at the new interpretation of Stark II. I have been very effected by the new ruling because my old MD referral sources are now opening up their own clinics and are no longer referring patients over to my clinic. It also seems that the doctors are referring every and all patients due to the financial incentives without concern on whether it is really medically necessary. It also seems the quality of PT in the physcian owned setting has diminished because they mostly employ PTA's and new grads verses someone like myself who has been practicing for eight years and has achieved further schooling and credentialing (orthopedic clinical specialist). If CMS is worried about its budget and fraudulent practices, I would think that overutilzation and quality of care would be high priority, yet with this ruling, it does not seem that it is a priority. Please consider the patients being affected by unnecessary or inadequate care and make some changes to the interpretation.
Sincerely,

Melissa Martin, PT, OCS

Submitter : David **Date:** 06/22/2004

Organization : David

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am a PT in Nashville, TN, and I have been practicing since 1/87.

I would like to comment on the March 26 interim rule on the 'Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).' I would like to ask for a more restrictive interpretation of the ban on physician self-referral and a removal or narrowing of the stated exceptions.

I recall the prior wave of physician owned services in the early 1990s, and I am distressed to see another occurrence as physicians again seek to add a new revenue source to their office practices. My colleagues and I have been told by several physicians and groups in our area that the decision to operate PT services in their offices is strictly a financial decision. We have also experienced abrupt losses of referrals from physicians who previously relied heavily on our clinical expertise, only to begin to refer almost exclusively to their own therapists after opening. We have private PT companies providing 'management services' to physicians in order to obtain access to their offices for a fee. I believe this type of arrangement is frought with opportunity for fraudulent and abusive practices, as the physicians have a financial incentive to refer more patients to therapy and keep them there for longer periods of time, and they no longer look primarily to the provider who will be of greatest benefit to their patients.

We saw the demise of most physician owned PT practices in the early 1990s as the federal regulations prohibited the owning and self-referral of ancillary services. We had a more level field where we had to compete for patients by the quality of the services we offered. Unfortunately, the 'in-office ancillary services' provision has opened a loophole facilitating the creation of potentially abusive referral arrangements. As more offices and groups seek to add ancillary services, I have no doubt that services, in some cases, will be provided by non-licensed personnel and billed under the physician's provider number, and I believe this type of 'physical therapy' will be of greater cost and lesser benefit, and it may greatly harm the patients that the physicians are sworn to serve.

I have no doubt that we, as independent providers of PT services, will continue to provide the best quality care of those patients who require PT, while at the same time providing cost effective care. I thank you for your willingness to review these comments. I trust that you will act in the best interest of the patients you serve.

David

Submitter : **Mr. David Damon** **Date: 06/22/2004**

Organization : **Kitsap Physical Therapy & Sports Clinics**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern:

Clearly the situation of allowing a refer for profit physician owned physical therapy (POPS)practice has built in bad policy. No doubt there will be greater utilization of therapy in such settings, and less use of outside perhaps more qualified therapy services.
This creates an environment where the competitive edge of providing a high quality product or service may have no bearing what-so-ever. The involved physician practice will most likely not consider using sources outside of their walls where profit is retained. Is this any different than the reasoning as to why we do not allow physicians to own a pharmacy?

My concern is of course to a large extent self preservation, but one only has to look at who is often providing therapy services in the physician owned practice to realize it should be a concern to the consumer as well. Physicians currently can, and often do, provide 'physical therapy' with non licensed staffing (medical techs, nurses, front office personel....) and bill for physical therapy services. Who wins in such cases???

Please do not be influenced by the power of the AMA. Please make your decisions about this practice based on concern for the patient as well as for those of us trying to provide the highest standards of care.

Sincerely,

David Damon, PT, OCS, ATC
Kitsap Physical Therapy & Sports Clinics
Silverdale, Wa.

Submitter : **Mr. Steve Anderson** **Date: 06/22/2004**

Organization : **Mr. Steve Anderson**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Medicare fraud exists. One reason points to the unscrupulous, less than honest providers who manipulate the system for financial gain. The other reason points to loopholes in the Medicare requirements that not only allow, but encourage, unethical practice and patient management for financial gain.

Fraud and abuse exist when physicians are able to refer Medicare beneficiaries to entities in which they have financial interest. This situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for Medicare beneficiaries to receive physical therapy services.

Medicare/CMS has an opportunity, and a responsibility, to make sure its requirements do not allow and encourage fraud and abuse of the tax dollars that support the Medicare system.

2. In-Office Ancillary Services Exception

On the one hand - In a private practice physical therapy clinic CMS will only reimburse for physical therapy services provided by a licensed physical therapist provider. It should also be noted that this reimbursement is at a reduced rate of the physician fee schedule.
On the other hand - CMS allows non-licensed, non-formally trained individuals to provide "physical therapy services" in a physicians office, under its In-Office Ancillary Services Exception. These services are then reimbursed at the full rate of the physician fee schedule.

The contradictory nature of these CMS rules leads to abuse, deception of the public, and wasted use of Medicare funds. It also allows for potential fraud and abuse by physicians who wish to pad their charges by providing so called "physical therapy srevices" by non physical therapists.

Does the contradictory nature of these two rules make anybody else scratch their head?

Submitter : **Mr. Jon** **Date: 06/22/2004**

Organization : **Mr. Jon**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist practicing in the state of Montana. I have practiced in an outpatient hospital rehab facility for more than 8 years now and for nearly 9 years as a PT. I have little financial interest in this decision as I am an employee of a hospital and have no financial incentives in my contract.

I strongly oppose the medicare rules that permit physician referrals to entities with which they have financial relationships on the basis of the following two points.

1) This rule gives physicians a financial incentive to provide more services than are absolutely necessary.

2) Since physician referral is required to receive physical therapy services, physicians determine not only who needs the services, but where those services will be provided, and by whom. Clearly this is not in the best interest of the patient.

I have recently seen a decline in the number of referrals to the rehab unit where I am employed at the same time a physician owned physical therapy clinic opened in town. Patients have commented that they would have preferred services to be provided by our rehab unit, but didn't know they had that option until they had initiated services.

A change is in order. This rule does not ensure that patient's treatment is cost effective. It also particularly leaves patient choice unprotected.

Submitter : David **Date:** 06/22/2004

Organization : David

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

testing

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

THis arrangement can work well as long as the legal and ethical issues are followed. Doctors and therapists should be held accountable for their decisions regardless of what they own.

Submitter : **Mr. Dennis Dougherty** **Date: 06/22/2004**

Organization : **Mr. Dennis Dougherty**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

This allows physicians to benefit financially from self referral. This will lead to overutilization and unnecessary services. Please use common sense and do notgive in to political pressure to the MD lobby. Physical Therapy should be an independent component of medical care and is not incidental to MD services.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am physical therapist in private practice in New Jersey. I have been in private practice for 25 years. I am very concerned about the dramatic changes in the way physical therapy services are being delivered to Medicare Beneficiares. As the reimbursement for medical services has declined ,physcian offices are actively seeking ways to increase their office income,either directly or indirectly. This means that many physicians have invested in off site physical therapy services as a means of gaining passive income.This arrangement only provides significant income if the physcian refers to the health care entity that they have a financial interest in. In the other financial arrangement, the physcian employs individuals in their office to provide "physical therapy". Most often the individual is not a physical therapist.If they are a physical therapist they are in an environment that places profits before patients. In the area in New Jersey that I practice in,(Somerset County), I have observed the proliferation of these arrangements from 3 practices in 1988 to over 25 in 2004. And that is just within a 10 mile radius of my office !! Under current Medicare regulations, Medicare patients must be referred to a physical therapist by their physician.They are additionally required to see their referring physician every 30 days after an intial 60 day interval.This environment is one in which physicians take advantage of Medicare requirements for their own financial gain.I think that the proposed interim final rules regarding physician referrals to health care entities that they have a financial interest in should be corrected in subsequent Phase III regulations because the current interim final rules interpretation gives too much leeway for abusive practices. Medicare Beneficiares are currently being harmed by these direct and indirect financial arrangements because the underlying premise for their existence is financial gain versus quality patient care.Additionally, these are much more costly to the Medicare Program and ultimately to every Medicare Beneficiary. The future of quality physical therapy being provided by physical therapists in private practice is at a critical crossroad. We can not keep our doors open to Medicare Beneficiares if Physician owned or operated facilities are allowed to proliferate. I want to thank CMS Administrator Mark McClellan for the opportunity to voice my concerns .I hope a greater awareness of how critical this situation is has been gained and the need to make changes in Phase III regulations will be followed through with.

Submitter : **Ms. Sheryl Valone** **Date: 06/22/2004**

Organization : **Bodies in Motion Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist working in a therapist-owned private outpatient orthopedic practice. I have been working as a physical therapist for 9 years in Northern Virginia. I am commenting on the March 26th interim final rule on 'Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships'. I have had patients who told me that when their physician gave them a prescription for physical therapy, he/she told them, 'just go next door and schedule an appointment' without disclosing the financial relationship or providing them with other options. The only reason the patient knew to go elsewhere was from prior physical therapy services at a different location. I also know that in physician-owned physical therapy practices, physical therapy is often provided by non-physical therapists, yet billed as physical therapy. This latest 'in-office ancillary services' provision does nothing to prevent this practice. These unskilled health care providers may prolong patient recovery because of errors in decision making, and cause greater cost to the medical system in the long run. I worry about the long-term consequences to the quality of care of physical therapy services when independently owned practices don't have the ability to compete with physician-owned practice. Gone is the incentive for a physician to send his/her patients to the best clinic out there when there is such a financial gain in sending patients to his/her own clinic with less trained personnel. Thank-you for the opportunity to provide this feedback.

Submitter : **Claudia Miller** **Date: 06/22/2004**

Organization : **Sto-Kent Physical Therapy, Inc**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

June 22, 2004
Dear Mr. McClellan:
I am a physical therapist in private practice, 23 years experience, working with an orthopedic population. I am writing to inform you of some practices that, in my opinion, accent the importance of strengthening the prohibition on physician self-referral. A group of family physicians across the street from my facility had been, until about 1 1/2 years ago, referring patients for out patient physical therapy, and we saw an average of 2-3 new patients per week from that group. Suddenly, the only new patients that we have seen from that same group for a year-and-a-half have been Medicaid patients. I reason that this may be because, in Ohio, a physical therapist must provide physical therapy to Medicaid clients, and that, very probably, the group steers patients with "better insurance" into their own, in-office "physical therapy" service. In another situation in which a physician-owned orthopedic practice of six doctors in my community prescribe physical therapy, the group now employs a grandfathered Physical Therapist Assistant to provide "in-office ancillary services" so that, now, the only patients we see from their group are patients that know from past experience that they can seek a provider of their choosing. I am certain that this group of doctors has no other reason for not referring out except that they stand to claim more healthcare dollars for themselves, since they are totally free to determine how much "therapy" their patients will receive. Now, I am aware that physicians are also being squeezed by the declining reimbursement that we all face. However, allowing physicians to "make up" their bottom line in this way is anti-competitive, especially since Medicare requires a physician referral for physical therapy services.
I ask that you increase the strength of the self-referral ban and increase the opportunity for Medicare beneficiaries to use the provider of their choice, thus minimizing the obvious potential abuse of the self-referral situation. Thank you for considering my comments. Very truly yours, Claudia L. Miller, PT, OCS

Submitter : Dale **Date:** 06/22/2004

Organization : Dale

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

My comments are to raise concern regarding the interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." It is my hope that these issues will be corrected in the subsequent "phase III" regulations.

My main concerns are the potential for fraud and abuse that exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. This situation is compounded by Medicare's requirement of a physician referral in order to beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices that they have invested in and to over utilize those services for financial reasons. This creates a financial drain on Medicare, which impacts future fee schedules.

The current definition of "in-office ancillary services" is so broad that it facilitates the creation of abusive referral arrangements. Why would a physician refer a patient to another physical therapy clinic and lose revenue when they can refer to a clinic that they have a financial interest in. The financial interest also makes them more likely to over utilize services for financial gain, not for patient benefit. This affects all therapists in that future fee schedules may be limited by Medicare as a way to balance the budget.

The "in-office ancillary services" exception has created a loophole that has resulted in the expansion of physician-owned practices (POP) that provide physical therapy services. Because of Medicare's strict referral requirements, and lack of reimbursable direct access to physical therapy, physicians have a captive referral base of physical therapy patients in their offices. This captive base makes it easy to abuse the arrangement, especially when reimbursement is limited. Having a secondary service (physical therapy) from which to bill Medicare can only increase the profit of owning a private practice.

A second alarming issue that arises is that the services provided in physicians' offices are often by non-physical therapists and billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. There is a reason that licensed therapists are required to go obtain the
level of education that they do. As a physical therapist it is my responsibility to provide safe treatment to my patients. Part of the way I do that is by performing a thorough initial evaluation to determine the source of pain. With the limited amount of time physicians are able to spend with patients, a thorough initial evaluation is paramount. The reason I went to school was to become an expert on musculoskeletal problems. Part of being an expert is knowing when a patient's pain/concerns is not coming from a musculoskeletal issue and then referring back to the physician for alternate sources of pain. Having a non-physical therapist providing "physical therapy" services is offensive to the years of schooling and continuing education I have done and more importantly it is dangerous for the patient under their care. This is a violation of the trust that patients place in their providers. Any and all measures to prevent this from occurring should be implemented.

Thank you for considering my comments in regard to the Mach 26 interim final rule on "Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).

Submitter : **Susan Sulley** **Date: 06/22/2004**

Organization : **Rascal Creek Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2004

Mark B. McClellan, MD, PhD
CMS, US Dept of Health and Human Services
Attn: CMS-1810-IFC
PO Box 8013
Baltimore MD 21244-8013

Re: Medicare Program ? Physician?s Referral to Health Care Entities with which they have Financial Relationships (Phase II), Interim Final Rule with Comment

I am a physical therapist in private practice in a community in the middle of California. I have been a PT for over 20 years and in private practice for over 17 years. I am writing to address my concerns regarding the March 26th interim final rule regarding physician?s referral to their own office personnel or other facility where they have a financial interest.

We have an orthopedic practice in our town that has a financial interest in a physical therapy practice. Often, we receive a referral for a patient who has been treated by those doctors, referred to that practice and then end up at our facility when they see another physician. They often report that they did not receive the level of care that they experience here. At the PT practice financially supported by the orthopedists, evaluations are cursory and often fail to identify the etiology of their complaints. Treatments are brief, often poorly supervised and the duration of treatment is usually fairly long ? longer than anticipated based on diagnosis and standards of care. After a more thorough evaluation here, we are usually able to address their underlying pathology and provide much shorter duration, intensive treatment where the emphasis is on exercise, independent home care and recovery.

Do the physicians with a financial interest in a PT practice take advantage of that financial incentive to self-refer? They do here. Is the treatment provided here better? I believe it is and patients treated here concur. In our practice, each patient is seen by licensed staff at each visit. That is not true, according to patients treated there, of the PT office financially supported by the orthopedists.

I urge you to consider addressing and correcting this loophole with ?phase III? regulations. There was a good reason to exclude physicians from self-referral to physical therapy in the past. There are even more great reasons to tighten up this loose end with the current financial problems facing CMS. Physicians cannot own or have a financial interest in pharmacies. A similar requirement for a ?prescription? exists for physical therapy services (based on Medicare guidelines). Similar regulations must exist to protect the patient who needs physical therapy. Remove the loophole that allows the financial connection between the referral for physical therapy and the physician.

Thank you for your attention to my comments. I look forward to hearing more about your actions with regards to the issue later this summer.

Sincerely yours,

Susan E. Sulley PT
President

Submitter : **Mrs. Christel Parvey** **Date: 06/22/2004**

Organization : **Mrs. Christel Parvey**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

These comments are in regards to 'Physician's Referrals to Health Care Entities With Which They Have Financial Relationships Phase II'.

As a practicing physical therapist for the past 3 years, I have seen the importance of speciality services. In a small community, Bemidji MN, our outpatient clinic has prided itself on providing the highest quality care. We have started women's health programs for populations such as prenatal, osteoporotic, urinary incontinence and pelvic pain. Our therapist's pay is not influenced by clinic revenue or productivity and therefore service is focused on outcomes and quality of care. If physicians are allowed to refer to themselves, patient risk losing a referral to these speicalized programs. Instead, they may be treated by an unqualified 'aide' or in a less optimal situation. This can occur because 'in office ancillary services' can be billed under the physician's provider number while in our clinic care must be orchestrated by a licensed physical therapist.

There is a significant possibility of the overutilization of physician owned physical therapy services (POPTs) for financial gain and potential for fraud. Patients may feel pressure to attend the POPT clinic because they trust their physician to choose the best source of care, not knowing there may be secondary gains involved. Even if there is not pressure, the patient's insurance may not reimburse without a physician's referral. Therefore the physician maintains control of the entire process and may allow their desires to superceed the needs of the patient.

In summary, I feel it is important in many aspects to achieve legal prohibition of POPTS. Patients and physicians could choose their physical therapy facility for highest quality and take the financial gain scenerio out of picture.

Sincerely,

Christel Parvey, MPT

Submitter : **Dr. PAUL PONTIER** **Date: 06/22/2004**

Organization : **Nephrology Assocaites of Tidewater, Chesapeake, VA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

10 Dialysis Medical Director Fee Proposal
I am a practicing Nephrologist. I am commenting on the fee schedule proposed for medical directors. What CMS is proposing is that we recieve as medical directors be drastically reduced. This would severely affect our practice income. We are currently are losing real income year by year.
So why is this a bad idea? If our medical director's fees were reduced as proposed then I would argue that our nephrology practice give up being medical directors. It would not be worth the renumeration that we are given. The only way to make up this income would be to abandon the medical directorship role of the corporate dialysis chain. We would then have to open up our own for profit dialysis units. In that way we could continue to exist financially.
I percieve that that government is attempting to drive us out of business. We work very hard doing the job that we do. I do not create the sick and ill patient to place into a dialysis unit. These patients are people who have the unfortunate illness placed upon them by fate. I can not see how fair compensation which allows us to keep our doors open is harmfull to the interests of our healthcare system and our citizens. Thank you for your time.

Submitter : Karla Hobart, PT, OCS **Date:** 06/22/2004

Organization : Karla Hobart, PT, OCS

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am commenting regarding physician referral to health care entities with which they have a financial relationship. I am a physical therapist and co-owner of a private physical therapy clinic in Broken Arrow, Oklahoma. Since I have been a private practic owner, I have seen a surge in physician-owned physical therapy centers. Not only are these centers competing with physical therapist-owned facilities, but I have witnessed a sharp decline in the referrals I had once received from those physicians who now own their own physical therapy facilities.

Patients are not being referred to a physical therapist that is close to home or to work or that they might prefer, they are being told by their physician to attend physical therapy at their facilities. Patients are also not being informed that they have a choice of physical therapy providers. I have even had a patient tell me that physical therapy was delayed by her physician because she would not attend the physician's physical therapy clinic. She insisted she wanted to have physical therapy at our clinic, and finally, her physician agreed to the referral, but only after the patient threatened legal action against the physician.

I see that this situation is only getting worse as physicians are building new facilities and including their own clinics within. They are also opening satellite physical therapy clinics to refer their patients who may desire to attend physical therapy at a facility that is closer to home.

I don't have a problem with physician's making money for themselves, but when they control the referrals and can monopolize them in this way, it makes it a very lop-sided market for a physical therapist in private practice. At this rate, there won't be any physical-therapist owned physical therapy clinics. We'll all be forced out of business and end up working for the physicians.

Submitter : **Mr. Philip Villacci** **Date: 06/22/2004**

Organization : **Resurgens Orthopaedics**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

The expansion of Stark II for ancillary referrals demonstrates the governments continued support to access of healthcare. Physician owned practices continue to perform and care exceptionally well. Direct referrals to free standing Rehabilitation Centers will increase health care costs by permitting patients to diagnose and prescribed who should take care of their aches and pains. HMO's were created on the gatekeeper concept, physicians today are clearly better control costs and in-office ancillaries continue to provide the most professional and clinically sound access for patients.

Submitter : Virginia Dunn **Date:** 06/22/2004

Organization : Virginia Dunn

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Physicians can provide PT services but often it is delegated to non-licensed personnel who do not have the education skills or background to be providing such services and actually could cause harm to the patient. The definition of in office ancillary services prpovides a loophole that has resulted in the expansion of physical owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base in the own offices resulting in financial incentive.

1. Financial Relationship-Definition

I have a concern that any ability to refer to your own practice, as physicians will be allowed to refer to their employed Physical Therapist, leads to overutilization of services due to the financial incentive that is inherent in such an arrangement. Referrals made be made due to the profitability rather than medical necessity of services. Will the employed PT buck the physician who is their employer when a patient no longer needs the skills of a PT and the MD continues to write referrals?

Submitter : **Mr. Jason Green** **Date: 06/22/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.

2. In-Office Ancillary Services Exception

The ?in-office ancillary services? exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.
In physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The ?in-office ancillary services? provision does nothing to prevent this practice from occurring. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. Personally I have had a patient pulled out of my office/care because the doctor told the patient that he had to go to his therapist - meanwhile the patient had progressed extremly well meeting LTG's within 3-4 wks and ready for D/c. I was recently called by patient 5-6 mos after he was last seen by myself and he was still receiving P.T. by the doctors place of service 7mos later and it appeared that he ready for d/c after 3-4 weeks of P.T. based on my professional judgement and scope of P.T. practice act/guidelines

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern:
I am a Physical Therapist with over 12 years of experience, who is currently working in a Corporately Owned Outpatient Physical Therapy practice. I would like to submit comments for your review regarding the March 26 interim final rule on Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (phase II).
I have personally experienced a detrimental effect to my profession and my business as a result of a Physician group purchasing a PT practice in the area. The effect was three fold: First of all, one of the MDs involved was our Medical Director and he did resign as our Medical Director but that left us without a Medical Director for a period of time and therefore out of compliance with CMS guidelines. Furthermore, I know of at least one instance where a Physician who has ownership in a PT practice is still the Active Medical Director of Record for another facility. I would think this would be a conflict of interest.
The second effect was the obvious loss of referrals and overall business. One Physician in the group who purchased their own PT practice stopped referring an average of 25 patients per month (which resulted in a loss of approximately 200 visits per month and loss of $17,600 per month).
The third effect was loss of staff. Unfortunately, as a result of this single event, we had to lay off staff.
Physician's having the ability to refer to their own PT practices is obviously detrimental to the profession of Physical Therapy as it has proven to cause a loss of jobs for some very skilled PTs but it is also detrimental to the patients. Many MD practices employ personnel other than licensed Physical Therapists to provide care and bill physical therapy services under the Physician's provider number- so the end result is that companies have had to lay off good, skilled Physical Therapists as a result of loss of revenue, and the patients are referred to non-therapists for Physical Therapy.
Thank you for consideration of these comments.

Submitter : **Mr. Richard Bettesworth** **Date: 06/22/2004**

Organization : **Physical Therapy Association of Washington**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

PLEASE NOTE: This letter was also sent via US mail, but we were concerned that it would not reach you by June 24.

June 21, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

RE: Medicare Program; Physician's Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

As President of the Physical Therapy Association of Washington, I am writing to represent our 1,900 members. Our membership has strong concerns about the interim final rule and requests that changes be made when the Phase III regulations are issued. We do not feel that the best interests of either the patient or the taxpayer are being served when physicians are allowed to benefit financially by referring patients to a physical therapy practice in which they have a financial interest. In our state, we have seen an explosion of physician-owned physical therapy practices. Physical therapy services are not a new phenomenon. Physicians have not just discovered physical therapy. What they have discovered is that they stand to benefit financially by having ownership interest in a physical therapy practice. The potential for fraud in these situations where there is incentive to refer to one's own practice and to over-utilize services simply must be restricted if the public is to be protected.

In this state, physical therapists, in most cases, must have a referral from a physician in order to be reimbursed for services. This raises restraint of trade concerns on the part of our membership.
Additionally, there is the potential for non-physical therapists to be providing services in a physician office and for those services to be billed under a physician's provider number as physical therapy.

Thank you for the opportunity to comment on the proposed rule. We hope that CMS will reconsider its stance and put limits on physician-owned physical therapy services.

Sincerely,

Rich Bettesworth, PT
President

Submitter : **Mr. Patrick Mathias** **Date: 06/22/2004**

Organization : **Mr. Patrick Mathias**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

There is a simple concept that has to date kept our healthcare clean of corruption. This is the concept that your physician will send you, the patient, to the most competent and appropriate healthcare professional with the intent of improving your health or disease state. This ruling threatens to corrupt this trust by providing financial incentive to a physician to not only order excess physical therapy but order it to the clinic that he is getting a "kick back" from. Allowing this to continue would truly be a sad day for medicine

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

June 21, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
US Dept. of Health and Human Services
Attn: CMS-1810-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am a physical therapist and owner of several outpatient physical therapy and hand therapy clinics in western Washington. I have been practicing physical therapy for 15 years.

I wish to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." I have concerns about this rule and would like these to be addressed or corrected in the "Phase III" regulations. There is more than potential for fraud and abuse when a physician is allowed to refer patients to physical therapists who are employed by the physician or physician group. These physicians have a built in financial incentive to refer their patients to the physical therapy practice that they have invested in and to over utilize those services for financial reasons.

We have observed that these patients are not educated fairly by the physician. The patient does not know or understand that they have a right to go wherever they choose for physical therapy services. The majority of patients do what their physician requests without asking questions. Patients have told us that they were not given any options and therefore complied with the physician's recommendations.

Physicians with ownership in a physical therapy practice have a captive referral base of physical therapy patients in their offices. This has significantly impacted the number of patients we see in our clinics per month. We have been able to track the decrease in our referrals from these physicians when their own physical therapy practice opens. The expansion of the POPs and the potential to drive business away from privately owned physical therapy clinics is staggering at the financial level. Eventually, many privately owned physical therapy clinics will be driven out of business due to POPs.

Thank you for consideration of my comments on behalf of myself and the physical therapists that we employ.

Sincerely,

98208

Submitter : **Miss. Anna Musselman** **Date: 06/22/2004**

Organization : **Blue Ridge Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I graduated from physical therapy school one year ago and am now a full-time, practicing physical therapist in Virginia. I would like to comment on the recent interpretation of the Stark II laws, which now allows physicians to own physical therapy centers and refer patients to these centers. Not only do these physician-owned clinics put other privately owned or hospital owned clinics in danger of shutting down, but they also do not necessarily pose a benefit for patients. Research conducted in Florida shows that the number of visits per patient is 43% higher in physician-owned clinics as compared to PT owned clinics, which results in a 31% higher revenue per patient. This higher number of visits does not necessarily guarantee that the patients are receiving better care. The same study found that physical therapists who work in physician-owned clinics also treated 62% more patients than therapists who work in PT owned clinics. This information led the researchers to make the conclusion that patients in physician-owned clinics receive lower quality of care because their visits are of shorter duration and treatments may be delegated to non-licensed therapy workers. A study conducted of the California Workers Compensation Program by William M. Mercer, Inc. found that if injured workers were first treated by physicians who owned a physical therapy clinic, these patients were referred to therapy 66% of the time. On the other hand, if the injured worker was initially treated by a physician who did not own a therapy clinic, the patient was referred to PT only 32% of the time. This demonstrates the fact that physicians can take advantage of their ability to refer patients for physical therapy services if they are able to make a financial gain from the situation. The study conducted by William M. Mercer, Inc. also concluded that due to physicians' involvement in physical therapy clinics in 1992, "physical therapy services for workers' compensation in California generated $233 million per year in services delivered for economic rather than clinical reasons". Due to the rate of inflation, I am sure that figure is more significant now than it was in 1992. The loopholes in the Stark II laws that allow this sort of abuse of the health care system to take place must be mended in order to insure quality care for patients and proper use of workers compensation and insurance benefits. Please make every effort to regulate physicians' referral to physician-owned physical therapy clinics. Thank you. Anna E. Musselman, MPT; Blue Ridge Physical Therapy, Lexington, VA

Submitter : **Date: 06/22/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist of 26 years that works primarily at a community college setting but I also do some PRN work at in an outpatient orthopedic setting. I wish to comment on the physician-financial relationships and 'in-office ancillary services'. The setting that I work in has 3 seasoned therapist with satisfied customers and good outcomes. Our patients were seen in a timely fashion and for years we had a good relationship with an orthopedic group. Just two short months ago, the orthopedic group opened up their own physical therapy clinic. Sadly, they were satisfied to hire brand new physical therapy graduates which I feel was not in the best interests of their patients or these new graduates. Most patients do not realize that they can see a physical therapist of their choosing. If they did, they would likely choose to see one with several years of experience or those that have additional training in a specific content area. Instead, in a physician owned therapy clinic, there is an inherent financial incentive to refer patients to the therapy clinic that they own opposed to a therapist who might be a more appropriate provider. My frustration is much higher regarding the 'in-office ancillary services'. So many times I have learned from friends, family and patients that they were getting physical therapy in their doctor's office. After questioning the therapist's credentials and what treatments were being provided it is clear that the individual does not have a license to practice anything, and that the services being provided are 'canned' and a waste of time and money. Once again, it saddens me that physicians are willing to provide minimal care for their patients and sell it as physical therapy. Physical therapist in my state are required by licensure to have 40 hours of continuing education every two years in order to retain their license to practice. We are also accountable to a Code of Ethics and Standards of Practice. Most physicians have not been trained to provide modalities, such as ultrsound, or traction. Plus, providing exercises by the untrained eye may be perfomed incorrectly with inappropriate muscle substitution that might make the orginal complaint worse. The non-licensed provider has no formal training, no required examination of competency, no oversight, is accountable to no one. Thank you for the opportunity to provide these comments.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 21-24

21. Exceptions-Temporary Noncompliance

The current exception for temporary noncompliance applies only to relationships that were compliant and then became noncompliance. The exception should also be applied to relationships that were unintentionally noncompliant and are then promptly brought into compliance. Specifically, the exception for temporary noncompliance should be extended to financial relationships between an entity and a referring physicians that are out of compliance for reasons beyond the control of the DHS entity, but that are rectified such that after the noncompliance is identified, the relationship is made compliant and remains in compliance for at least 180 consecutive calendar days immediately after the date on which the financial relationship was brought into compliance. Once a noncompliant relationship is identified, it should be brought into compliance promptly ? within 30 days of the date the noncompliance becomes known to either the entity or the referring physician, whichever learns of the noncompliance first. The rest of the parameters contained in Sec. 411.353(f) should continue to apply to this expanded exception. This expansion would protect DHS entities which inadvertently enter into a noncompliant relationship and want to remedy the deficiency and while maintaining the relationship.

Submitter : **Date: 06/22/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To:Mark B. McClellan, MD,PhD
Administrator
Attn:CMS-1810-IFC

This note is to comment about the Medicare program;Physician's referrals to Health Care Entities with which they have financial relationships (phase II);Interim final rule with comment.

My name is Jenny. I've been practicing in Memphis, TN in out-patient physical therapy for the almost 10 years.

The recent changes made to the stark law are disturbing to me. Since physican owned PT has become more prevelant I've noticed a significant decrease in the quality of care given in those practices. Because of financial gain the doctor is referring significantly more patients to PT, which decreases the amount of time each patient gets and therefore the quality of care. Furthermore, therapists like myself generally refuse to work in an environment like that, partly because of ethics, but also because its important to me to give quality care. (which can't be done if I'm having to see 4-6 people an hour by myself). I can't honestly see or think of any viable reason for physician owned PT other than financial gain/greed.

Also the "in-office ancillary services" does nothing to stop doctors from using non-physical therapists from providing treatment and then billing for that treatment under the physician's provider number. That in my opinion is the ultimate form of fraud and abuse. The delivery of so-called PT in that situation could be harmful to the patient. I certainly wouldn't want a 20 year old athletic trainer treating my mother after a stroke...would you? The "in-office ancillary services" exception has set up the potential to create abusive referral arrangements and poor rehab outcomes if less than adequate services are provided.

Thanks for your time.

Submitter : **Mr. Dan Dourney** **Date: 06/22/2004**

Organization : **HEALTHSOUTH Corporation**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Having been in healthcare the last 24 years and seen the rise and fall and now rise again of POPTS, I would like to see some rules and regulations that level the playing field and allow for patient choice when it comes to out patient therapeutic intervention. Another revenue stream is the widely held belief why some physicians open their own Rehab Services clinic. With a direct financial benefit and profit from self referral I am unclear how this is not seen as a "kick back." There are no barriers to entry as the previous Pete Fortney Stark bills have all been watered down over the years by special interest groups and AMA lobbyist. They typically do not see Medicare patients and hence by pass the rules and regulations which govern that particular payor class that many other insurance companies default to for and audit trail. A recent study for FL shows a drastic increase in utilization and visits per referral when patients are referred to POPTS by physician owners. I refer you to the APTA web site. Since this new wave has begun we have seen as much as a 95% decline in referrals away from free standing clinics in general market populations like Tampa or Jacksonville, FL. No amout of marketing or sales will create this type of volume replacement and hence has a negative impact to the fiscal therapy of these clinics and then narrows the choices for any patients when they close.
I would like to encourage some debate on this issue and look for new solutions that level the playing field as no insurance carrier will pay for any Physical or Occupational Therapy without a Physician's Prescription and hence as the "gate keeper" they can direct all care to whom they care to. The industry as a whole must begin to look at outcomes and who does the best job for patient satisfaction and evidence based medicine. They should be the ones that prosper not because they can direct the referral but deliver the most cost effective care and superior functional outcomes.

Thanks for your time and attention, in advance.

Submitter : **Ms. Katharine Ayres** **Date: 06/22/2004**

Organization : **Body Mechanics Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am opposed to the government legislating that is legal for a physician to have ANY financial interest in physical therapy practices. This diminishes the ability of independent physical therapy practices to thrive, yet that business is a physical therapist's ONLY way to make a living. This is in contrast to a physician, who has training for another field entirely. Therefore, physician owned physical therapy practices encroaches on a physical therapist's right to an independent living.

Additionally, financial interest in a physical therapy practice is a slippery slope for a physician, because the argument could always be made that he/she is overutilizing physical therapy due to a financial interest.

CMS-1810-IFC-196-Attach-1.doc

Submitter : **Mr. John Sargeant** **Date: 06/22/2004**

Organization : **Executive Rehabilitation**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I feel this exception has defeated the entire purpose of the Stark II laws. I am an independent practioner of 35+ years experience, 30 of which are in the private sector. I have had relationships with at least 4 different orthopedic practices(within 5 miles of my practice) for greater than 25 years. I have personnally treated 5 of the orthopedists on multiple ocasions over these time spans. Since the Stark II exceptions, all practices have opened their own clinics. They no longer consult me, or proactively refer to me. This termination is exclusively due to their having their own practices. In fact,one of the groups, in my building, no longer will place my clinic name on their "other provider list." I found out this is due to the fact they list their own practice at this location, and mention of my practice would affect their own practice. This is absurd, when you factor the long standing, positive relationship. This bill allows the "self serving physician one more opportunity to corner the financial market.

I have heard most of the usual arguments offered by the Drs... We have a closer working relationship with "our therapists," and we can keep a closer eye on the patients progress." If you solicite comments from PT's who do work in this arena, I believe you will find all this is not true. In fact, I believe very few Physicians take the time to go into their PT clinics, solicite input from the PT, or truly check on their progress. In theory, yes, in practicum, probably not. The reality is I have provided quality care for these Dr.s patients for many years, repeatedly being told re: the good outcomes, positive communication skills(a must when you are "competeing in a tough arena), yet I am now a cast off!. I can't convince you by this letter, as you may say it is "sour grapes." But I hope you will truly investigate costs, utilization, and speak with the PT's who have chosen to work in these clinics(not many other jobs between Drs and private corps buying out all the PT practices.) and I feel confident wy views will be echoed by many. This bill is self serving in my opinion. It takes away from the true free enterprise system in the health care arena, as MDs have to refer CMS patients. You must review this issue, and reverse it as I feel there is no redeeming virtue to it's existance. Thank you for your time and attention to my thoughts.

Sincerely yours, John B Sargeant, PT

Submitter : **Mr. Redge Campbell** **Date: 06/22/2004**

Organization : **Harrison Hospital**

Category : **Hospital**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Language allowing physicians to own therapy services within their professional practice creates an opportunity for significant over utilization of services. Clearly, within the construct of rehabilitation services, appropriate incentives should be to appropriately utilize therapy dollars within the available budget. A review of the marketing information surrounding this issue consistently discusses huge revenue opportunities to physicians who own their own therapy practices resulting in revenue of $50,000 a month and more. As a provider of comprehensive rehabilitation services whose focus is on efficient and appropriate delivery of care, allowing physicians to own rehabilitation practices is bad medicine and bad for the economics of health care.

Submitter : **Mr. allister brookes** **Date: 06/22/2004**

Organization : **cms-1810-ifc**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a physical therapist physician owned practices has decreased my visits 40% in a single year. This self referral is anti competitive and self serving. This allows physicians to control a healthcare environment in which they are not trained in. Self referral will eliminate the individual physical therapy practitioner if not changed. Thanks for your time Allister Brookes MPT.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist. I am writing this to express my concerns regarding the March 26 interim final rule and would like the regulations to be amended so as to prevent abuse.

I worked for a POPTS clinic a few years ago. In fact, I started the clinic for an orthopaedic group practice. Till then, I had no exposure to private practice. Once the clinic was set up, I realized that there was gross overutilization of physical therapy services. The patients were specifically told by the MDs to see me in the PT department for treatment. I was categorically told by one of the MDs that I should not discharge the patients even if the therapy was not helping them. We had weekly meetings with the MDs on how to maximize patient visits and how many units were to be billed, irrespective of the actual treatment time. I was also exposed to other methods of keeping the patients on therapy longer. I was also told not to bill for group therapy even if more than one patient was being treated. Patients with higher insurance reimbursement were kept on program the longest.

Needless to say that I was terminated when my concerns were voiced. I am aware now of another POPTS where PT services are being billed on the physician's ID number even though the physician is not present during the session. The therapists doing the treatment do not even have individual provider numbers.

I am not in favor of MDs owning such practices, because their motive is money, rather than the well-being of the patient. I sincerely hope that I will be able to get Medicare services when I am of the age where I need them.

Submitter : **Dr. Erin Hytrek** **Date: 06/23/2004**

Organization : **Dr. Erin Hytrek**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am writing to comment on the March 26 interim final rule on Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I am concerned about the interim final rule and would like to have these concerns addressed in the phase III regulations.

I am a Physical Therapist in Iowa. I have a Doctorate degree in Physical Therapy and have been practicing for eight years. I have had the opportunity to work in a variety of settings in both small and large cities. I am currently working in Cherokee, Iowa, a town of approximately 5,000 people for the local hospital. I specialize in Womens Health and in Orthopedics.

I think that it should be obvious to most everyone, that in situations where a physician is able to refer to entities in which he or she has a financial interest, the potential for fraud and abuse is very real. As if now stands, Medicare requires a physician referral for physical therapy services. This simply makes the problem even larger. The physicians who own or have partnerships in physical therapy practices have a financial incentive to refer patients to these services. There can be no doubt that this can lead to overutilization of services. This also potentially takes away the patients ability to choose where he or she receives services.

This can also create a lopsided market place. There is a local physicians group in a nearby city that owns physical therapy services that practice out of their office. There are patients who are so influenced by their physicians opinion on where they should go to therapy that they are driving in excess of 60 miles one way to receive services that can be provided in their own hometown. This is a hardship on the patients and their caregivers and is totally unnecessary. Were financial gain not an incentive, I would think that these physicians would keep their patients ease and comfort in mind when referring to therapy. In this case, the patients needs seem secondary to the monetary gain the physician sees.

In addition, the in-office ancillary services exception has provided a way for non-physical therapy providers to bill for physical therapy services. This practice is harmful to the patients and wasteful for Medicare. Physical therapy is a skilled service. Physical therapists are highly trained and licensed professionals. Physical therapy can not and should not be provided by, or billed for by, individuals who are not trained and licensed in this field. Patients seen by these providers could be prescribed exercises which may be more damaging to their condition. These providers are not able to fully evaluate the patient?s condition or modify programs for co-morbidities. For instance, a cardiac patient being seen for knee rehabilitation could easily work too hard on the treadmill. Physical therapists can accurately and thoroughly assess patients and design treatment interventions that benefit the patient and are efficient, and therefore cost effective, to Medicare.

I feel that this is a crucial area to correct and I thank you very much for considering these comments.

Sincerely,

Dr. Erin Hytrek

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am opposed to any physician ownership of Physical Therapy services.The potential for selective over-utilization is high & there is a tendency for doctors to steer clients away from other competent PT's in favor of their own "shop". I have seen this personally; emphasis on volume & charges rather than quality of treatment.

Submitter : **Ms.** **Date: 06/23/2004**

Organization : **Ms.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

TO: Mrk B. McClellan, MD, PhD, Administrator, CMS

ATTENTION: CMS-1810-IFC

SUBJECT: Medicare; Physician's Referrals to Health Care Entities With Which They Have Financial Relatilonships (Phase II); Interim Final Rule with Comment

I have been a physical therapist for 3 years in the metropolitan area of Atlanta, GA. I work as a staff physical therapist in a physical therapist-owned, outpatient orthopedic clinic. The clinic in which I work has suffered a severe financial blow by the continued growth of doctor-owned physical therapy services. Physical therapists are required by federal law to have a physician's referral in order to treat a patient. There is no economic incentive for a doctor to refer patients outside of his own office when the doctor owns his own physical therapy services. As a result, non-physician owned therapy clinics can hardly keep their doors open since most physicians are no longer referring patients to outside clinics. Instead of working full-time, my clinic can only afford to have me work on a part-time basis. At least the clinic in which I work has stayed in business; many others in Georgia have closed due to the drop in volume of Medicare patient referrals. Doctors who own their own physical therapy clinics have no incentive to refer Medicare patients to services outside of their own clinics.

There is a huge potiential for fraud and abuse when doctors are able to refer Medicare patients to clinics in which they have a financial interest. I predict that Medicare costs will rise due to overutilization of those services due to the financial gain that is possible for the doctors, who both refer the patients and profit from the relationship. Surely that is what the Stark II law was trying to avoid!

In the physician-owned clinics, who is providing the "in-office ancillary services"? The public assumes that physical therapists are providing the physical therapy services, but that is not necessarily the case. In fact, physical therapy services in physician offices can be provided by unqualified individuals, ones without state licensure as physical therapists, when the services are billed as "in-office ancillary services." The public is not being protected by such loopholes in the law, and in fact, its health has been put at risk. Would you want friends or family to be treated for an ACL tear in the knee, a lumbar herniated disk, or shoulder impingement by someone who may only have a high school diploma and no degree in physical therapy, no state license to practice physical therapy, and instead just have on the job training? That is how some doctors are trying to increase their own profits at the public's expense. If physical therapy education is that easy that doctors can train someone in their office to do it, then why are our nation's universities issuing master's and doctorate degrees in physical therapy? It is no longer even possible in the USA to obtain a degree in physical therapy with just a bachlor's degree. So can a high school graduate with no degree in physical therapy provide real physical therapy services? Why is Medicare willing to reimburse doctors for such sham services and risk the health of the public?

Thank you for consideration of my concerns.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Mark B. McClellan, MD,PhD
Administratot
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am a physical therapist and owner of a Medicare Certified Rehab Agency in my town since 1984. My practice is involved in the treatment of orthopedic and sports related injuries and approximately 40% of my patients are covered under the Medicare program. Prior to 2003, I received many of my referrals from a large, multi-physician orthopedic surgery group in my town and in neighboring towns. Last year, both of these practices opened their own physician-owned physical therapy service in their buildings. The physicians and their patients were always most satisfied with the quality of my service and the results of my rehabilitation programs. The referrals from these physicians have stopped. Patients are asked to use the physician-owned physical therapy unit without given a choice or informed that there is a financial relationship and benefit for the physician. Patients have been told if they do not receive therapy from the physician that he 'may not be able to continue to be their doctor and the results from the therapy cannot guarenteed. Patients have been asked to receive physical therapy at the physician's office even if they have to travel 10-20 miles when a closer provider is available. One physician group has coerced home health agencies by making threats that they would not refer the patients to this agency unless the agency therapist is certain to arrange for the patient to continue out-patient therapy only at the physician's office. Again, the patient is not being given choices as to where they might receive physical therapy. Under Medicare, the patient may chose his doctor, and should have the right the select the most qualified physical therapist. Patients are intimidated by the physician-patient relationship to obey the wishes of their doctor, not understanding that there is an underlying motivation for financial gain by the physician. My practice patient load has been reduced 30-40% since the opening of the physican-owned pratices in our are and we have been forced to reduce our staff size due to falling patient load and revenue. I feel that these regulations have been defined too broadly causing overutilizing physical therapy service for financial gain. A 1992 Florida Study clearly documented this very situation and we now see more abuses than ever.

Your consideration in this important matter is greatly appreciated.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr McClellan, MD, PhD

I am a physical therapist practicing in Rhode Isalnd and am the owner of an independentely owned private practice employing. I have been practicing for 10 years and have much pride in the care physical therapists provide in treating patients with movement related disorder.
I am writing to comment on the March 26 interim final rule on
Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I have a number of concerns about the interim final rule due to the potential for fraud and abuse and ask that they be addressed and corrected in the phase III regulations.

Unfortunately when physicians are able to self refer, fraud and abuse issues must be considered since financial interest may become a factor in such referrals. This potentially leads to overutilization of PT services. This possibility is compounded by Medicare?s requirement of a physician referral in order fo patients to receive physical therapy.
Recentely I have observed such practice - for example, a patient is referred to physical therapy by their family care physician and begins treatment at a private practice. The patient is also referred to an orthopedic surgeon, who then tells the patient they must have PT at his/her office. This, disrupts the course of treatment, automatically adds to the cost pf care as the physician owned practice must then bill Medicare another evaluation and finally takes away the ability of the patient to make their own choice of care givers
Another concern, is that PT services in physicians offices are often provided by a non-physical therapist. Delivary of physical therapy by unqualified personnel is harmful to the profession of physical therapy and especially harmful and dangerous to the patients we see.

Thank you for considering these comments.

Submitter : **Dr. Bradford Bentley** **Date: 06/23/2004**

Organization : **Advance Physical Therapy & Sports Rehab.**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. Mark McClellan,

I would like to offer my thoughts on the Stark II Self-Referral Regulations. I believe that referral for profit is unethical, and unbecoming of a noble profession such as medicine. Referrals to physical therapy should be made to licensed physical therapists who may feel free to discharge patients when they deem it necessary and also may feel free to choose treatments regardless of profit margins. I have a doctorate degree in physical therapy and I am board certified as an orthopaedic physical therapy specialist and I am a primary care provider in Washington state. If patients want high quality physical therapy care, they can come see me and if needed I am happy to refer them out to an M.D. (and I do not expect any compensation for it either, which is the entire point). Physical therapists are NOT ancillary staff, they are licensed professionals trained at the doctorate level, and therefore the "in-office ancillary services" exception cannot apply to physical therapists.

Please consider closing any loopholes that unethical physicians can use to refer their patients for profit for physical therapy services. The general public and the medical profession would both be better served by not allowing this behavior.

Thank you,

Bradford Bentley, DPT, OCS, CSCS, Cert. MDT
206-444-6320
brad@advancetherapy.com

Submitter : **Mr. J. Smith** **Date: 06/23/2004**

Organization : **Evergreen Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan: I am a physical therapist in Mount Vernon, WA. I have practiced in the same area since 1979. I currently own & operate Evergreen Physical Therapy which employees 5 physical therapists, 1 occupational therapist & 2 physical therapy assistants. I would like to comment on the March 26 interim final rule on 'physicians referrals to health care entities with which they have a financial relationship (phase 2).' 1) I am sure you have heard from many of my colleagues regarding the potential for over-referral to physical therapy services when the referring physician(s) have a financial investment in those services. I will not belabour that point though it cannot be minimized. 2) I have additional concerns regarding patients receiving appropriate interventions when only 1 physical therapist is available. Our profession, like medicine, has sub-specialty categories. Not all physical therapists are equal in training or skills. I have recently spoken with an individual who was treated for a diagnosis of shoulder impingement whose treatment actually worsened his condition. Subsequent diagnosis revealed a severely arthritic shoulder. There are several clinical tests that would help differentiate these 2 diagnoses & would have prevented this gentleman's situation. Unfortunately, the physical therapist he saw did not have advanced orthopedic training. It is a case of a general medical practice physician's assistant referring to a physical therapist with advanced training in geriatrics. 3) There are currently 3 group practices in our area who employ physical therapists. Last year there were none. Each practice employs only 1 therapist & has allocated minimum floor space for provision of therapy services. In my experience, for effective rehabilitation a single physical therapy practictioner should have approximately 1000 sq ft. The most spacious accomodations afforded these PT's is 600 sq ft. The lack of space is due to cost constraints & a lack of understanding regarding provision of rehabilitation services. It will seriously constrain the type of patients seen to those requiring minimal services. 4) I am also concerned that physical therapy services in physician owned practices are often provided by individuals other than licensed physical therapists. In light of shrinking reimbursement dollars the attraction to employ & utilize less expensive help is great but can be catastrophic. At our facility the physical therapy assistants do not assume full responsibility for any individual treatment session. They work closely in close proximity to a licensed physical therapist at all times. Thank you very much for opportunity to provide feed back & for your consideration of my comments.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

The evidence is clear that physicians that gain financially from physical therapy make more referrals. The proposed rules make it easier for physicians to refer Medicare patients for physical therapy services they will profit from. This will result in a greater utilization of services at a greater cost to the Medicare program and ultimately the tax payer.

Issues 1-10

2. In-Office Ancillary Services Exception

I am concerned that the proposed rule relaxes current restrictions on the provision of physical therapy services in a physician office by unlicensed personnel. The use of unlicensed personnel creates a safety and efficacy issue for beneficiaries. Adoption of the proposed rule will increase exposure to potential injury or at least waste resources as treatment efficacy is lost.

Submitter : **Kent Osborn** **Date: 06/23/2004**

Organization : **Kent Osborn**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madame:
I am a physical therapist with ten years of experience who spends hundreds and even thousands of dollars annually to further my education and skill in orthopedic/manual therapy. My investment of time, vacation days, and money has resulted in dramatically improved my patient outcomes.
One might assume that most physicians would consider the abilities and education of a physical therapist when refering patients. The recovery of the patient should be the only consideration. It is not. I have had an orthopedist offer to send his patients to me IF he received $12000 per year in kickbacks. What is even more pervasive is the recent proliferation of physician owned physical therapy practices as cash cows. This obvious conflict of interest was well documented in Florida and the financial cost led to the Stark laws. While the study showed that we all pay the price for this in higher insurance and Medicare costs, the patient often pays with more pain and decreased quality of life. My state of Georgia allows physicans to hire assistants, with no training in physical therapy, and bill for physical therapy services performed by these untrained aids. I have seen this done by a podiatrist in the building next to my office. This epitomizes what physicians will do in the name of money. Your interpretations of this law directly affect what physicians do.
If you give the incentive to profit, they will at the expense of the patients and taxpayers.
Thank you for your consideration.
Sincerely,
Kent Osborn PT MTC

Submitter : **Mr. Bruce Weston** **Date: 06/23/2004**

Organization : **Tri-County Rehabilitation, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am concerned that the ?in office ancillary services? exception will encourage the further expansion of physician-owned physical therapy practices. I see this trend occurring rapidly in my community and believe this to be a threat to not only my livelihood, but to the quality and convenience of physical therapy care provided to those in my community. I am a fifty year old physical therapist with 27 years of experience, 15 in private practice. I own a small clinic in Youngstown, Ohio. Clinical treatment is provided by me and a licensed physical therapy assistant. Although competition is fierce, we have enjoyed a successful practice and built a fine reputation. My staff and I work very hard on our clinic?s reputation. We strive to provide the best quality physical therapy possible, in a friendly and convenient atmosphere. Our patient outcomes and satisfaction have been consistently high. We enjoy good feedback from our referral sources. I strive to keep abreast of the evolving knowledge base in physical therapy by consistently exceeding my state?s continuing education requirements. I am one of two physical therapists in my county board certified as a specialist in orthopedic physical therapy by the American Physical Therapy Association, and one of only 61 such physical therapists in the state of Ohio. Presently, I am completing the requirements toward a clinical doctorate in physical therapy. With two children in college, the addition of Dad?s tuition creates quite a financial burden. I tell you this to emphasize the importance I place on providing the best care possible to my patients whose lives, comfort, and function are of utmost importance. Also, I tell you this to further emphasize the efforts that I take to remain successful in a competitive environment. Not one of the 126 referral sources in my data base has a financial or organizational tie to me. In order to get their referrals they must consider me to be the best and most convenient option for their patients'. I must provide exceptional care to patients as well as record and write outstanding reports. If I fail, until I get my act together and improve in what ever area needs improvement, my referrals from these physicians decline.Now the problem: over the past few years four of my primary referring physicians have become involved in physician-owned physical therapy practices. While this has had a negative impact on referrals to my clinic, we have been fortunate to make up the loss through new referral sources and increased referrals from other physicians, so far.In addition, there are three physician owned physical therapy practices, involving approximately thirteen physicians, within two miles of my clinic. One clinic provides physical therapy with office support staff. I believe that this service is billed using the same codes that I use. I am concerned about how this reflects on the overall picture of ?physical therapy.?
While I believe that fair competition improves patient care delivery, physician-ownership of physical therapy clinics is not fair competition. I believe that the potential for passive income creates a very strong incentive for physicians with ownership interests, in physical therapy clinics, to refer to their own clinics. I believe that this financial incentive frequently overshadows concerns for quality, efficiency, or patient convenience. Patients believe that their physician?s decisions are based on what is best for their care. In this light, only the strongest patient is likely to insist that he come to my office rather than drive the extra 25 minutes across town. I thank you for allowing me to voice my opinions on this issue and ask that you consider them, along with the opinion of my professional organization, The American Physical Therapy Association, when formulating policy on this topic.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a Physical Therapist who has been practicing in outpatient clinics in the NorthWest suburbs of Chicago for the past 5 years. I would like to make a few comments on the March 26th interim final rule regarding Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I believe that the current regulations provide an enormous loophole for Physicians to abuse the medicare system when they are allowed to own or invest in physical therapy clinics. Physicians who own therpay clinics are in a no lose situation as far as generating revenue from Medicare to improve their business profits. A patient sent to a physician owned clinic will generate revenue regardless if the therapy was justified. Two weeks later when the patient makes no progress the physicain can just have them return to the medical office for a second visit and generate more revenue. I have had numerous medicare patients mention to me in my clinic that their doctor had insisted that they go to the physician owned facility one or two towns away even though it would mean a 20 to 30 minute commute each way. These are patients that were in considerable pain or were recovering from surgery and therefore travel was not an easy activity or any driving required finding a friend to get them to therapy. I believe the current laws are damaging to the physical therapy profession because a clinic that is owned by an MD does not have the incentive that an outside party does to strive for clinical excellence. I work for a private company and I have to strive to treat my patient in a cost efficient and time efficient manner. By performing the therapy in the shortest and most cost efficient manner possible I demonstrate to my local physcians the excellent training I obtained from physical therapy school and hoepfully earn more business from them. A physician owned clinic does not have the incentive to be cost efficient for medicare as the clinic will always have a steady flow of patients straight from the physicians that own the clinic. Therefore there is not the sense of urgency to accelerate and upgrade patients therapy in the most timely manner possible. Besides the physcians feeding a captive referral base to their own clinics they can easily request additional therapy when it is not appropriate per Medicare guidelines. Currently physicians have no checks and balances to keep them from hoarding patients and performing fraud by pushing patients to therapy or keeping them in therapy when the patient does not require it. On a side note, a clinic owned by a physical therapist or a private company does have checks and balances in that if a therapist was trying to keep a patient in therapy longer then needed to overbill medciare for services then the physician can easily stop the therapy by not authorizing any new Plan of Care notes. I would like to close by encouraging the government to stop physician owned physical therapy clinics with phase III. Thank you for your time.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Re: "CMS-1810-IFC - Medicare Program; Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)."

I am a physical therapy student at this time. I have endured two years of intense education, training by expert clinicians, and despite the extensive knowledge and skills that I and my colleagues have obtained in order to provide exceptional and the highest of quality care, we will be trained and molded for yet another year. One patient asked me why physical therapy students had to go to school for so long, and I asked him if he would want to be treated by someone who did not know everything about his pathology, the details of all the intricate body structures and the manner in which they heal, atrophy, and how to correct these changes.His eyes widened with realization.

Allowing physician owned physical therapy services has stirred up the Therapy profession. Rightly so. The thought of having patients being treated by anyone without necessarily a degree, or any education for that matter, and charge it as "physical therapy" deprives the patient of the best possible care. It is my hope that these important issues are considered in the Phase III regulations in order to bring the focus back on to what we are talking about here, people that want to heal and get better.

Submitter : **Mrs.** **Date: 06/23/2004**

Organization : **Mrs.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have worked in a Physician owned clinic for 9 years. We have many Medicare patients that are treated daily and that I believe receive exceptional care. We are onsite with the physicians that treat them surgically and non-surgically. We are able to bring more one on one care for these patients with their physicians. Having the physicians onsite within the clinic allows us to diagnose quickly possible life threatening problems. Furthermore, I do not believe that the physician should be the "bad guy" because they are trying to provide a service for their patients. Our physicians have always had a stance that the patient is free to go to ANY physical therapy clinic they wish to go to. Many patient like the convenience of having "one stop shopping" along with a billing department that follows the patients claims. The Physician stongly supports each therapist and trust our judgement. They justly compensate us and support our continuing education. Our clinic is well staffed and our equipement is top notch. I do not agree with the APTA stance on physician owned clinics. By eliminating these type of clinics you could be doing an enourmous dis-service to the patient being treated. Let the patient have the freedom of choice where they want to seek medical care I believe that a service speaks for itself. If you provide a sound practice the patients can and will come to your facility. Thank-you.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am concerned that a new payment system for medical directorships based on hourly wages will be unfair. This is especially true if the hourly wages do not take into account the total number of hours that the director is available to the dialysis unit "on call" in case of emergency and if the hourly wages are not adjusted based on the "severity" or "complexity" of the call/service. This issue is distinct and separate from being "on call" for patient related issues as an attending physician. As an example, there have been a number of unforseen times when the dialysis units I have worked with have been unable to provide dialysis services to scheduled patients due to technical problems. The facility policy is for the medical director to be emergently notified. Subsequent decisions regarding how to provide the scheduled patients dialysis needs as well as how to fix the underlying facility problem have to be made. Some of these times, I have had to cancel scheduled appointments or postpone rounding in order to assist the unit. As another example, there are times during the week that I am paged (again unscheduled) with questions regarding facility related issues and policies. I believe that directorship fees solely linked to the number of hours spent performing tasks does not appropriately value the service provided. The facility operator is depending on the medical director to provide expertise, responsibility, AND availability during all hours of operation. In my opinion, payment only based on the amount of time spent in the unit does not adequately reflect the committment required of a medical director nor does it account for the quality of service provided. I think that the value of this service is best determined by the involved parties and that this new proposal should be withdrawn.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist in Tualatin, OR., and I consider myself very fortunate to have worked in physical therapist owned private practices for the entire 14 years of my career.

What has prompted me to write this commentary is that I have significant concerns regarding the potential ramifications of the Phase II interim final rule to our profession, to Medicare, and to the quality of care rendered to Medicare patients.

From a professional standpoint, I began my career in physical therapy in 1990 and, at that time, the physician based physical therapy practice seemed to be more prevalent. I have witnessed the dissatisfaction from patients who had received care in that setting on a previous occasion. The patients, in many cases, were not aware of their right to seek out other options for physical therapy care, as it was never discussed with them. I have also heard complaints from physicians whose clinics have hired a physical therapist on their staff. Earlier this year, two medical practices that we worked closely with called to inform us that they were told to refer exclusively 'in house', even though they were very pleased with the care that their patient's received at our clinic. The physicians were essentially asked to choose a physical therapy provider for their patient based on financial gain for their clinic, not because of the quality of care.

The definition that was outlined in Phase I, and reiterated in Phase II clearly states that 'a direct relationship is defined as an ownership or investment interest of a referring physician or immediate family member in the entity furnishing the DHS'. As I looked at this, it seems that I was reading the definition of a physician owned physical therapy practice! According to what I have read, if this is found to be true, the provider cannot bill for those services, and payment would not be given for those services if billed. The reality is, because of the loopholes that are inevitably in place, thousands of dollars are being spent every year to pay into this 'double dipping' of services by the physicians who own these clinics and refer in this manner. There is a definite conflict of interest, as there is a monitary gain factor in this type of in house referral based practice, and the potential for abuse/overutilization of services is astounding.

I also have concerns regarding the in office ancillary service provision, as there is also potential abuse with this as well. If services are provided by unqualified personnel, but billed under a physician's provider number as physical therapy services, this is not only unethical, but also can be very harmful to the patient, as they do not have the training to recognize contraindications to treatments, or to evaluate for other structural involvement in order to modify the plan of care. It is imperative there be strict regulations to protect the patient, and to avoid fraudulent billing.

I urge you to consider the long term ramifications that this interim final ruling will have on maintaining quality patient care and on the potential overutilization and 'double dipping' when physical therapy referrals are made by physicians to practices with which they have financial interests. Thank you so much for your consideration in this matter.

Submitter : Dr. J L **Date:** 06/23/2004

Organization : Dr. J L

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Subject: Medicare Program: Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II): Interim Final Rule with comment. "In-house ancillary services"

I am an academician and a private physical therapist practitioner in a small city. It has become more and more prevalent to have physicians in this community to build massive practices that include physical therapy services. Most of these practices do not inform their patients that they may go to another physical therapist for therapy services. Often their office staff just make an appointment directly with their own physical therapy staff without allowing the patient to decide if that is where they want to go.

This practice is very damaging to the private physical therapist owned practices in the community. Because our state requires that physical therapy treatment be "by physician referral only" the physician owned physical therapy" (POPTs) practices reap the benefits and the private PT owned practices are quickly going out of business. As a couple of PTs said to me " I can't have my own practice, because I won't get any business referrals from the docs in this city". So what did they do? They were hired by the POPTs! This does not promote private (competitive) enterprise in the institution of medical practice.

This practice is also potentially damaging to the patients themselves. They do not always know that they have a choice to go elsewhere. This captive referral base of physical therapy patients within their offices is facilitated by the fact that Medicare has very specific referral requirements. One patient told me that she was "afraid to go anywhere else for fear her doctor would not like that".

The patients may not be getting the best care. Some of the best physical therapists may cost the physician's practice too much money, so they hire less qualified therapist ("so the profit is higher"). This creates an abusive referral arrangement to a lesser qualified PT.

There are also instances where the patient receive "physical therapy" under the "direct supervision" of the physician (generally performed out of the line of sight of the doctor) by non-physical therapists and are billed under the physician's provider number as physical therapy services.

Thank you for considering my comments as you make revisions to the policy.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program: Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II): Interim Final Rule with Comment

Dear Dr. McClellan:

My name is Amy C. Dixon. I am the Executive Director of Desert States Physical Therapy Network. We are a group of 23 privately owned, independent physical therapy clinics throughout the state of New Mexico, representing approximately 75 physical therapists.

We wish to comment on the March 26 Interim Final Rule on Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (PhaseII).

We strongly oppose arrangements that create incentives to underutilize or overutilize services for personal or institutional profit, or that are in any way based on the financial interest of the referral source.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. This situation is compounded by Medicares requirement of a physician referral in order for beneficiaries to receive physical therapy.

Please consider the following scenario: A patient has been referred for physical therapy by a primary care physician. The therapist deems it necessary for an orthopaedic surgeon to evaluate the musculoskeletal problem. The patient is then seen by an orthopaedist. The patient states they want to continue therapy at a particular clinic and are told they MUST go to therapy at the physician-owned clinic. This patient does not want to lose access to his/her physician and continues therapy where the doctor has told him/her to go!

It is our understanding that financially-motivated incentive arrangements are to be disclosed to the patient population. However, in New Mexico, we have a shortage of physicians -- especially ones who will see Medicare patients. Whether or not this is true, there is a perception that if these older, more vulnerable patients do not follow the doctors orders, they will lose access to their physicians. Disclosure of such practices will not make any difference.

The in-office ancillary services exception is defined so broadly that it invites the creation of abusive referral arrangements. Physicians who own practices providing physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.

We believe referral-for-profit of any kind is a poor policy. It does not serve the patient or, in this case, the Medicare beneficiaries, well at all.

Thank you for your consideration of our comments.

Sincerely,

Amy C. Dixon

Submitter : **Mr. Andy Whitener** **Date: 06/23/2004**

Organization : **Mr. Andy Whitener**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am very concerned about what I see happening. Physicians are opening therapy practices in their offices and physicians who used to use therapy rarely are now referring many. I can't help but see this as just a money opportunity at the expense of the patient and payor. Physicians see this as money they don't have to work for. This is not like lab work needed by physicians to complete their diagnosis and treatment. This is putting private practice therapists and hospital therapy practices out of business, then who sees the no pay and Medicaid patients? Hospitals have very few revenue centers left and I believe none of these are free from physicians starting a competing business (lab, radiology, therapy, outpatient surgery) Where will the physicians refer their patients?, to their own service as long as they have a payor source. This is happening now and in my opinion is detrimental to ethical care and the survivibility of our community hospitals. We need clear guidelines that limit situations that can become abusive, I believe the physicians need this as well as our communities and hospitals. Thank you for considering my comments.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a Physical Therapist practicing in Columbia, Missouri for the last 23 years. I am quite concerned about the interim final rule regarding physician referral to clinics where they have a financial interest. We passed legislation in our state because of the abuse found in such situations. We saw overutilization of therapy services, poor quality of care under these situations, and patients were advised that they had no other choices for therapy services by their physicians. I am in a private clinic where we strive to provide quality care at reasonable costs, but we cannot compete when patients are not given the freedom to select their physical therapist. Patients have been told that our therapists did not know what they were doing just so the physicians could direct the patients to their clinics. The facts are that we have exceptional therapists and have helped many of the patients who received less than quality care under the physician owned therapy clinic. Patients are required to have a physician referral to therapy and then need subsequent follow-up and referral under the Medicare guidelines. The health care consumers trust the the physicians are providing good advice, and when that advice is biased by financial self-interest, the consumer is not being protected. I am very concerned that we are taking a step backward after working so hard to protect the consumers. I want to provide excellent service to all the community, but I cannot do that if I cannot gain access to those patients. This ruling will take the choice away from the consumers again. This ruling will hurt the private physical therapists who pride themselves on the delivery of quality care. Therapists working under the physician ownership lose their control of the patient care because they are asked to provide certain treatments that inflate the costs to consumers and are not necessarily the most efficient provision of health care. I cannot work under those conditions nor should any therapist be willing to do so. I love this profession and I love helping people. With this interpretation, I may not be able to continue practicing. I urge you to reconsider the impact of this ruling. Let us not step backward. Let us continue to go forward to provide quality healthcare services to all Americans! Thank you for considering these comments.

Submitter : **Mrs. Marina Barber** **Date: 06/23/2004**

Organization : **Healthsouth**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Physicians should not own their own physical therapy as it is used for financial gain only, not for the common good of their patients.

2. In-Office Ancillary Services Exception

There should be no exceptions to physicians who gain financially in the interest of their own practice as additional services.

Submitter : **Ms. Deborah Craig** **Date: 06/23/2004**

Organization : **Ms. Deborah Craig**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I am a physical therapy clinician practicing in a private practice in North Carolina. I have been in practice for 22 years with the past 12 years dedicated toward building a reputable private practice facility in the community in which I reside. As part of building a successful practice I have the opportunity to work closely with the physicians in our area as well as providing PT services on an ongoing basis for the past 12 years. We have successfully competed in this arena based on healthy competition with hospitals and other private institutions. This "healthy competition" has prompted us to be more educated, more efficient, and more service based to ensure survival in a competitive market. It has also prompted us to evaluate internally our outcome data regarding return to function, case cost and number of visits by diagnosis. All of these activities have been viewed as a process of improving the services we provide to those in our community. With the explosion of physician owned PT practices I have seen physicians from as far as 45 miles away require their patients to drive that 45 mile distance for PT services even when comparable services are available in their own community. The patients I have dealt with are unaware that they have a right to chose where services are provided. The physicians are not informing these patients of their financial interest in these facilities. Our community is now faced with the development of a physician owned PT clinic by our only orthopedic group.I was personally approached by this practice to consider employment in their new facility with the incentive of " a high salary and good bonuses". Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. When would an incentive bonus be appropriate? When you generate more charges and increase revenue? There is no incentive for providing quality, efficient and cost effective care since you do not need those values for your patient base. Most importantly, will these same physicians disclose to their patients that they derive direct financial gain for their referral to their facility? The patients who are currently driving 30-45 miles for therapy services at this time are not aware of the financial arrangements in those facilities.

Having been involved in management in for-profit, non-profit, state funded and now private practice I can assure you that the potential for fraud and abuse is a real threat if left unchecked. Medicare has compounded this problem by requiring a physician referral in order for PT services to be provided. Now the patient is placed directly in the middle of a "profit" situation and it will be nearly impossible for the patient to have a right to chose the facility where they feel they will recieve the best care. For those of us who have succeeded in this business of private practice, the Medicare guidelines as they are written eliminate the ability to compete based on quality of care and functional outcomes. Referral will be based on "financial incentive".

Thank you for your consideration of my comments.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Private Industry**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Local orthopaedic drs. hired a P.T. to see patients in their office on an incident to basis. Then to be more profitable began to see their surgery patients for 2 weeks before rleasing them to other P.T. providers. They also now keep a majority of their private insurance patients for their P.T. to see and only release the MEDICARE patients to be seen by other P.T.s. This has dramaticaaly changed the volume and profile of our outpatients.

Submitter : **Mrs. Colleen Whiteford** **Date: 06/23/2004**

Organization : **Appalachian Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Colleen Whiteford, PT, OCS
Board Certified Specialist in Orthopedic Physical Therapy
Appalachian Physical Therapy
171 East Springbrook Rd.
Broadway, VA 22815
Phone: (540) 901 - 9501
Fax: (540) 901 - 8773

Submitter : **Dr. Lynn Millar** **Date: 06/23/2004**

Organization : **Andrews University**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Physician referral to entities in which they have a financial relationship represents a serious ethical problem. If the physician refers only to those entities, the patient is not being allowed to make their own choice and the quality of care may not be comparable. Even when a patient is informed that there are other options, they may select the physician recommended referral because they believe it to be the best therapy available, rather than one which will profit the physician. At a time when there has been a notable lack of ethics in business we should not be condoning such practices in health care, but rather looking to improve ethical practices. Do not allow finances to contaminate the practice of medicine.

Submitter : **Dr. Spencer Schreckengaust** **Date: 06/23/2004**

Organization : **Gaspar Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Dr. Spencer Schreckengaust and I am currently working at Gaspar Physical Therapy in Solana Beach, CA. I earned my Doctorate in Physical Therapy from the University of Southern California in 1999. Furthermore, I also received my Orthopedic Clinical Specialist (OCS) in 2002. I have been practcing physical therapy for the past 5 years in an outpatient setting (4+ yrs in Michigan and ~1 yr in California).

I wish to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which Thery Have Financial Relationships (Phase II). I hope my concerns will be addressed and corrected in the subsequent "phase III" regulations.

Due to Medicare's requirement of a physician's referral in order for beneficiaries to receive physical therapy, physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practice they have invested in and to overutilize those services for financial reasons.

Such a broad definition of "in-office ancillary services" exception might create and allow abuses of the referral arrangements. This loophole has caused the expansion of physician-owned practices that provide physical therapy. Now, these physicians have a captive referral base of physical therapy patients in their offices. The patients who participate in physical therapy in these settings might be overutilized and overcharged.

Plus, these physical therapy services provided in those clinics are typically provided by non-physical therapists and billed under the physician provider number as PT services. The patient will go to the clinic advised by their physician and it will damage the competition and make the patient less likely to choose other clinics, resulting in higher costs due to lack of competition.

I worked extremely hard to earn my degree (4 yrs at Wake Forest University for BS and 3 yrs at USC for my DPT) and this loophole can endanger my profession as well as the welfare and health of Medicare beneficiaries since they could receive improper care from non-licensed persons who work in physical therapy clinics owned by physicians.

This loophole will potentially create abuses of the Medicare system. It will cost the Medicare system more money due to the overutilization and overcharging of physical therapy services by physician-owned clinics. It could place the Medicare beneficiaries at risk by being treated by unqualified personnel. Lastly, it will diminish the important role of physical therapists in the health care system.

Thank you for your time.

Thank you for the consideration of my comments.

Submitter : **Mr. Timothy McHenry** **Date: 06/23/2004**

Organization : **One on 1 Physical Therapy Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

What about a PT practice that is owned by a Health Care Corporation that in order to lock in physician referrals has somehow included a physician practice into their pension plan. The physician practice then insists their members refer exclusively to that PT practice because it will influence the member's pension.

Submitter : **Mr. Alan Finston** **Date: 06/23/2004**

Organization : **Whatcom Physical Therapy, Inc, P.S.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I wish to comment on the March 26 interim final rule on 'Physican's Referral to Health Care Entities With Which They Have Financial Relationships' (CMS-1810-IFC). I am concered about the interim rule and ask they my concerns be addressed in the subsequent phase III regulations.

The potential for fraud and abuse exists when physician's are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicans who own practices that provide physical therapy services have an inherent financial incentive to refer patients to the practices they have invested in and to overutilize those services for financial reasons. Thank you for your consideration of these comments on CMS-1810-IFC.

Sincerely,

Alan Finston, PT OCS
Whatcom Physical Therapy
Blaine, WA 98230

Issues 1-10

2. In-Office Ancillary Services Exception

In physician offices, services are often provided by non-physical therapists and billed under the physican's provider number as physical therapy services. The "in-office ancillary services" provision does nothing to prevent this practice from occuring. The delivery of so called "physical therapy" services by unqualified personnell is harmful to the patient and wasteful to the Medicare program.

Submitter : **Mr. Joseph Maccio** **Date: 06/23/2004**

Organization : **Mr. Joseph Maccio**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Dear Dr. McClellan,

I wish to comment on the March 26 interim final rule on ?Physicians? Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II).? I would like to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

I have been a licensed physical therapist for 27 years. I have owned my own independent physical therapy practice for the past seventeen years. I have a Masters degree in ergonomics and occupational biomechanics and am a Diplomat in Mechanical Diagnosis and Therapy from the McKenzie Institute International. Despite my experience, credentials and reputation in the physician and patient community, my existence as an independent physical therapy provider is in jeopardy. I have been approached by five different physician groups over the past several years to either work directly for them or be involved in some sort of financial arrangement. As a result of not participating, each of these practices has developed their own physical therapy clinics and has usually stopped referring to us independent practitioners. Not because our clinical skills or outcomes have changed but simply because there is no financial incentive for them. The exception of course is when the physician, family member or friend is in need of my clinical skills. Patients who are referred to an independent physical therapist are those that a physician determines have a need for our services or would like more diagnostic information and have nothing to do with profit for referral.

Another area of concern is the recent development of hospital owned physician services. Hospital groups have purchased physician practices or entered into joint ventures in which all patients are directed to in house physical therapy preventing the consumer a choice on whom they can see.

Not only is this whole process immoral and repulsive to me as a professional, but it has resulted in enormous expense on the Medicare system and patients. A recent study ?The role of repeated end-range/pain response assessment in the management of symptomatic lumbar disc? by F. Todd Wetzel,MD, R. Donelson, MD, MS published in The Spine Journal 3 (2003) 146-154 summarizes the diagnostic and therapeutic benefits of Mechanical Diagnosis and Therapy. This process contributes to improving the selection process of spinal surgical patients. Do we want a physical therapy profession that can lower the cost of unnecessary diagnostics testing, surgery and ineffective conservative care or a system that allows physicians to profit for sub standard care? The elimination of profit for referral would offer tremendous savings to the Medicare system and demand the highest quality of physical therapy care.

In closing, I have attached an advertisement I received which highlights the absurdity of the current rules.

Sincerely,

Joseph G. Maccio, M.A., P.T., Dip. MDT

CMS-1810-IFC-228-Attach-1.pdf

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Submitter : **Matt Zurek** **Date: 06/23/2004**

Organization : **Matt Zurek**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Dr. McClellan: Thank you for the opportunity to comment on the issue of physician's referrals to healthcare entities with which they have a fincancial relationship. I am a physical therapist licensed and practicing in the state of Texas. My facility is certified under CMS to provide Physical therapy services to Medicare recipients. As such, we comply with all conditions for participation. We take these conditions very seriously, and constantly review to insure full compliance. Our Medicare patients recieve care only from licensed providers (physical therapists and physical therapist assistants under direct supervision). All of our therapist fulfill continuing education requirements mandated under our state practice act to ensure we stay up-to-date with current practice patterns. We pride our selves on the quality of care we provide to all, and our efforts to return our patients to a pre-morbid level of function.

Our referrals come from a wide array of physicians who we have created a relationship based on the quality of care and service that we provide to the patient and physician customers. We work in a competitive medical community that thrives due to the nature of this competition to provide high quality healthcare. The open market allows patients (including Medicare recipients) to choose who they receive physical therapy services from based on the physician's knowledge of who provides the best services. It is competition amongst service providers that is the basis for improving ones skill set that ultimately improves the quality of care to all patients.

CMS's Interim Final Rule on Stark II allowing broader expansion of in-office ancillary services undermines the spirtit of competition and ultimately reduces the quality of physical therapy services to Medicare recipients in the following way:

1). Services can be provided by non-licensed, non-trained staff that often are usually not under direct supervision of the physician. Only physical therapists and physical therapist assistants are trained in accredited institutions and then licensed and regulated by state agencies. Physicians themselves receive no specific training in physical therapy services. The in-office exception allows for physical therapy services to be provided by non-licensed, non-trained, non-regulated individuals simply because these individuals are employees of physicians who have no specific training in physical therapy. This arrangement is completely inconsistent with CMS's conditions of participation and state regulations placed upon all physical therapists that practice out side of physician owned entities.

2). As in all service based markets, competition is the stimulant to improving quality. Removing or limiting competition in service markets eliminates this key ingredient to all receiving services regardless of the nature of the industry. The In-Office Ancillary Services Exception removes/limits competition. The decisions of where to send the patient based on the quality of services, need for specialized care, convenience to the patient are all clouded by opportunity to financially gain from self-referral. Often, special patient needs can not be meet by the In-Office staff, or the In-Office provider is not the most qualified to provide appropriate treatment. Michael Porter and Elizabeth Olmstead Teisberg (Harvard Business Review: Re-Defining Competition in Health Care, June 2004, pg. 69)state that "zero-sum competition restricts choice and access to services instead of making care better and more efficient."

In summary, I urge you and CMS to reconsider the the Interim Final Rule in respect to the In-Office Ancillary Sevices Exception and restrict the option to allow self-referral of Medicare recipients in this arrangement. Restriction versus expansion will improve competition and allow for improved quality of care and convenience to patients.

Thank you for your consideration,

Matt Zurek, PT

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Adress to : Mark B. McMclellan , MD, PhD
Admiistrator
Centers for Medicare and Medicaid Services
Attetion: CMS-1810-IFC

I am a Physical Therapist of 17 years working in Stuart, Fl since 1992. I hold a Ph.D. and I am certified in Ergonomics.
I have worked for the county hosptial where I occupied the postion as Clinical Director until I decided to open my own clinic.
My partner and I opened our Outpatient Clinic in 2000, where we are a licensed Medicare Part B provider. Our clinic provided Physical and Occupational Therpay services.
Since then our clinic and staff have been well known and appreciated by the Doctors and the people in our community. Due to our dedication to our patients our referral source has simply been by word of mouth.
Our clinic provides the attention patients need, alot of education and dedication. Inculding working with the same therapist from start to finish.This is no the case in my past experience with some of the Physician Owned Clinics.
We have felt a level of discrimination from the local Orthopaedic Doctors that own in-office Physical Therapy Clinics. In the past we have had good communication we the offices and patients outcomes have been good. Now we have not seen any of the Physicians patients even if the patients request to come to our clinic.
We do know that patients are being forced to see the in-office therapist. Patients do not have the opportunity to choose.
Since the Physician Owned Clinic have opened this has hit the private clinics hard.The dramatic drop in referrals have a large effect on the clinics.
Our clinic has seen a number of patients who have finished their treatments at the clinics and have come to us with many complaints of poor quality and poor disappointing outcomes. And Medicare is paying for the services.
Physical Therpay offices owned by Physicians are causing more damage than benefitting the patients since they do not have control with the quality of services.The abuse of referring to the in-office clinic causes high volume and lenghty waiting lists.
Surley we know that there are nonphysical therpayist treating. Why? Because they can! Services are being billed under the Physicians provider number. Again this causes more harm than good along with poor service and disappointing outcomes.
Physician Owned Clinics have warned the local Home Health agencies that they are not to refer their patients to any other clinics but back to the Physician Owned Clinics as a clear reference as a kick back.
As a personal attack, a local Orthopaedic Owned Clinic represenative has gone to the point of going directly to the Administrator a Home Health agency where I am a contracted Physical Therapist. This representative has made very clear that they are not to let me treat any of the Physicians patients, in worry of the competition.
As a result of this the agency will not assign any patients that have referred to the agency by the Orthopaedic Owned Clinic in fear the Physican will find out and in-turn not refer to the agency.This is an unfair situation to both patients and myself who are dissatisfied with poor treatment.
The "in-office ancillary services" exception is defined so broadly in the regulations that it faciliates the creation of abusive referral arrangments.
The "in-office ancillary services" execption has a loophole that has resulted in the expansion of physicain-owned practices that provide physical therpay services.
Because of Medicare referral requirments, physicians have a captive referral base of physical therpay patients in their offices.
But, this problem is nationwide and needs to be addressed. A clear law needs to be passed to allow a fair and balanced competition in the healthcare market. This only would benefit the patients. This should be the main goal of all our efforts.
Please take in consideration the points that I have expressed to you.

Submitter : **Mr. David Bock** **Date: 06/23/2004**

Organization : **Mr. David Bock**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

I am a physical therapist currently working in a hospital based outpatient clinic. I am writing concernig my objections that currently relate to physician self referral.

In my experience, physicians rarely give patients a choice about where to recieve there therapy services. Patients blindly follow their doctor's wishes. A patient may be referred to a home health agency instead of outpatient therapy even though they are not technically "home bound". This financial interest driven referral is given when in many circumstances the patient would have benefitted more from outpatient services. Patients are referred to their doctor's owned outpatient PT practice even though they may live over an hour's drive away where clinics closer to their home could as easily service them. I could go on.

It is simple common sense that self referral situations are unethical and should be made illegal. In a system that supposedly wants to save money and provide healthcare to more people, you are creating a situation that rewards overutilization of services. It is unethical to have a conflict of interest in any business, especially healthcare.

These practices also give physicians an unfair advantage in the markeplace of therapy services. Without a level playing field private practice physical therapy clinics are driven out of bussiness.

I urge you to consider these points in future legislation. Physician self referral should be made illegal in all instances.

Thank you for your time,
David Bock, MPT

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Physicians in our hospital who own their own PT practice, do not admit to patients their financial incentives, nor, the fact that the patient has an option to go to any facility. They tell patients they are required to go to their facility.

Issues 21-24

24. Impact

Patients have gone to the physician owned practice where they are seen by new graduate PT's working alone with aides (turn-over is quite high); Once the insurance is exhausted, and the pt is not any better, they come to us and we have had to get benefits reinstated due to the poor quality of care they have received in the physician owned practice; The physicians refer patients to the hospital clinic if the reimbursment is not favorable.

Submitter : **Mr. CHARLES MANGUS** **Date: 06/23/2004**

Organization : **NORTH PLATTE PHYSICAL THERAPY**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I REPRESENT THE LARGEST PHYSICAL THERAPY GROUP IN THE STATE OF WYOMING. I DO NOT BELIEVE THAT A PHYSICAN OWED THERAPY COMPANY IS IN THE BEST INTEREST OF THE PATIENT. LIKE A PHYSICAN OWED PHARMACY A PHYSICIAN OWED PHYSICAL THERAPY PRACTICE BECOMES A FOR PROFIT SITUATION. DOCTORS ONLY REFER TO THEIR THERAPIST, PATIENTS ARE NOT GIVEN A CHOICE. AN EXAMPLE OF THIS IS IN OUR POWELL, WYOMING CLINIC. PATIENTS ARE REFERRED TO THERAPY FOR EVERY THING. PATIENTS WHO WOULD LIKE TO GO TO OUR CLINIC ARE REPRIMANDED. WE CONSIDERED THIS AN UNFAIR BUSINESS PRACTICE.

SINCERELY,

CHUCK MANGUS
NORTH PLATTE PHYSICAL THERAPY

Submitter : **Dr. Nola Peacock** **Date: 06/23/2004**

Organization : **Dr. Nola Peacock**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist. I have practiced physical therapy in an outpatient orthopedic setting for ten years. The purpose of my comments is to raise concerns about the interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)". The potential for fraud and abuse exists when physicians are able to refer Medicare benficiaries to entities in which they have a financial interest. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. Please consider seriously this potential for fraud and abuse. Thank you for consideration of these comments.

Submitter : **Miss. Diane Brozowsky** **Date: 06/23/2004**

Organization : **Miss. Diane Brozowsky**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Greetings. Thank you for welcoming my comment. I am a licensed physical therapist in the state of Texas and have been a physical therapist for 10 years. I am putting forth my comment regarding the March 26th interim final rule on "Physician's Referrals to HealthCare Entities With Which They Have Financial Relationships (Phase II)". I am significantly concerned about the potential for overutilization of services and fraud and abuse within our profession. I am fully opposed to this Stark II interpretation allowing Physicians to self refer for physical therapy services and strongly encourage this to be addressed in Stark III. Physicians who own these practices are inherently financially incentivized to refer to the practices to which they have a financial interest. This limits the patient's choice of where they receive physical therapy services and means they may have to drive farther and are extremely limited in choice of providers. I have directly observed this in my area. Patients do what their physician tells them and if/when he says to go to physical therapy in his office, they do. They are not educated that they have other choices!

I sincerely thank you for accepting my comments.

Submitter : **Julie Mankinen** **Date: 06/23/2004**

Organization : **Julie Mankinen**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist from Austin, TX who has been practicing in outpatient orthopedics for 7 years. I would like to express my significant concerns about the CMS-1810-IFC interim final rule.

My main concern with the rule is that it will encourage the limitation of patient/client choice as to their physical therapy service provider. There is a huge potential for fraud & abuse in a system that allows physicians to refer patients to themselves. Patients are unlikely to realize, unless specifically advised, that a prescription for physical therapy is theirs to use at the facility of their choice. When a physician refers & encourages patients to utilize the physician's own clinic, the patient loses the ability to individually choose a provider & a facility that will be most beneficial to their specific situation. The patient may in fact be encouraged to sever a preexisting relationship with a physical therapist or group of therapists with whom they have had successful & satisfactory outcomes in the past. I personally am aware of multiple 'lost' referrals to physician owned practice. As a competitive soccer player, I have had several acquaintances who have required knee surgeries over the last year. Several of them chose to have a particular surgeon perform their surgeries. After surgery, they made the surgeon aware that they personally knew (& in some cases had worked with after prior injuries) a physical therapist with whom they wanted to pursue therapy. In each case they were told that the physician preferred that they attend therapy in his own PT clinic. The patients with only 1 exception attended therapy in the physician's clinic as they did not feel they could argue with his recommendation.

Another significant concern regarding this ruling is that it encourages physicians to make referral recommendations based on financial interest. Clearly, it is inviting to recommend more therapy or further therapy than may be specifically & objectively necessary if such practices increase revenues to a specific practice. While I wholeheartedly support PT referrals, as even minor injuries benefit from PT services, particularly when they are addressed acutely rather than after years of chronic dysfunction, I do not support a change in physician referral pattern based on having an interest in a PT practice. I would be interested to note whether or not specific physicians' referral patterns change when they initiate a new PT business portion of their practice.

Thirdly, this rule is of concern to me because of the potential to 'stretch' the definition of 'in-office ancillary services'. I am conerned that patients in a physician owned practice situation may be receiving care from staff who does not meet licensure requirements required under our PT Practice Act. If a physician provider number allows them to bill for the provision of PT services, I do not see what prevents patient care from being provided by ancillary staff members such as unsupervised PTAs, ATCs, RMTs, etc. & billed as if it was a standard PT service. This sort of practice would certainly limit the quality of care that patients might receive, and would also skirt existing guidelines to practice that were put in place to ensure optimal patient management, safety, & care.

As a therapist who is specifically focused on the constant improvement of clinical skills, patient relationships, & the profession of physical therapy as a whole, I am disturbed by the current interpretations of the CMS=1810-IFC rule. It is my hope that these comments, amongst many others, will serve to help to educate the public about the potential problems that exist with the current system, and that future review will remedy the potential for misuse that is evident in the interpretation of the current rule.

Thank you for your consideration of my comments & professional opinion.

Julie Mankinen, MSPT, OCS, FAAOMPT

Submitter : **Ms. Lori Ellwood** **Date: 06/23/2004**

Organization : **Resurgens Orthopaedics**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

I would like to take this opportunity to comment on this issue from the provider/nurse advocate standpoint. Because we hire our own rehab specialists (PT/OT), we are able to hire highly qualified practitioners that specialize in specific areas of the body, ie spine, hand, sports medicine, etc. This helps us assure that the patients receive the highest quality care and the care that is necessary for their specific injury/problem. I specialize in the spine and when we are forced, because of insurance reasons, to send our patients outside of our clinic, often they come back and are no better and when we talk to them, they have had no active exercise, only modalities such as heat, ice, ultrasound, and massage. While these have a place in acute injuries, there is to date no research that shows that these modalities actually make patients better, actually just the opposite, that the patients often become dependent on them for their temporary pain relief. They are very costly modalities that do not assist the patient to get back to their highest level of function. We are also able to communicate and manage the patients care and outcomes better because the therapists and physicians communicate back and forth about the patients care. If a patient is not progressing or if a patient experiences a problem, it is communicated to the physician immediately. Often times, when the patients are seen by an outside clinic and therapist, the only time that the physicians or nurses know that the patient has not been progressing is at their follow-up visit several weeks later. The longer a person is in pain or the longer that a problem goes on, it adds additional costs in the area of disability and lost time from work, as well as the increasing costs the the healthcare insurance companies.

Thank you for taking the time to review my comments on this issue. The patients do benefit from therapy that is available in physician office settings.

Lori Ellwood, RN, ONC

Submitter : **Mr. Scott** **Date: 06/23/2004**

Organization : **Mr. Scott**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To: Mark McClellan MD, PhD
Subject: Medicare Program: Physician Referral's to HC facilities with which they have financial interests.

I am a physical therapist who has been practicing for five years. I have worked in private practice settings and under physician owned practices. Unfortunately I have seen the continued expansion of POPTPs which I creates a situation where a referring physician is 'incentivized' to refer to his/her own practice. I have often seen patients strongly encouraged to go to the doctor's rehab facility even when it means the patient will have to wait longer to begin rehab because this particular facility was overbooked. I have also seen needless inconvience for patients who end up driving for an hour or more when a facility closer to home could have served them just as well. These practices create an uncomfortable ethical problem for the doctor, patient, and therapist and in the long run the patient suffers due to lack of choice he/she feels is available. Thank you for considering these concerns, Scott

Submitter : **Ms. Jennifer Verkamp** **Date: 06/23/2004**

Organization : **Helmer, Martins,**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I respectfully submit the following comment in regard to proposed federal regulation 41 CFR Section 411.354(c)(2).

In the proposed regulation, an indirect compensation relationship exists if the entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS--as measured by the nonownership or noninvestment interest closest to the referring physician. 411.354(c)(2).

In situations where an entity furnishing DHS (A) has a compensation relationship with a third party (B) that provides services through a physician or physicians (such as a group practice or a management services company), it is my understanding that Section 411.354(c)(2) was not intended to authorize B to compensate its physicians based on the volume or value of their referrals to A nor to exempt the relationship between A and B from compliance with the Stark laws. In other words, the lack of knowledge by A of a compensation relationship between B and physicians does not in and of itself immunize A and B from violations of the Stark laws. For example, provider A violates the Stark laws by paying a group practice (B) an amount based on the volume or value of referrals generated for A, even if A has no knowledge of how those funds are disbursed to individual physicians. Likewise, provider A violates the Stark laws by paying a management services company (B) a fee based on the volume or value of referrals generated for A, even if A has no knowledge of the nature of B`s relationships with physicians.

Please clarify that proposed Section 411.354(c)(2) is not intended to exclude individual links in the chain of an indirect relationship from the prohibitions of Stark laws.

Thank you for your consideration.

CMS-1810-IFC-239-Attach-1.pdf

Submitter : **Mrs. Mary Ellen Burstein** **Date: 06/23/2004**

Organization : **Mrs. Mary Ellen Burstein**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the March 26 interum final rule on 'Physicians' Referrals to HC Entities with which they have financial relationships (phaseII)'. I am concerned with the potential for fraud and abuse that exists when physicians are able to refer MC beneficiaries to entities in which they have financial interest. This is compounded in my profession by MC's requirement that a physician must refer in order for beneficiaries to recieve PT services. Physicians who own practices that provide PT have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for finacial reasons. In addition, the broad definition of 'in-office ancillary services' in the regulations facilitates the creation of abusive referral arrangements. I would like to see this addressed in Phase III.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

My concerns about the interim final rule center around the potential for fraud and abuse which exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive 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. This potential for self referral can also compromise the beneficiary's choice of physical therapy provider.

2. In-Office Ancillary Services Exception

Physicians' offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The 'in-office ancillary services' provision does nothing to prevent this practice from occurring. The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. I have personally seen the physical harm these unqualified individuals can inflict on consumers. When these patients finally get to see a real physical therapist their previous treatments have rendered little to no positive functional outcomes. Experiencing the skilled intervention of a physical therapist for the first time usually prompts comments like 'no one has ever done this thorough of an evaluation of my problem including my doctor!' When they efficiently reach their functional outcomes they are very skeptical of what has happened in previous physician owned clinics. Unfortunately, the Medicare program has had to pay more than needed for such cases and the beneficiary's choice of physical therapy providers has been compromised. I understand that reimbursements for all healthcare providers have declined, however such practices should not be allowed to continue for the financial gain of the physician and the disservice to the beneficiaries.

Please consider the potential for this kind of fraud and abuse in the subsequent 'phase III' regulations.

Thank you for this opportunity to comment and your dedication to our seniors!

Submitter : **Mr. Peter Towne** **Date: 06/23/2004**

Organization : **Peter A. Towne Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

See Attachment

CMS-1810-IFC-242-Attach-1.doc

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : **Miss. Lori** **Date: 06/23/2004**

Organization : **PRORehab, PC**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist working in Missouri and have been practicing for 5 years. I have worked both in a privately owned outpatient clinic as well as the hospital setting. I am concerned with the final rule on March 26 dealing with "Physician's Referrals to Health Care Entities With Which They Have Financial Relationships" and how that will affect the overutilization of physical therapy services. I believe that this helps to set up a situation in which fraud and abuse may exist. We have worked so hard as therapists to work on managing the services we deliver.
The sitatuation affecting physcial therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.
Thank you for considering my comments!
Sincerely, Lori Bailey, Physical therapist

Submitter : **Mr. Rod McHenry** **Date: 06/23/2004**

Organization : **Mr. Rod McHenry**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I am a licensed Physical Therapist with 8 years of experience in out-patient orthopedics. I write you on the March 26th interim final rule on Physicians referrals to entities that they have financial relationships phase II.

I have seen many Physical Therapy practices including corporate, industrial, private practice, and Physician owned. With the influence of managed care on the health care system and the growing competition for the "medical dollar" it is concerning the conflict of interest that a Physician owned practice poses to our system. With the APTA 2020 vision and action of movement toward the clincal Doctorate degree in PT, the continuing education requirements and the extensive schooling required to become a Physical Therapist, the practicing PT should be quite able to determine when a patient is appropriate for discharge based on plateau of care. It is my concern that when the Physician has a direct financial incentive to refer the patient for more care that Physical Therapy services will be over-utilized. This will create further conflict of interest should the Physician financially incentive their clinicians to see a certain volume of patients. Is this truely quality of care?

Of even greater concern would be the billing of Physical Therapy services by the non-licensed clincians that this would enable under the direction of a Physician.

The majority of Physicians do not have an appreciable understanding of what we do as Physical Therapists and leaving the Physician community in charge of directing care, managing a clinic, and the financial incentives this could create is scarey.

Thank-you for your consideration of my comments.

Submitter : **Ms. Jill Tomasello** **Date: 06/23/2004**

Organization : **Advanced PT Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Issue #2:
I wish to comment on the interim rule on 'physicians' referrals for health care entities with which they have a financial relationship (phase II) because I believe that the public is being mis-treated and mis-lead.

I have been in private practice for almost 15 years and had developed professional relationships with physician's in my community by the quality of my work, not the size of the gift. Physician's would refer patients needing PT and I would supply them with honest clinical and functional data regarding their treatment and progress.

However, most recently physicians in my area have opened their own PT center. Their response: 'you do a great job, but this is business'. I have watched my practice shrink 40%, but worse, I hear MD's tell their patients they can have PT but only in their office. This now rescticts a patients right to choose and sets up physical therapy services as a monolopy.

Having once worked in a physician's office, I can honestly attest that when a physician is the one paying your salary, a PT is less likely to challenge a diagnosis, plan of care or even suggest a second opinion. A referral to another provider should act as a an opportunity for a 'second opinion'. Only when PTs can act autonomously, will that professional line be upheld and that will futher protect patients.

Research has shown that Physican owned PT services charge more, deliver less skilled care and keep patient in treatment longer that PT owned clinics. So why would our already struggling health care system allow more abuse? Physican owned PT centers are set up for the sole purpose of generating for the physician. Period. There is no competition, no need to improve level of care, no need to increase skill level, no incentive to get better outcomes...the more visits the more money is made, the bigger the bonus. However, in a competitive, fair market system, one PT may utilize skills or techniques that provide better patient outcomes, therefore earn themself a more positive reputation and wider referral base. Without this competition, a monolopy exists, forcing out independent PTs and encouraging more abuse. Wasn't that the real reason behind the Stark Law to begin with?

I ask that you closely review this ruling and find 'in-office ancillary services' unethical and illegal, especially when performed by unqualified personnel.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam,
I wish to comment on the "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships" interim final rule. I am a physical therapist with 10 years experience. I have taken special courses to allow me to be licensed for direct access. I have seen instances I feel were wasteful to the Medicare program because Medicare requires me to have a physicain referral to treat patients. I have had physicians send me Medicare patients with as few as 3 to as many as 12 visits prescribed for the same kind of problem. I have had people with obvious (Medicare allowed) treatable problems come to me only to be told they have to see a physician to confirm an obvious problem. Because Medicare requires me to have a physician referral I have worked very hard to develop a referral base from the local physicians. As a clinic owner I have seen the local outpatient clinic run by the hospital receive exceptions to exclusive insurance contracts because they are owned by the hospital. They are still an outpatient clinic in direct competition with me and the other independent clinics in this area. I am concerned that the present interpretation of the Stark II law will encourage the same kind of competition in my area from physician owned clinics. Already in this area there is a physician that provides physical therapy services "in-office" using a certified athletic trainer. The "in-office ancillary services" provision does nothing to prevent this practice. A certified athletic trainer is trained to focus on different things than a physical therapist. A certified athletic trainer will not be able to provide the same level of care as a licensed physical therapist, so to use them in place of a PT, is not in the best interest of the patient. I would like to see Medicare eliminate existing abuse of the system and stop potential abuse by: 1)allowing physical therapists licensed by their state for direct access to practice direct access with Medicare patients. 2) To stop the "in-office" use of other specialties to provide "physical therapy". I believe patients will benefit from a better level of care, and Medicare will save funds from implementing these changes.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

Under the physician recruitment exception in the Stark II Phase II regulations, a physician or a physician practice is prohibited from 'imposing additional practice restrictions on the recruited physician other than conditions related to quality of care.' In the commentary on this rule, a non-compete agreement is specifically cited as a prohibited practice restriction.

It seems reasonable that the purpose of the rule is to prevent a physician or a physician practice from restricting a recruited physician's ability to practice in the hospital service area to which the recruited physician relocated, in the event that the recruited physician leaves the practice to which he was recruited. This is consistent with the spirit of the physician recruitment exception, which is to ensure adequate medical care in the underserved hospital service area.

However, it does not seem proper to prohibit a physician or physician practice from imposing a non-compete agreement that would affect the recruited physician's ability to practice outside of the hospital service area, specifically, where the recruiting physician or physician practice has an established practice unaffected by any recruiting agreement. The blanket application of this rule places an unreasonable restriction on recruiting physicians with established practices in other geographic areas.

I request that the scope of this rule be further explained. Does the prohibition on non-competes apply to agreements restricting the recruited physician's ability to practice in the hospital service area only, or to all such agreements? If the intent of the rule is to apply to all agreements, please explain the reasoning behind such a broad application of the rule.

Submitter : **Dr. Sachiko Komagata** **Date: 06/23/2004**

Organization : **Dr. Sachiko Komagata**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Please find the attached letter. Thank you.

CMS-1810-IFC-248-Attach-1.pdf

CMS-1810-IFC-248-Attach-2.pdf

Sachiko Komagata, PT, PhD
13 Sabrina Drive
Ewing, NJ 08628

NJ License: 40QA01005800
PA License: PT008093L

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1810-IFC - Medicare Program; Physicians? "Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II)."

June 23, 2004

Dear Dr. Mark B. McClellan,

I am a licensed physical therapist in both New Jersey and the Commonwealth of Pennsylvania. I have been a member of the American Physical Therapy Association for the past 14 years, while my past 10 years of physical therapy practice has been in Pennsylvania.

I would like to comment on the final rule on "Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II)." I appreciate your effort to respond to public comments; however, when the exceptions are broadened as you mentioned in the docket (CMS-1810-IFC), the chances and the opportunities for fraud and abuse seem to be inherent. As much as I would like to trust "the Secretary's discretionary authority under the statute to create exceptions that pose no risk of fraud or abuse," I would like you to be aware of my concern, which is the inherent risk of fraud and abuse by broadening the exceptions.

For example, patients who receive elective orthopedic surgeries may be compliant with their surgeons' recommendations about post-operative physical therapy services. When the surgeon has his own physical therapy practice located within the hospital property, patients would not even ask where else they could receive post-operative outpatient physical therapy.

Thank you for your consideration of my comments above. I appreciate your dedication and caring about minimizing the risk of fraud and abuse by the physicians whose referrals influence their financial gain or loss.

Sincerely,

Sachiko Komagata, PT, PhD

Submitter : **Ms. Ingi-Mai Loorand** **Date: 06/23/2004**

Organization : **Ms. Ingi-Mai Loorand**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

Under the physician recruitment exception in the Stark II Phase II regulations, a physician or a physician practice is prohibited from 'imposing additional practice restrictions on the recruited physician other than conditions related to quality of care.' In the commentary on this rule, a non-compete agreement is specifically cited as a prohibited practice restriction.

It seems reasonable that the purpose of the rule is to prevent a physician or a physician practice from restricting a recruited physician's ability to practice in the hospital service area to which the recruited physician relocated, in the event that the recruited physician leaves the practice to which he was recruited. This is consistent with the spirit of the physician recruitment exception, which is to ensure adequate medical care in the underserved hospital service area.

However, it does not seem proper to prohibit a physician or physician practice from imposing a non-compete agreement that would affect the recruited physician's ability to practice outside of the hospital service area, specifically, where the recruiting physician or physician practice has an established practice unaffected by any recruiting agreement. The blanket application of this rule places an unreasonable restriction on recruiting physicians with established practices in other geographic areas.

I request that the scope of this rule be further explained. Does the prohibition on non-competes apply to agreements restricting the recruited physician's ability to practice in the hospital service area only, or to all such agreements? If the intent of the rule is to apply to all agreements, please explain the reasoning behind such a broad application of the rule.

Submitter : **Mr. Simon Gibson** **Date: 06/23/2004**

Organization : **Montclair Physical Therapy, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

06/23/04

Mark B. McClellan, MD, PhD
Administrator Centers for Medicare and Medicaid
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Sir:

I am the owner of a Physical Therapy Clinic in Oakland, California. Our business was started in 1989.

I wish to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." My comments are intended to raise concerns about the interim final rule and ask that these concerns be addressed and corrected in the subsequent "phase III" regulations.

It is clear that the potential for fraud and abuse exists when
physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The Medicare regulations compound the situation affecting physical therapy because they require a physician referral in order for beneficiaries to receive 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.

I know of at least two physician owned PT practices here in Oakland where this is the case. It needs to be made illegal for anyone not a physical therapist to own a physical therapy practice.

In addition, the "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In physicians' offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. Again, I know of at least two physician owned practices where this is the case.

Thank you for your consideration. Please alter the phase III regulations to incorporate and address these concerns.

Sincerely,
Simon Gibson PT
Montclair Physical Therapy, Inc.

Submitter : **Dr. michael germain** **Date: 06/23/2004**

Organization : **WNERTA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The proposed safe harbors for dialysis unit medical directors should be based on what the market is willing to pay. There is almost always a choice of doctors willing to do the job and are qualified. That should determine the reimmburment of the service. Doctors have more years of education and training that almost any professionals. They also shoulder tremendous responsiblities and liabilities, this should be reflected in the payment for their services.
The medical director job also is quite high level in terms of administrative, budgeting, quality assurance, problem solving and personel management skills.
Rememeber each of these facilities have revenues that are equal to many medium size buisnesses. the proposed rule will in practice fix the market value for these services which is inappropriate.
It is inappropriate to base compensation for these activities on an hourly wage rate basis
? Safe harbor methodologies were developed virtually exclusively for use in criminal contexts to a civil context such as physician self- referral and this rule for physician compensation is therefore inappropriate. The absence of a full comment and review process on this issue of critical importance to nephrology is also inappropriate.

Submitter : **Mr. Gary Kearns** **Date: 06/23/2004**

Organization : **HEALTHSOUTH**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist in an outpatient clinic. I have been practicing for 2 years, the last year and a half with HEALTHSOUTH. I would like to comment on the March 26 interim final rule on
of your letter: ?Physicians? Referrals to Health Care Entities With Which They Have
Financial Relationships (Phase II).? I want to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations. Specifically there lies the potential for fraud and abuse when physicians are able to refer
Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. In the Phase II ruling the ?in-office ancillary services? exception is defined so broadly in the regulations that it potentially facilitates the creation of abusive referral arrangements. This exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In physicians? offices, services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. The ?in-office ancillary services? provision does nothing to prevent this practice from occurring. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. On a more personal note, when financial interests come into play with referral patterns, the patient often gets lost in the confusion and treated more as a number than a human being who requires skilled physical therapy from a licensed physical therapist. On more than one occasion, patients that have had experience with a physician owned physical therapy practice express a common feeling of lack of skilled care due to the excessive high number of people receiving care at one time describing it as feeling like "cattle being herded". This often dilutes the quality of one-on-one care that our profession is proud of and would like to maintain. Please remember that this is an issue of the quality of care for a patient. Please do not let the money making side of our profession blur this fact. Thank you for your consideration of my comments.

Submitter : **Mr. Dave Taylor** **Date: 06/23/2004**

Organization : **Vaughn - Buchanan**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

It has been my experience in FL, GA, and SC that physicians are only entering into the rehab business for financial gain. I have witnessed them take away the freedom of choice to their patients on several occassions (more than 50). I have witnessed them open practices in less than desireable conditions (unsafe spacing, uncleanly, inadequate equipment in which they are submitting charges to medicare for). On two occassions I can recall the head physical therapists working for a POPS practice being coerced into allowing a PTA (Physical Therapist Assistant) into doing an initial evaluation of a patient in their absence so that the physician (Part owner) could get the revenue in on that day. It is truly not for the benefit of the patient nor for the livelihood of Physical therapists practice that these physicians have opened POPS in FL, GA, and SC. It is to line their own pockets with financial gain, while us real professionals in practice pay the consequences. Thank You! David Taylor, PT

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Attention: Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

I am writing in reference to the Interim Final Rule regarding Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) - Medicare Program. As a physical therapist who practices in a therapist-owned private clinic, I have serious concerns about the impact that the interim final rule will have on patient care and costs. A risk of practice abuse and escalated costs exists with physician owned physical therapy clinics. It is far to easy for physicians to abuse the referral of patients to physical therapy services, either for services that are not needed or for a greater number of visits than is necessary, if a personal financial gain exists. Furthermore, any suggestion or directive by a physician to obtain physical therapy services from a specific provider (in-house therapy)conflicts with a patient's right to select their own provider. Your consideration of the adverse impact that the interim final rule will have on patient rights and physical therapist practice will be greatly appreciated during phase III review of Medicare's Physician's Referrals to Health Care Entities With Which They Have Financial Relationships.

Submitter : **Ms. Heidi Prado** **Date: 06/23/2004**

Organization : **St. Josephs/Candler physical therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Please restrict the utilization of physician owned physical therapy (POPTS) clinics. Studies indicate that higher utilization and costs associated with physical therapy services occur with POPTS. Please help us keep health care costs under control by limiting the use of POPTS. thank you!

Submitter : **Ms. Saundra Stark** **Date: 06/23/2004**

Organization : **Mercy Memorial Hospital**

Category : **Hospital**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Financial Relationship Definition

The proposed final rule offers two methods for determining fair market value for a physician's personal services. Both are potentially problematic.

The first method uses the "average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market." The rate paid emergency room physicians may not be relevant when recruiting certain subspecialties or when recruiting to certain localities.

The second method requires the use of four out of five national compensation surveys. Unfortunately, the data in these surveys are proprietary and available only at a fairly substantial cost to the hospital. Furthermore, the data are often one to two years old when publilshed.

We understand the purpose of providing guidance in establishing fair market value but believe that the regulation should allow for the use of data for the appropriate specialty and locality and the use of data that is available without cost.

Issues 11-20

11. Physician Recruitment Exception

Physician Recruitment Exception

As defined in the proposed regulation "geographic area served by the hospital" diminishes a hospital's ability to recruit physicians in rural areas. In regions where a single hospital serves a large geographic area but is located in the population center of the region, 75% of the hospital's inpatients may come from the nearest 2 or 3 zip codes while other areas of the region are underserved with respect to access to physicians. Conversely, as currently defined, the proposed rule favors urban areas.

It may also happen that a region includes one or more medically underserved areas that fall outside the "geographic area served by the hospital." In that case, the hospital would not be able to help recruit physicians to an area that the Federal government has indicated needs addtional physicians.

The revised physician recruitment exception imposes a number of requirements that were not included in prior regulations, or even suggested in the comments to prior regulations. Therefore, many providers are parties to recruitment arrangements which complied with the then current Stark regulations at the time the arrangement was entered into, but which will become non-compliant with Stark on July 26. We recommend that CMS exempt from the new regulations recruitment arrangements that were entered into prior to July 26 and which comply with the pre-July 26 regulations and continue to comply with the prior version of the rules.

We understand the intent of the definition to minimize cross town recruitment and "bidding wars" between competing hospital systems, however, we believe that as presently worded, the rule may have unintended negative consequences.

Issues 21-24

23. Exceptions-Community-wide Information Services

Non-Monetary Compensation up to $300 and Medical Staff Incidental Benefits; Community Health Information Network

CMS has announced an initiative to encourage the development of electronic medical record systems. Others, including the Leapfrog Group, have encouraged the use of clinical data repositories and computerized physician order entry systems to increase quality and decrease costs in health care. There are efficiencies for hospitals, physicians and other providers as well.

However, the proposed Phase II rule is not consistent with these initiatives. In order to develop effective electronic clinical data systems, hospitals need to be able to assist their medical staff members to establish uniform high speed connectivity and acquire the software and hardware necessary to participate in the network. When such assistance is not tied to referrals there is little risk for abuse. In addition, the proposed rule provides for development of a 'Community Health Information Network.' More information is needed about what elements are included in such a network. The rule also needs to recognize that such a network would be developed in stages, over time and allow for each stage to fall within the protection of the rule. Thank you for the opportunity to comment on these proposes rules.

Saundra Stark, Director, Corporate Responsibility
Patricia Poupard, General Counsel
Daniel Wakeman, President and CEO

Submitter : **Ms. Theresa Roberts** **Date: 06/23/2004**

Organization : **Rehabilitex, Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

See Attached Document

CMS-1810-IFC-257-Attach-1.doc

June 23, 2004

Mark B McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

ATTN: CMS-1810-IFC

This letter is in response to the March 26, interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). I am an office manager of a private outpatient physical therapy practice and feel very strongly against this type of referral based system.

This "in-office ancillary" services exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. I have experienced many episodes of patients going over their visit limit because a physician's off ice gave the patient electrical stimulation and a hot pack and billed for physical therapy services. The patient is never made aware that the services provided are going against their outpatient physical therapy benefits.

Also of note, I have had many patients state that an exercise physiologist, athletic trainer, or an aide gave them exercises to do or provided other miscellaneous services and billed for physical therapy services. Patients are amazed at the services that they receive at our facility because their perception of physical therapy consisted of passive modalities and exercise programs given by unqualified personnel. People get a bad feel for physical therapy due to the fact that they truly are not receiving physical therapy from a degreed physical therapist but, they still assume this is what physical therapy is all about. Our therapist go through extensive training to provide physical therapy services and have the profession looked on favorably by the people they serve; this has become difficult to do secondary to physician practice providing so-called physical therapy services.

Please consider the physical therapy professionals in your final decision.

Sincerely,

Theresa
Office Manager

Submitter : **Ms. Temple Sellers** **Date: 06/23/2004**

Organization : **Georgia Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 11-20

11. Physician Recruitment Exception

Re: CMS-1810-IFC - Physicians - Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) (69 Federal Register 16054)

On behalf of the Georgia Hospital Association (GHA) and its approximately 180 member hospitals and health systems, I appreciate this opportunity to comment on Phase II of the Centers for Medicare and Medicaid Services' (CMS) interim final rule on physicians? referrals to health care entities with which they have financial relationships (Phase II).

GHA supports the comments submitted by the American Hospital Association (AHA) that address many aspects of the rule, including the physician recruitment exception, the exception for retention payments in underserved areas, disproportionate penalties and the exception for remuneration unrelated to designated health services.

Of particular concern to GHA is the provision addressing income guarantees, which prohibits cost allocations by the physicians or physician practice to the recruited physician greater than actual incremental costs attributable to the recruited physician. This very narrow approach prohibits common business practice of allocating ongoing overhead from an established medical practice to a new physician, for example, when a physician partner retires or dies and a replacement is recruited.

Prohibiting allocation of a new physician?s pro rata share of office space, equipment and personnel expenses when recruitment is to replace deceased or departing physicians will result in increased costs to the existing practice and will hamper hospital efforts to address community need for medical services. It may actually result in higher costs if a hospital must recruit a new physician into a solo practice setting with its separate expenses for rent, equipment and staff. Large regions of the State of Georgia are rural with very low population density and few physicians in entire communities. GHA is concerned this provision of Phase II will make recruiting to rural Georgia even tougher.

GHA urges CMS to consider amending this provision to allow hospitals to provide for office space, personnel and equipment rental to an established medical practice in instances where a deceased, relocating or retiring physician is being replaced.

Thank you again for your consideration and the opportunity to comment.

CMS-1810-IFC-258-Attach-1.doc

Submitter : **Date: 06/23/2004**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Physician's Referrals to Health Care Entities Which They Have Financial Relationships (Phase II): I wish to comment on the March 26 interim final rule above. I am a Physical Therapist who has been in practice for about 10 years, currently working for a health care system. I have concerns about the interim final rule and request that they be addressed and corrected in the subsequent 'phase III' regulations. The concern of potential for fraud and abuse in this situation is very real and does occur. By using this 'loop hole' in the system, physicians benefit from the therapy services longer than the patient requires, and often the choice that patients are given by law to choose the clinic from which they recieve therapy is taken away. I have am aware of situations that have occurred in my area where patients have been pointedly told 'no' to their request to receive therapy where they had been in the past, and told they had to receive their treatment in the physicians office that referred them for therapy. I am also aware of the potential for the physician-owned clinic keeping patients through the full insurance benefit, then referring them on to another clinic to assist the patient. Both of these situations are real and are just a tiny sample of the potential of abuse of the system as it is set up now. 'Physician-owned' clinics decrease the market for every other Physical Therapy Clinic, whether large or small due to the maximum percentage of patients being referred to their own in-office practice. There are many other concerns regarding this issue, but my biggest concerned mentioned above is that patients are not given the right to choose where they receive therapy. Many are denied their request, but do not challenge the issue to prevent animosity in the doctor/patient relationship. That is a violation that goes unreported by patients for the same reason. Thank you for your consideration of the comments you recieve on this issue. I know that through the process, things will be better for the patients we try to serve as clinicians around the country.

Submitter : **Mr. Robert Robinson** **Date: 06/23/2004**

Organization : **St. Joseph Hosptal**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have many conerns regarding the recent trends in physician owned physical therapy. Employees of physicians such as athletic trainers are delivering services billed under physical therapy which negates our practice act stating that only licensed physical therapist or physical therapist assistant. Our respective programs require very specific training in the proper delivery of physical therapy. Physical therapy is rapidly becoming reduced from a autonomous profession to a "service". We are being looked upon as another avenue to generate income. Specialization that is aquired through years of experience and advanced training and testing is being lost as many physician owned clinics prefer to hire new graduates as they are less expensive. Lastly, I feel it would be beneficial to track referral patterns with physician practices prior building their own physical therapy clinic. I would guess that the number of patients that require physical therapy will markedly increase. As a physical therapist, I cannot compete for more appropriate referrals or dream of owning my own clinic as I cannot refer to myself. This has been the most difficult year in my professional career. Thank you.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

It is clear to me that physician utilization of ancillary services and referral patterns are effected by any financial relationship to the provider. I offer the following experiences I have had:
1. The large, multi-specialty physician group in town opened up their own PT/OT clinic in town several years ago. Prior to that time, several individual physicians referred very little to PT/OT, but their referrals quickly increased. I assume the referrals are appropriate and not abusive, but it was clear to me that utilization patterns are clearly altered when there is a financial relationship.
2. Financial relationship definition needs to be broad. The physician group contracts with a large rehab company and operates under the same name of the physician group in town. While I do not know the specifics, I do know that each physician sees a line on their monthly production report that indicates the revenue from their referrals to therapy. I don't know how it gets credited to them but in the past few years doctors had referred to the financial impact of referring to outside providers. I have also learned that management of the physician practice tracks closely these referrals and influences physicians in the practice.
3. As recently as February 2004 I had a physician mad at me that a patient he referred to his PT clinic ended up in our hospital owned clinic. He stated to me over the phone "Nothing personal, but it costs me money to refer patients to you." He also said the bottom line is what is important and he gets a percentage of his PT referrals, and that it is just business and it covers his overhead.
4. Loyal patients of ours have returned to their physician and referred back to PT. The patients return to the physician reception desk and they are handed a card with their PT appointment already established at the physician owned clinic. They were not given a choice of where to receive therapy. If they would not have known they could come to us, they would have gone to the physician's PT.

I do not feel inappropriate referral to therapies is occurring in our town due to the financial relationship individual and group physicians have with PT/OT clinics. However, I know that the patient's right to choose where they get rehab services is not maintained even though every physician will say they give a choice. I can not say whether the therapy duration and frequency is appropriate, but I have my concerns with this due to the clear financial relationship to the individual provider, even though it is a contract arrangement with the large physician group. Individual provider's utilization is clearly altered.

In addition to the financial relationship concerns, I also feel PT services need to be supervised by a licensed therapist. In physician office ancillary services should not be allowed. Several physicians refer for modalities such as ultrasound only. Licensed therapists will take that into consideration into their care plan, but commonly provide more appropriate treatment to include manual therapy, therapeutic exercise, and patient education. If the physician could supervise this in his office, it may be multiple treatments of US only and the patient would not benefit as much.

Thank-you for consideration of my comments. I hope "Stark III" is more restrictive to protect the public's right to choose and over utilization of rehab services.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dr. McClellan,

I am an outpatient orthopedic physical therapist in Charleston, SC and am concerned about the potential for overuse/underuse of physical therapy services if physician ownership of these practices is allowed. I recently traveled to South Africa on a medical missions trip, where I spent time with a number of physicians, nurses, pharmacists, physical therapists, occupational therapists, and students from Charleston, SC. While working closely with these health care professionals, I quickly became aware of how relatively little we understand/know about all the different aspects of the individual fields. Physicians and med students commented that they had not seen or heard of some of the treatments we (PTs) administered. In light of this experience, I am concerned that if physicians provide physical therapy services "in house" by non-licensed personnel, the patients could miss out on valuable treatments. In addition, there is the potential for overuse if physicians are receiving financial compensation for physical therapy services that may not be indicated.

Thank you for your time.

Angie Mullins MHS, PT

Submitter : **Dr. steven wertheim** **Date: 06/23/2004**

Organization : **resurgens orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

there needs to be the exception for in-office services, especially PT and MRI. These in office services provide better patient care, easier access, more convenience and better quality. as with all physician services, utilization patterns are monitorred by the insurance companies and medicare and physicians are contacted about utilization patterns. Free standing physical therapy centers, either private or part of public companies, have profit as a driving force and have much more of an incentive to overutilize services and frequency than in physician owned centers, where closer monitoring and communication are done between physician and therapist. This results in better care for the patient. Any patient not happy with a physician owned arrangement can go elsewhere for their PT.

Submitter : **Mr. Mark** **Date: 06/23/2004**

Organization : **Mr. Mark**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I find there to be conflict of interest with physicians owning ancilliary services, as I have witnessed the overutilization of rehab services and physicians providing rehab services with non-qualified personnel. My best approach in this forum to support my case against physician ownership of in-office ancilliary services is by providing information and examples that involve physical therapy that I have both witnessed and been involved in.

Several studies have been performed that demonstrate the utilization of rehab services increases when physicians own the rehab component in their practice. Therapists that have worked closely with physicians in rehabing their patients have been approached by physicians with the recent relaxation of Stark and asked to come to work for the MD. If the therapist rejects the offer the physicians have been threatening and then sending their patients to other practices until they establish their own rehab. Physicians also have been hiring non-licensed personnel to provide these services. This is obviously a financial decision. A treating physician supplying physical therapy with non-licensed personnel creates several situations 1) Typically these are existing staff that have no experience in rehab that get trained in turning e-stim and ultrasound units on and off and provide no further care to the patient. 2) This allows the physician to pay a lower salary rate (than that of a licensed physical therapist) and still bill for electromodalities. 3)Many studies support the utilization of manual therapy, exercise, and electromodalities in the rehabilitation of multiple musculoskeletal injuries. This situation creates a less than satisfactory provision of care for the patient, extends rehab bouts and the cost towards rehab goes exponentially higher.

The bottom line is the patients level of functional improvement per dollar spent on rehab. With the present state of our healthcare dollars we cannot afford situations like this that only provide one component of rehab to occur.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

See attached letter

CMS-1810-IFC-265-Attach-1.doc

Mark B. McLellan, M.D., Phd.
Administrator Center for Medicare and Medicaid Services
US Dept. of Health & Human Services
Attention: CMS – 1810–IFC
P.O. Box 8013
Baltimore, MA 21244-8013

6/23/04

Dear Sir:

I am writing about the Physicians' Referral to Healthcare Entities With Which They Have Financial Relationships (Phase II) in regards to the interim final rule. I am a physical therapist who has been practicing in Washington state for 29 years, including working in hospitals, nursing homes, home health, and in a private practice for the last 17 years. I served for 3 terms on the board of directors for the Washington chapter of the American Physical Therapy Association. I have been a longtime opponent of physician ownership of physical therapy offices and not just because I work in a private practice setting. I feel this places physicians and physical therapists in an unethical relationship, or at least presents a strong potential for one. I am aware of several situations in Washington state involving physician owned physical therapy practices, and the majority were practicing in an unethical and possibly even illegal manner. I will give 2 examples with which I am most familiar.

In the first instance, a physical therapist friend of mine was employed by a solo physician in the Olympia area. Initially things went well until a second physician was added to the practice. He told her one day that the physical therapy revenue was low and he intended to send all his patients to physical therapy. She replied that her contract required her to operate in an ethical manner. He responded, "You did not hear me. I said I am sending all my patients to physical therapy." She again replied that she could not accept this as it was not ethical. She was fired within the week and the grounds for termination was "inability to communicate." Unfortunately, she had an agreement with the physicians that did not permit her to openly discuss her employment after termination.

The second instance is from my direct experience. I have owned a practice in Battle Ground, Washington for 17 years and enjoyed a good relationship with the 2 local groups of physicians. The larger of the 2 groups routinely referred an average of 40 new patients per month to our clinic and frequently expressed great satisfaction in our care. Unfortunately, a year ago they added physical therapy services to one of their branch offices approximately 8 miles away. Within a short time we saw nearly a 75% decrease in referrals from that group. I asked some of the physicians if there were any problems with our care and they replied that they were quite happy with our care and had many good reports from their patients. Now one could easily say, "Tough luck. That's just business." However, this had a significant impact on a great many patients, many of whom are Medicare beneficiaries. The problem is that most were not given a choice and were simply referred to a PT office that was significantly farther away, cost substantially more per treatment than our office charges, and often could

not be scheduled for their initial evaluation for several days, whereas most patients can be seen within 1-2 days at our clinic. Although they employed competent therapists, the argument cannot be made that the patients were getting superior care at their branch office. The therapists at our clinic have many more years of experience (our therapists average over 20 years of experience each, with some being 30-year practitioners). When many of our prior patients who had new physical therapy orders requested to see us, the majority were simply scheduled at the physicians' office. This created a hardship for many patients due to the increased costs and travel distances. In fact, some patients were referred to another of the physicians' branch P.T. offices that was over 15 miles away. One of their employees informed me that at a general staff meeting, they were instructed by the clinic manager to refer patients to their clinics' therapists as it helped their "profit center."

These are just a few of many examples in which patients' welfare is negatively impacted and the costs are increased. It would seem patients should have the right to choose where they receive their physical therapy, particularly if it's closer to their home and less expensive.

Furthermore, I fail to see the distinction between physicians not being allowed to refer patients to a pharmacy in which they have ownership, yet they can refer patients for profit to a physical therapy clinic they own while comparable services are readily available elsewhere in the community. It has nothing to do with need and everything to do with greed. It destroys the competition or marketplace principle that is needed to keep healthcare costs down and quality of care up. Our Medicare beneficiaries deserve better and my tax dollars need to be spent more efficiently. If Medicare is to remain viable, the concept of physician as gatekeeper is not reasonable if the only gate that is opened is to the physician's own business.

No matter how low of a fee I charge or how good of care I provide to patients, there is no way I can compete with another office from which the physician receives payment for each and every patient he refers there. If I were to pay a physician for referrals, it would be considered a kickback and would be illegal. I would appreciate an explanation of how this is different from a physician making a significant profit on the patients he refers to his own therapist.

Lastly, as we all know, there are many good, ethical physicians in the U.S., but the temptation and potential for abuse is extremely high when physicians may directly profit from self-referrals to their own physical therapy offices. I urge you to tighten the loopholes for abuse of physical therapy, as well as all other in-office ancillary services. At the very least, we need to level the playing field, give patients a choice, and stop the abuse of referral for profit.

Thank you for your time and consideration.

Sincerely,

Pete Bartel, P.T.
23874 NW Hillhurst Rd.

Submitter : **Dr. Kay Kirkpatrick** **Date: 06/23/2004**

Organization : **Resurgens Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am working in a practice with rehab in several of our offices. I was previously in a situation where I referred my patients out. I must say that the quality of care my patients are getting has improved greatly since having access to in-house rehab services. We hired the best therapists, and have ready access to the notes and the actual providers. Our patients are happy and we have control of the quality of the service provided. I would be strongly opposed to not allowing this very valuable in-house service. The people who would ultimately suffer the most are the patients.

Submitter : **Ms. Ann Giffin** **Date: 06/23/2004**

Organization : **University of Tennessee Medical Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached letter

CMS-1810-IFC-267-Attach-1.rtf

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : **Jennifer Wesley** **Date:** **06/23/2004**

Organization : **Harada PTRS**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I believe that allowing physicians to easily refer their patients to their own practice puts the patient at a possible disadvantage because it allows the line between patient care and physcian profit to be crossed.

Submitter : **Mrs. Ann Porretto-Loehrke** **Date: 06/23/2004**

Organization : **Mrs. Ann Porretto-Loehrke**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2004

Mark B. McClellan, MD, PhD
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
PO Box 8013
Baltimore, MD 21244-8013

Dr. Mark McClellan,

I am a physical therapist and certified hand therapist who works with four hand surgeons who provide a very ethical, professional work environment. This arrangement provides the utmost in quality care, by allowing physical therapists to work side-by-side with physicians.

I am writing to comment on the March 26 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? I work for a physician-owned physical therapy clinic and want you to know that this arrangement can provide a means for excellent quality of care and should not be entirely eliminated. I realize there is a potential for fraud and abuse with this situation; however, this potential exists in any arrangement.

Our clinic provides care to Medicare clients. We do not limit our physical therapy referrals solely to our own clinic. Medicare clients are given the choice as to where they would like to attend therapy. All physical therapy services in our clinic are provided by quality, licensed physical therapists.

Please consider that there are physician-owned physical therapy services that provide the highest quality of care. The practice is very ethical and professional. To not allow this type of situation to continue would negatively impact the quality of care we can provide for our Medicare clients.

Sincerely,

Ann Porretto-Loehrke, PT/CHT/COMT

Submitter : **Date: 06/23/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist in Michigan and I work in an outpatient orthopedic clinic. I would like to comment on the March 26 interim final rule on Physicians' referrals to health care entities with which they have financial relationships (Phase II). I am concerned about the interim final rule and ask that they be addressed and corrected in the subsequent "phase III" regulations. I have been a PT for 5 years and have witnessed physician-owned PT practices practicing unethically. There is great potential for fraud and abuse when physicians are able to refer patients to entities in which they have a financial interest. The situation affecting PT is worsened by Medicare's requir3ement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. Thank you for your consideration of my comments.

Submitter : **Dr. glenn jonas** **Date: 06/23/2004**

Organization : **Resurgeons**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

As a physician I have referred patients to both physician-owned and non-physician owned rehab offices. Abuse is rarely an issue with physicians as their reputation is tested by each referral and outcomes are much more closely controlled. There is better communication between patient, doctor and therapist wich leads to less cost and abuse. Outpatient therapy are run by business men not held to the same ethical standards which mosst doctors value much greater than the income derived from owning a therapy unit.

Submitter : **Dr. Frank Joseph** **Date: 06/23/2004**

Organization : **Resurgens Orthpaedics**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Having practiced for over twenty years as an orthopaedic surgeon, I can testify that the QUALITY of Physical Therapy on our self own facilities is FAR superior to free standing PT units. HealthSouth as led the area on poor patient quality. This is a quality of care issue. The private PT/OT companies have done a terrible job in terms of quality over the pasat 10 years as they have tried to maximize corporate profits. Thank You Frank R. Joseph MD

Submitter : **Dr. Reuben Sloan** **Date: 06/23/2004**

Organization : **Resurgens Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

In office physical therapy provides my patients with highest level of customer service in a number of way off site therapy cannot. First, my patients are assured that they are receiving outstanding therapy as they know I was responsible for selecting the therapist have recommended. Second, the patient is able benefit from 'problem specific physical therapy protocols' the therapists and doctors designed together (this does not happen with outside therapists). Finally, having the doctors and the therapists under the roof allows for easy, effective two-way communication. All of these benefit the patient. This is what should always be kept in mind. We can pass all the laws and implement all the rule changes we want, but as health care providers we must never lose sight of the fact that the patients' needs must come first.

Submitter : **Ms. Julie** **Date: 06/23/2004**

Organization : **Ms. Julie**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a staff physical therapist/athletic trainer working in Missouri. I have been working in Missouri for almost 2.5 years now. I am practicing in a privately owned, outpatient sports medicine. The purpose of this letter is to comment on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships(Phase II)." I am concerned that about the current interim ruling and the potential this has of weakening the STARK II laws. I think it is unethical and could potentially allow abusive referral for physical therapy services if the physicians themselves are benefitting from these referrals financially. There is a tremendous potential for fraud if physicians are able to refer Medicare patients to their own clinics. This is a conflict for physical therapists due to the fact that we aren't allowed to treat Medicare patients without a referral from a doctor. Physicians who own their own physical therapy clinics have a financial incentive to refer to their own clincs and could even overutilize these services. In the practice that my company has we strive to give our patients the best treatment and make their therapy valuable, making their pain and difficulties go away in the least amount of time incurring the least financial burden to them. Thank you for your time and consideration. Julie, Missouri PT

Submitter : **Mr. DERRICK ATTARD** **Date: 06/23/2004**

Organization : **NORTH BEACH PHYSICAL THERAPY**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Subject: Medicare Program, Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment

Dear Dr. McClellan,

Please find letter attached regarding the unfair business of physicians referring patients to physical therapy to facilities where they have financial interest on it.

Thank you for your attention in this matter

Sincerely,

Derrick J. Attard, M.S.P.T.

CMS-1810-IFC-275-Attach-1.txt

Submitter : **Ms. Pamela Wood** **Date: 06/23/2004**

Organization : **Hand-N-Hand THerapy, LLC**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Pamela A. Wood, PT, LLCC
1201 S. Barton St. #147
Arlington, VA 22204
703-979-5468

June 23, 2004
Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013
Subject: Medicare Program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment
Dear Dr. McClellan,
I am writing as a ?seasoned? physical therapist with 25 years of experience. The term ?seasoned? suggests that I have seen the field of rehabilitation make many twists and turns. But somehow, the twists and turns regarding physician owned physical therapy practice has come back to the dilemma of an inherent conflict of interest with self referral.
As a physician, you are aware that patients may ONLY receive physical therapy services upon a physician referral. And until most recently, these patients had to return to the physician every 30 days for a recertification of physical therapy care. So, these physicians benefit financially from the 30 and 60 day recertification clause, however to allow continued loopholes for sidestepping the Stark Law essentially enables them to capture a ?captive patient base? which does not breed a healthy Medicare market.
Furthermore, I was dismayed to find many legal websites listing all the ways for physicians to ?get the most out of Medicare reimbursement? by tapping outpatient physical therapy services. I would love to believe these physicians are truly interested in providing a needed service, but as seen in these webpages, this is simply NOT true. There are plenty of physical therapy clinics to serve the public. But with these continued loopholes, I sadly fear that the level of professional physical therapy care will dwindle as the bottom line for many of these self referral clinics are clearly focusing on the dollar.
Please correct the weaknesses in the Medicare system and correct Phase III of the Stark regulations. Thank you for your time.

Pamela A. Wood, PT, LLCC

Submitter : **Mr. Michael Kleinpeter** **Date: 06/23/2004**

Organization : **Orthopedic Center, P.C.**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

There has been a lot of conversation and debate nationwide and even locally (Savannah, GA) regarding physician owned physical therapy services (POPTS). I'm afraid most of the conversations are one-sided and don't present the entire facts, so let me try and continue or complete the conversation.

There are many owners of PT facilities (i.e. hospitals, private clinics, big rehab companies, physician groups, etc.). They all have at least two things in common - (1) they have all assumed some financial risk and (2) they would all like a return (on their investment) for taking that risk. Physician groups (like hospitals) have a core (primary) line of business. They see patients in the clinic and sometimes have to perform surgery or some other procedure. Again, this is their primary function. Sometimes a physician group needs ancillary (secondary) services to help in the diagnostic or treatment process. Therapy is just one part of the ancillary service arena that allows physicians to better treat patients.

Therapists working for a physician-owned center have more accountability because they work for their referring physicians. I believe these physician-owned therapy centers are less likely to abuse referral patterns for several reasons - (1) it is secondary income, (2) physicians have therapy clinics to enhance the care of their patients - overutilization goes against this line of thought and can be dangerous to the patients, and (3) the risks of overutilization far outweigh the return. Which center is more apt to push the lines of ethics? A center whose only source of income is PT or the center whose secondary source of income is PT? When compared to non-POPTS, most physician groups that own POPTS will have better facilities, better (and adequate) equipment, better communication among practitioners, and better patient satisfaction. This, in turn, will enhance the physician practice (primary business).

I'm confused as to why the APTA and local chapters spend so much time, money, and energy on the POPTS issue. Individuals in every profession (including physicians and attorneys) work for other individuals or employers. We would all like to own successful business, wouldn't we? The only problem is with return comes risk. Most people aren't willing to take that risk. Therefore, they have to work for other people. What's the difference between a therapist working for the hospital or a physician group? Both the hospital and physician group want to make money. Both services are ancillary services. Who has more to lose by bad patient results - the physician or the hospital?

While the APTA has been spending time, money, and energy on capitalistic issues, the number of patients therapists can see per hour and the reimbursement per procedure has drastically decreased. As a result, the average PT salary is lower than it was 5-8 years ago. Furthermore, the educational requirements have increased. This has a two-fold effect - (1) therapists are in greater debt when they start working and (2) they lose critical earning years in their retirement planning. Also worth mentioning is the change in the health insurance plans. Therapy is being cut tremendously. The number of visits and reimbursement is being cut, and perhaps most detrimentally, the patient copays are increasing. Patients have to pay $25-$40 per visit now when seeing a therapist. This is difficult to pay 2 or 3 times a week.

In conclusion, I applaud the entrepreneurial spirit of those therapists who want to own their own business. You are living the American Dream. However, to punish those therapists who have no interest in this is self-serving. By discontinuing POPTS, you would make therapists work for employers they have chosen not to work for. There will always be therapists who work for others. As profit margins continue to decrease, I feel the issue of POPTS will decrease and the APTA will be willing to tackle the real issues.

Submitter : **Dr. Mitchell Fogel** **Date: 06/23/2004**

Organization : **Nephrology Associates PC**

Category : **Physician**

Issue Areas/Comments

Issues 11-20

15. Anti-Kickback Safe Harbor Exception

June 23, 2004

To Whom It May Concern:

I am writing regarding ESRD Facility Medical Director Compensation benchmark.
This policy will, for all practical purposes, set fees that dialysis units pay due to their concern that they remain in a Safe Harbor.

Setting an hourly wage does not compensate for levels of supervision that is federally mandated. Medical Director Compensation should be based more on a CEO model that an hourly worker as the responsibility to oversee dialysis units extends even when the Medical Director is not physically present. To base an hourly wage on an ER physician standard is not appropriate as nephrologists have longer training than ER physicians. Furthermore, dialysis unit Medical Directors must ensure compliance with a wide range of infectious disease, water treatment, and required federal and state programs in addition to supervising medical care. Unlike ER doctors, practice overhead expenses are substantial.

Finally, implementing the proposed guidelines will do little to save CMS money, but rather will redistribute income to increasingly for-profit providers rather than physicians. In an environment where physician compensation is falling yet practice expenses (including malpractice) are skyrocketing, these rules are fundamentally unfair to nephrologists. I respectfully request that this provision be withdrawn.

Sincerely,

Mitchell A. Fogel, M.D.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the benefits of in office physical therapy.
First, the patients like to be able to receive their therapy services at the same location where they see the doctor. For most of them, they feel that this is an added convenience. Secondly, there is continuity of care. Communication between therapist and physican is enhanced. It cuts down on the lack of communication that can often times occur with outside facilities when patient updates are not received in a timely manner. Finally, by having in house therapy, we feel that we are able to control the quality of the physical thrapy received by the patient. My particular interest is in the area of spine and good spine therapist are not easy to find. Our group has taken the time and effort to hire several of the best spine therapist in this area. I know exactly what my patient is getting when I send them to see one of our spine therapists. I have had numerous patients who come to see us for evaluation because they have attended PT elsewhere without improvement and after treating with our spine therapists, make significant improvement.

Submitter : **Dr. Carl Blond** **Date: 06/23/2004**

Organization : **San Antonio Kidney Disease Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The role a the medical director is not an hourly job. We are availiable and contacted for a multitude of problems and emergencies that can occur in a dialysis clinic. A good director protects the quality and the striving for excellence in a dialysis program. We are also liable for errors. The proposed hourly wage is unacceptable for the stress and responsibility of this job. As an expert in the medical legal arena the hourly fee is substantially more and the responsibility less, perhaps time is better spent in this and reviewing the care of cut rate medical directors. Carl BlondMD

Submitter : **Dr. Orthopaedic Surgeon** **Date: 06/23/2004**

Organization : **Atlanta Orthopaedic Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Physician owned PT is one of the main reasons that PT has evolved into it's present status. Generally, MD owned PT has excellent PT/MD communication, convenient access, good patient compliance and MD's have personal and working knowledge of the PT's abilities and special skills. PT's have greater incentives for good results when ownership relationships are favorable. The potential for abuse exists, but that is the case with any business venture. In my experience, the relationship has been positive for PT's, MD's and most importantly patients. Patient's are much less likely to fall through the cracks, and written and verbal PT/MD communication tends to be better in MD owned PT ventures

Submitter : **Mr. Carl Bowman** **Date: 06/23/2004**

Organization : **Stinson Morrison Hecker LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 21-24

21. Exceptions-Temporary Noncompliance

This comment is addressed to the issue of the requirement to "fully comply with an applicable exception . . . for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliance with the exception." This regulation requires that the falling out of compliance be for reasons "beyond the control of the entity" and, for this reason, the required 180 days of prior compliance is not needed nor appropriate. The Preamble discusses an example of the change in a HPSA as one such event that could cause an otherwise excepted arrangement to fall out of compliance. However, if a DHS entity had access to information that the HPSA was going to change at the time it entered into an arrangement, such falling out of compliance would not be "beyond the control of the entity" whether the HPSA change occurs 30, 60 or 180 consecutive days prior to the change. The requirement that the failure to continue to comply be for reasons "beyond the control of the entity" eliminates any need for a consecutive day period of compliance. An excepted arrangement that was made 60 days prior to its falling out of compliance should be entitled to the 90 days time period to bring it back into compliance if the reason for its non-compliance was "beyond the control of the entity." The 90 day period would be needed for any arrangement regardless as to how long it had been in effect. In the example, if the information concerning the change to a HPSA was not available to the DHS entity it should not be denied this 90 day time period to correct compliance just because the deal was made less than 180 days prior to the HPSA information or change.

If the issue is an attempt to draw a bright line, this fails. There remains the issue of whether it was, in fact, "beyond the control of the entity." Therefore, I suggest the 180 consecutive days of compliance be eliminated due to the fact that it must fall out of compliance due to reasons "beyond the control of the entity."

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

RE: Medicare Program; Physician?s Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment.

Part I of Comments: D.R. PT
I am currently a practicing physical therapist in Southeastern Kentucky. I have my DPT, defined as a clinical Doctorate of Physical Therapy. I am treating patients who experience a variety of functional limitations. The private practice, outpatient orthopedic setting in rural Kentucky deals with a multitude of symptoms and limitations that require competent, specialized care. I would like to discuss how physical therapy access is being manipulated by physicians for personal financial gain, how physical therapy services are being provided by untrained personnel, and how patient care issues are confounded further when these two situations occur concurrently.

Section 1877 of the Social Security Act, also known as Stark II, prohibits a physician from making referrals for physical therapy services to an entity in which the physician or immediate family member has a financial relationship, unless an exception applies. The definition of an ?exception? is so broad that fraud and abuse is not prevented, but overlooked. The relationship of the provider can be determined by CMS tests that delineate whether a direct or indirect compensation relationship exists. These ?tests? are ambiguous and inadequate to prevent physicians from abusing in office billing codes to enhance their profit levels.

The billing of physical therapy services is often billed under the physician?s provider number as the one providing the service. Current legislation defines ?directly supervised? in such a way that the ?in office ancillary services? billing code allows for physical therapy services to be provided without the physician in the building.

The ?in-office ancillary services? clause of this legislation has provided physicians with a loophole allowing for the expansion of physician-owned physical therapy services for financial gain. The potential for fraud and abuse increases exponentially when physicians, who control the referral process, are allowed to refer Medicare beneficiaries to practices in which they have a financial interest. Quality patient care is further hindered due to Medicare?s requirement for a patient to have a physician?s referral to receive physical therapy services. In Southeastern Kentucky, this arrangement prevents patients from receiving qualified patient care by a licensed physical therapist. This unfair market practice prevents physical therapists who have undergone extensive training from having access to the very patients they are trying to help. Livelihoods are unduly harmed, care is withheld, and financial abuse goes unchecked.

The services provided under ?in office ancillary? codes are not necessarily being provided by licensed physical therapists, but may be provided by other individuals who do not have the training required by law to provide physical therapy. These individuals could read a book on spinal manipulation and perform the technique without any further hands-on training or experience to know what precautions must be taken, and injure a patient. This loophole removes any accountability these individuals face regarding their standard of care. Additionally, to get around this issue, physicians are hiring physical therapists to perform treatments so that they may continue to retain financial benefits.

Submitter : **Miss. Martha Sommers** **Date: 06/23/2004**

Organization : **Appalachian Physical Therpay**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I would like to comment on the effect that the March 26 interim final rule on "phase II" regulations regarding Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships. I am currently practicing in a privately owned out patient orthopedic facility. Since a "POPTS" has recently opened near us, there has been a decrease in the amount of referrals from physicians involved in the organization. I have also had patients comment to feeling pressured to attend physical therapy with "their" therapists even though they may live 30 miles closer to our clinic. While I am not questioning the services provided by "their" physical therapists, I do question the ethics behind pressuring patients to see their physical therapy providers, especially when these patients live closer to another provider and may have had a positive past experience/relationship with another provider. To use thier influence as a doctor to increase their finances even though it may be less convienient for the patient is morally and ethically wrong. I would like to petition that these issues be addressed and corrected in the subsequent "phase III" regulations.
Thank you.
Martha K. Sommers, MS, PT

Submitter : **Dr. Herschel Beker** **Date: 06/23/2004**

Organization : **Dr. Herschel Beker**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Allowing in office physical therapy or rehabilitation services permits the treating physcian to maintain quality control over the service, rapid response to changing patient needs and improved communication between therapist, patient and doctor.

Submitter : **Mr. David Ray** **Date: 06/23/2004**

Organization : **Dzh, Inc. dba Therapy Services of Georgia**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

The problem with physician self referral is that physicians can bill using physical therapy codes under the physicians license. This creates an opportunity for potentially dangerous health care as secretaries and janitors can legally be used to deliver physical therapy. So there are two problems which are readily apparant with physician self referral: 1. denying physical therapists direct access is simply a waste of Medicare resources. 2. physician self referral creates the environment for physicians padding their pockets while providing potentially sub par and likely ineffective physical therapy.

Submitter : **Dr. Robert Snow** **Date: 06/23/2004**

Organization : **Dr. Robert Snow**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have been practicing physical therapist for two years, and involved in the profession for the past five years. With the new Stark II regulations, and in my marketing experience and subsequent conversations with Physicians; I've noticed a new excietment among physicians in regard to providing thier own physical therapys services. While some physician groups are attempting to provide better care, some groups and individuals are seeking to make a profit from referral for profit. I've personally spoken to a board certified internist who is starting his own physical therapy practice for "all of my patients with arthritis" since all patients with arthritis "need physical therapy" I feel that there exists a significant opportunity for physicans to abuse the medicare system by directly referring patients to their own practice, where they have a monetary interest.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a licensed Physical Therapist and have practiced in good standing for the past 27 years in various settings. Currently, I am employed by a physician group and function under the guidelines of the In-Office Ancillary Services Exception. I am also, and always have been, a member of the APTA. Although I am generally supportive of the APTA and their beliefs, I DO NOT support their stand against the Stark II In-Office Exception. One of their objections is that physical therapy within physicians offices is performed by non-physical therapist personnel. In all the physician practices that I am personally aware of and in my own setting, all physical therapy services are performed by licensed PTs or PTAs at all times. I certainly function ethically and in accordance with our state practice act as do the other individuals. The physicians in our group initially referred their patients out to PTs in the surrounding communities, but due to their specialization, to frequently found that the care rendered was not providing the patients with the satisfactory outcome expected. It was for this reason that they decided to hire physical therapists. Having PTs that are directly avaiable to them, provides the opportunity for ongoing education and training of the PT staff. Problems can be resolved timely and communication is ongoing. The patients constantly comment on the positive level and ease onf communication between us as PTs and the physicians. The PTs are more effectively able to rehab the specific types of problems their patient population presents. This is particularly true for surgical patients since the procedure can vary even physician to physician. Communication between the PT, physician and patient is excellent due to the services being offered on-site. Urgent issues or emergencies are easily handled due to immediate access of the physician. There are times in caring for a patient that a PT sees something that concerns them. In the physician setting, it is a simple matter of walking the patient down the hall for the physician to evaluate and provide intervention if necessary. I have personally done this with patients and we have been able to avoid serious infections or complications. This is not possible for outside PT's. They can recommend that the patient return to see the physician or call the physician themselves, however this is not routinely done. This may be due to time restraints as patient volumes can be high in other settings ie. hospitals, but that immediate access is just not there. It is important to note that despite the fact that the practice offers physical therapy to their patients they continue to refer many patients to various facilites according to the patient's prefernce. This may be based on location, previous history with another PT, etc. The initial concerns regarding poor outcomes from outside referrals have lessened however. This is due to the avaiability of our own PTs for training and consultation. The relationships have been positive in both directions. The PT staff ia always treated as a respected member of the medical team. They are proved with consultations for evaluation and treatment. The PT then is responsible for determining the appropriate level of care and time for discharge. The issue of over utilization is a NON-Issue as it is up to the PT to practice accordingly to their state laws, regulation and code of ethics. The setting in and of its self doesnot create abuse. A physicians practice can be an excellent setting for a PT to practice and learn. It should continue to be an option for the profession. I thank the you, as the Administrator, for your consideration of my comments.

Submitter : **Mrs. Elizabeth Soika** **Date: 06/23/2004**

Organization : **Mrs. Elizabeth Soika**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

My name is Elizabeth Soika, and I am a physical therapist currently working in a physician-owned therapy practice. This letter is intended to comment on the March 26, 2004 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? For the past 18 months I have been a member of a flourishing practice in which physicians and therapists share an ethical and practical working relationship that focuses on the best interest of the patient. It is truly unfortunate that some facilities are abusive and fraudulent in their means of practice. However, the answer does not lie in the elimination of all physician owned clinics. As long as the best possible care is afforded to the patient, and the services provided are appropriate and ethical, it should not matter who owns the practice.

As a therapist who has worked in a non-physician owned clinic prior to holding my current position, I know that my views regarding practices owned by physicians have changed. I am certain that many clinicians have valid reasons for their oppositions. I do not feel, however, that eradicating all practices owned by physicians is the answer. It is our duty as practitioners to uphold ethical means of practice, regardless of the setting in which we work. Perhaps the answer lies in regulating, not outlawing, these practices. The dissolution of these clinics would do great disservice to patients who benefit from the ethical and moral corroborations between referring provider and therapist. Simply because there is a potential for fraud and abuse, it does not mean that it occurs in all instances. My Medicare patients receive the highest quality of comprehensive care in this facility, but they do have the choice to receive therapy elsewhere if desired.

I feel very strongly about this issue at hand. Your consideration on this matter is greatly appreciated.

Sincerely,

Elizabeth Soika, MS, PT

Submitter : **Mr. David** **Date: 06/23/2004**

Organization : **Mr. David**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist who has practiced in a hospital setting for over 13 years. I am concerned about the potential for abuse and the potential to avoid putting quality patient care first as a result of allowing physicians to refer to PT clinics in which they have a financial stake. I would like to share one example.
I am aware of a PT who rented office space from an orthopedic surgeons' practice in order to run his practice out of the same building. They referred many patients to him as they were happy with his treatment of their patients. They then decided to open their own practice in the same building when the Stark laws were modified and informed him that they would no longer be sending patients to him for physical therapy but would rather be referring to their rehabilitation practice. The practitioner in their practice was not even a physical therapist. Did they consider the quality of service that their patients would be getting or did they look at their financial interests first? This is only one incident in the state of Ohio but I think the potential for abuse under such a system is obvious. I hope you will reconsider such a system for the good of the patient.
Sincerely,
David

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Of greater concern is the care received by patients when a physician is allowed to limit the required referral system to entities in which they are financially invested, as well as offer physical therapy services that are not provided by a licensed physical therapist. In many areas, many individuals are not trained to evaluate a patient for functional limitations in a differential diagnostic fashion. Physical therapists are trained to do so. Physical therapy services that are provided by anyone other than a qualified, licensed physical therapist endangers the patient and the accountability of our profession. In many states, many individuals are certified to perform certain health duties, but are not licensed. These individuals are not subject to any accountability for how they treat clients or patients. Each state has developed clear practice acts that delineate the scope of practice for a physical therapist, as well as for many of these other individuals. Physical therapists must graduate from a physical therapy graduate program as determined by state and national boards, and must sit for the licensing exam following completion of said program. State law has stated that other individuals are exempt from providing specific services reserved for the specialty of physical therapy. In my town, one doctor was investigated and fined for allowing his athletic trainer to provide ?physical therapy services? when he was not in the office. He simply moved to another town, and opened up another clinic and advertises the provision of ?physical management,? and continues to bill for physical therapy services under the in-office ancillary services provision. Treatment continues to be provided by an athletic trainer, who has not had any physical therapy training, as a result of Stark II loopholes.

The profession of physical therapy provides an unparalleled service to individuals who require skilled, hands-on treatment to re-establish functional performance in daily activities and beyond. As function specialists, we are trained to evaluate, treat and maintain a progression of treatment to ensure a return to optimal function. Legislation for any issue is often defined through interpretation. Our practice in Southeastern Kentucky does not specifically say we cannot perform surgery, but we do not because we are not adequately trained. A similar analogy can be applied to why orthopedic doctors fail to offer extensive rehabilitation and exercise regimens for each patient. Most physicians recognize that they have limited experience in exercise and functional rehabilitation, and therefore refer patients to physical therapy. Thus, our profession has enjoyed a mutual relationship with physicians for some time. When physical therapists and doctors begin to communicate and perform their individual jobs well, everyone benefits, especially the patient.

Submitter : **Mr. Michael Burke** **Date: 06/23/2004**

Organization : **Kalogredis, Sansweet, Dearden and Burke, Ltd.**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Please clarify that where the Stark II regulations discuss an entity "wholly owned by a group practice", that this would include ownership of an entity that is wholly owned by all of the owners of a group practice (and not just by the group practice entity itself). There may be tax or other reasons for desiring to structure an entity in this way.

6. Rural Providers Exception

Please clarify the definition of "rural" entity. While the definition referred to in the regulations has not changed, the definitions used by the Office of Management and Budget in defining rural areas have expanded since the Stark legislation and regulations were originally developed. It is our opinion that the definition of rural area should remain as is (as an area outside of a Metropolitation Statistical Area), and areas such as Micropolitan Statistical Areas should not be considered as rural areas. It may make sense to explicity define rural area in the Stark II regulations themselves, rather than referring to another regulatory section that has little to do with Stark.

Issues 11-20

13. Definitions

An exception should be added to allow a physician to refer to an immediate family member where the financial relationship of the family member falls within a Stark exception. It is difficult to see the reason that would prohibit a physician from making a referral to a family member where the family member does not benefit from the referral in a manner which violates Stark. Given the detailed exception for indirect interests (which are acceptable where the physician does not receive remuneration that takes into account the volume or value of referrals or other business generated by the referring physician to the entity), a similar exception should be made for referrals to family members where the family member's remuneration does not violate these basic tenets. At a minimum, this proposed exception should apply to physician to physician referrals.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

As a result of Stark II, physical therapy patients are facing further limitations to quality care as a result of physicians? desires for increased profit rather than what may be best for the patient. Individuals with a PhD are given the title of ?doctor,? but continue to refrain from performing surgery if they have not been trained. A doctor may have some training in physical therapy services, but this does not translate over to an athletic trainer or aide they may employ. Should the doctor provide physical therapy services, having had a class or two, again, this does not translate into a trained, refined ability to create and manage a responsible functional rehabilitation or exercise program. Physical therapists do have this level of functional, rehabilitation training. The patients that require this care are deserving of the highest quality of care. This level of care can only be provided by a licensed physical therapist. To ensure the highest standard of care, physical therapy services need to be held accountable to a discriminating public by an open referral system. I appreciate your time and consideration of my profession, my patients and the effect of this legislation. I know your time is valuable and you have the responsibility of synthesizing all the comments into a concise legislative approach. I look forward to the resolution of these loopholes to insure a higher standard for our patients, our profession, and the health care community. Thank you.

Submitter : **Date: 06/23/2004**

Organization :

Category : **Private Industry**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Mark B. McClellan. MD. PhD
Administrator
Centers for Medicare and Medicaid Services
US Dept of Health and Human Services
attention; CMS-1810-IFC

I am a Physical Therapist in Iowa. I have practiced here for 14 years. I do not wish to inhibit the free enterprise system, but it has been established in the past that certain free enterprises are not good combinations and allow monopolies or abuses. Physicians and medications are one such combination. Physicians and physician-owned therapy practices is another.

One year ago our local orthopaedic surgeons hired their own PT to meet incidental-to office visit needs of their pts. and to oversee their crew of athletic trainers. This was allowed then because of incidental-to allowances in the Stark laws. Soon after it was disclosed that the orthopods would be having their surgery patients see their PT for 2 weeks after surgery and THEN allowed to seek other PT care. We have also noticed that the largest percentage of pts we do eventually see are Medicare pts, which have a lower reimbursement rate. The private pay and insurance pts are apparently being seen through the full course of therapy by the orthopod's PT. This has obviously changed our volume and profile of patients. This has gone far past the incident-to reasoning for having an in-house PT. This is also not an area where PT is hard to get to or find. Two other clinics are available within 1 block of the orthopod's office. It is not a rural area in need of physician owned PT services to meet the publics needs. Patients do not know that they have a choice where they receive their physical therapy. If their surgeon tells them they should get it with their own PT, then that is where the majority or pts will go. They know no better. Respectfully submitted.

Submitter : **Dr. Thomas Dopson** **Date: 06/23/2004**

Organization : **Resurgens Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

In office PT services allow excellent and consistant quality of personell. Therapist may talk directly with the physician regarding the patients rehab program. There is direct control over utilization of resurces. Patients choose a therapist who works directly with their physcian when given a choice.

Submitter : **Ms. Kimberly Lammers** **Date: 06/23/2004**

Organization : **Kutak Rock LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 11-20

13. Definitions

"Physician in the group practice" is defined as "a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement with the group practice to provide services to the group practice's patients in the group practice's facilities . . . " The reassignment rules for the Medicare program were recently changed to allow independent contractors to provide services to a group practice, and to reassign their right to receive payment for those services to the group, without requiring that such services be provided on-site at the group practice's facilities. See ?30.2.7 - Payment for Services Provided Under a Contractual Arrangement - Carrier Claims Only, Medicare Claims Processing Manual (CMS Pub. 100-04). Is this definition intended to be more restrictive than what is required under the Medicare reassignment rules? It would seem that if a physician has a contractual arrangement with a group practice that allows the physician to see patients of the group and to reassign his or her rights to bill to the group, that the physician should qualify as a "physician in the group practice" regardless of where the services are provided.

Submitter : SW FL PT **Date:** 06/23/2004

Organization : SW FL PT

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I have noticed a resurgence of physician owned physical therapy practices in SW Florida and decreased outside referrals to private practices in turn. This arrangement fosters self-referral of physical therapy services that can even be performed by non-licensed personnel in a physician?s office. Not only is this dangerous to the public, but sets up fraud and abuse issues as well. Medicare requires that rehab agencies and CORFs undergo stringent site inspection, utilization review, and documentation audits to be certified. Why is not the case with physician owned rehab? Why are services that require the skilled intervention of a licensed physical therapist allowed to be billed to Medicare even when performed by non-physical therapists?
I am a practicing physical therapist with a private practice that is dedicated to providing individual one-on-one care following CMS and APTA guidelines. Physician owned practices are financially devastating to private practice owners. The public is required to have a physician prescription in order to be reimbursed by Medicare services even though Florida legally has direct access to physical therapy services without a physician prescription.
I have a neighbor that underwent total knee replacement and was told that she needed to have therapy at the physician?s office. When she asked if she could come to my practice she was told that they could keep a better eye on her progress at their facility. I told my neighbor she had the right to go to any practice she desired. She stated that she had already started therapy and did not want to upset her physician. This happens frequently in our area and is very frustrating to private practice owners. Not only does this degrade the reputation of physical therapy it creates incentives for utilization abuse of the physical therapy services.
I strongly urge CMS to be cautious with loosening the ropes on stark2 and please address and correct this in the upcoming stark3 regulations. Allowing self referral of physical therapy services will be critical blow to individuals quality of care, physical therapists jobs, physical therapy private practioners, and the Medicare system.

Submitter : **Ms. Bridgett Wallace** **Date: 06/24/2004**

Organization : **Balance Therapy of Texas**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

1. Financial Relationship-Definition

June 23, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Physician?s Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Dr. McClellan,

I am a physical therapist that specializes in the evaluation and treatment of dizziness and balance disorders. I have been specializing solely in this area since 1996 and lecture nationwide to a variety of healthcare providers on dizziness and balance problems. Prior to starting my private practice (Balance Therapy of Texas) in 2002, I was co-founder of a Texas-based limited partnership with three physicians who also specialized in vestibular disorders.

Because I have practiced as a licensed physical therapist in a physician's office, I feel compelled to comment on the March 26 interim final rule on 'Physician?s Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II).' My comments are intended to highlight my concerns and ask that they be addressed and corrected in consideration of the (Phase III) regulations. Although I was aware of the potential for fraud and abuse when billing for physical therapy in a doctor's office, I was optimistic about the opportunity to collaborate my services with physicians. Unfortunately, my concerns became a reality. Within a short time, one of the partners began to refer all his patients to physical therapy when it was not medically necessary. There is no doubt in my mind that the quantity of care became more important than the quality of care, which was simply unethical. I soon dissolved the partnership and have since this time become an advocate for separating billing practices for physical therapy and physician services.

I now maintain an excellent relationship with two of the physicians from the partnership and they, too, acknowledge the risk for over-utilization of in-house physical therapy for financial gain. Unfortunately, the growth of such practices continue to multiply in this area and almost every city where I provide lectures. The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful for the Medicare program. It has become a local, state and national concern. In my particular area of specialty, I see a rapid growth of physicians utilizing non-physical therapists to provide the vestibular rehabilitation as an 'in-office ancillary service'. It would shock you to hear the number of patients that are misdiagnosed and/or are receiving inappropriate treatment, especially related to dizziness and balance problems.

The 'in-office ancillary services' exception compounded with the ability for physicians to refer to entities in which they have a financial interest increases the risk for fraud and abuse. In short, it becomes a threat -- a threat to the physical therapy profession, a threat to Medicare and, above all, a threat to the patient. I would like to ask that you strongly refine the broad regulatory exceptions to the self-referral ban and close the loophole on in-house ancillary services. I thank you for your time, Dr. McClellan, for consideration of my comments.

Sincerely,

Bridgett Wallace, PT
President

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist that is employed by a privately owned outpatient clinic in north Alabama. The purpose of my comments are to raise concerns about physician referrals to other health care services in which they have a financial interest. These physicians have financial incentive to refer patients to the services that they own. This relationship creates the very real danger for fraud and abuse of the medicare system as well as all insurance providers. The problem is further complicated by the fact that beneficiaries of medicare are required to have a physician referral in order to receive their physical therapy services. Also it becomes more difficult for an independent practice to compete in a market where physicians are allowed to refer to their own facilities. No one benefits from this practice except for the referring physician. Eliminating this practice would directly save medicare money as well as creating a more competitive market. The "in-office ancillary services" exception created a loophole that has resulted in an expansion of thes services. Medicare's referral requirements have given the physicians a captive referral base of physical therapy patients in their offices. Often these services provided in the physicians office are provided by non-physical therapists and are billed under the physicians provider number as physical therapy services. When these services are provided by unskilled and unqualified personnel is not only harmful to the patient, but also it is wasteful to medicare. Thank you for your time and consideration of my comments. I hope that the right thing will be done for all that are involved and that this loophole will be permanantly closed.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Hello,
I am a physical therapist in the state of South Carolina and have been practicing for about three years. I would like to comment on the March 26 interim rule on 'Physicians' referrals to health care entities with which they have financial relationships (Phase II). When physicians own his/her own physical therapy services, they have a financial incentive to refer that patient to physical therapy (even though that patient may not neccessarily need it). There is a huge potential for overutilization of services when the physician has a financial stake in physical therapy services. What it also does is limit patient choice to the most qualified physical therapist for that individual patient with individual needs. If a patient has a certain diagnosis and there is a physical therapist who specializes in treating that diagnosis (but who is not employed by the patient's physician), that patient will not be able to see that physical therapist. Instead he/she will be seeing a physical therapist who may not be as qualified to treat that patient. In a particular example, a patient that I had treated in the past wanted to come back to my clinic for treatment (for a different diagnosis), but the MD refused her request and told her she needed to go to his clinic. Why did she tell him to go to his clinic????? For FINANCIAL INCENTIVE!!!!!!!!!!!!!!!!!!!! I see this happening all the time and it is costing the Medicare system an enormous amount of money each year, and is detrimental to patients. Let the patients have choice to go to the therapist that they wish to see and who is the most qualified to treat that patient. The fact is, the physicians do not let the patients have a choice of who they are to see (as I have heard time and time again). This needs to STOP!!!! We need a system where a patient is treated for physical therapy because he/she needs it, and not because of financial gain. So please, we need to take a step forward and completely BAN physician owned physical therapy services. There are too many 'loopholes' in the current ruling, and thing will not change (probably get worse). Please make no exceptions when it comes to reffering with entities to which a physician has a financial relationship.

Sincerely,
A Concerned Physical therapist

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a Physical Therapist. Over the years I have seen many patients. Previous patients call for information. I have been contacted by several patients who have been referred for physical therapy about returning to my clinic. They have been referred by a doctor who has their own physical therapist. They want to come to me but are fearful that their doctor would get angry if they don't 'go to his therapist'. This population is at risk to be coerced. Even if the MD's have supplied a list, the office personnel ask why they aren't going to 'our therapist'. There are published studies showing over utilization of PT (physical therapy) and increased frequecy of referral by MD's who own their own clinic. One was from Florida and one was actually published in JAMA. I am sure a conversation with the American Physical Therapy Association would bring a wealth of citations and studies. CMS is looking at 'incident to' billing in 2004. The MD is to be on-site however PT clinic hours many times occur when the MD is not. The supervision level is minimal as compared to a Physical Therapist in Private Practice. The MD can oversee a Physical Therapist Assistant in the same building while the PTA is treating a medicare patient, but the PT in Private practice must be in the same room. Remember the PTA could be working in both scenerios (2 jobs) and have dramatically different supervision. The current MD periodicals boast how MD's can bring in house MRI's, outpatient surgi-centers, own hospitals and team w/other MD's to enhance a bottom line that has been eroded by decreasing reimbursement. Bringing PT into the office is a profit center to the MD, rather than an attempt to provide therapy in a region that lacks quality and qualified therapists. With this underlining motive, ther is greater emphasis on 'production'. Remember, congress froze specialty hospitals. Why? It was evident that MD's where directing the more profitable patients to themselves and leaving the more involved and complicated cases to the hospitals. This maximizes revenue and minimizes expenditures leaving the general hospitals to care for the expensive, complicated patients. 'Incident to' implies the service was incident to the MD's treatment, however physical therapy occurs without the MD present and by a qualified PT who is responsible to establish a plan of care. This is an independent profession. In fact, in South Carolina is against the PT licese to 'split-fees' with a referral source. I would ask that CMS carefully consider the environment of today's healthcare and the age of the 'incident to' regulation in 1965 medicare. Just as medicare needed modernization w/prescriptions, it needs to be modernized in other ways. Think, why the Stark Law was even suggested and passed? Medicare patients can, do and will get the physical therapy services they need without self-referral. I would argue if they had no perceived 'threat' from not going to their MD's PT, they would have FREEDOM of choice and access. Please consider these comments and tighten the Stark law's, speak with the law's author and prevent self-referral in a system that cries for fiscal control to preserve the benefit for our seniors. Thankyou.

Submitter : **Dr. Arnold Berns** **Date: 06/24/2004**

Organization : **Dr. Arnold Berns**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,

I will try to be brief and to the point. I am a Board Certified Internist and Nephrologist and for the past 26 years have tried to practice the highest quality medicine that I am capable of. I find myself in an over regulated, under funded, dysfunctional industry in which my primary business partner (Medicare) treats me like a potential criminal. My malpractice costs are up 63% in 3 years, and this is without a loss (settlement or verdict) in 26 years. I take care of the uninsured and the under insured and try to do with grace and equanimity.

I have been made aware that Dialysis Unit Medical Director's Fees may now be Federally regulated at an hourly rate, possibly comparable to an Emergency Room physician. I was a full time ER physician before I became a nephrologist and I speak from personal experience. The jobs are not even remotely comparable with regard to complexity, degree of difficulty or responsibility.

No job that demands years of training and experience, that carries with it enormous responsibility and almost unlimited accountability should be reimbursed hourly. These positions are CEO equivalents and need to be compensated as such. I therefore urge you to seriously consider the Renal Physicians Association (RPA) position which I completely support.

Respectfully yours,

Arnold S. Berns, M.D.

Submitter : C B **Date:** 06/24/2004

Organization : C B

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I feel that there should be no financial relationships between referring physician, group, partnership, etc. and the physical therapy provider. Such relationships increase cost, is dishonest, and denies patients their rights of selecting providers.

2. In-Office Ancillary Services Exception

This provision is in no way beneficial for recipients of healthcare services for a number of reasons. Of course I am addressing the issue as it relates to physical therapy services.

It is clear that it is not even expected that a physician will provide these services in that they already report insufficient time to get the things done which are required in their own specialties. Thus, leaving these services to provided by untrained (non-physical therapist)and unlicensed individuals with very limited if any supervision. This creates an unsafe situation for patients because physical therapist are highly trained not only in the treatment but the evaluation of disease and injuries. Often times this training has provided the opportunity for potential complications which may have been unseen by the physician. Henceforth, not only improved care for the patient but a financial savings for CMS/Medicare.

This ruling sets a situation for fraudulent actions such as provision of care by non-physical therapist, unlicensed individuals, followed with improper charges for services being submittedfor reimbursement by medicare. I have known of offices where persons were trained on the job to provide physical therapy services in a building adjacent to our office which had two trained and licensed physical therapist with over 25 years experience at the time. I also knew of a situation in which a physician had hired an individual who could not pass the licensing exam for physical therapy and a few other individuals with no formal training to provide physical therapy. An attempt was made by a colleague to report this situation and he was informed that only the patient could report and an investigation would pursue. So, this ruling would undoubtedly place undue stress on CMS.
It has been apparent that self referral creates a situation for over utilization of physical therapy services. This can happen because of physician having the captive patient base and use of the not most appropriate or effective choice of treatment. Wtih the pressure of decreased reimbursement this becomes a very inticing means of increasing revenue. It also deminishes the patients option of obtaining care in the facility of their choice, which we all know has an impact upon positive outcomes. It reduces competitive rates and places an increased risk of unethical practices between physician and therapist(employee or arrangement).

8. Employment Relationships Exception

I don't feel that physical therapist should be employed in physician offices or affiliates. This creates unfair and possible unethical practices. I feel such arrangements are not good for healthcare as a whole and eats away at the survival and quality of the physical therapy profession.

7. Space and Equipment Rental Exception

The only allowable space and equipment aggrements would have to base purely on fair market value and be established as if obtained from any other company. There should be in no way any deals relating to referrals.

Submitter : **Mr. Frederick B. Hahn** **Date: 06/24/2004**

Organization : **Park Physical Therapy Associates, Inc**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. Mark B. McClellan, MD, PhD,

My name is Frederick B. Hahn. I have been a practicing physical therapist in the state of New Jersey since 1966.

I wish to comment on the March 26 interim final rule on Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent phase III regulations.

Over these many years since 1966, I have witnessed both the valuable growth of the Medicare program services and currently now the decline in what the Medicare program services are purchasing for the Medicare recipient.

My observations are based upon real life experiences - not hypothetical 'cost savings' or 'expanded health care coverage?s'. The current state of the Medicare program is precarious - to say the least! In the 'old days' of Medicare, we were able to accept and treat patients by referral from our physician colleagues. There was a mutual respect for the physician and the therapist in providing 'essential and needed' services to the client. The physician served as the 'watch dog/ gate keeper' to insure that the patient was receiving both needed and ethical care. The 'vested interest' between physician and therapist was - the PATIENT.

Unfortunately, as the scope of care grew for physical therapy services to more and more Medicare recipients - so did the scope of financial motivation grow in the eyes of physicians. The specter of Physician Owned Physical Therapy Services (POPTS) began to raise its ugly head and the controversy over the 'need for physical therapy services' became clouded. This 'problem persisted for years until Stark I was created. For a period of time - the incentive to make money on Medicare clients waned. Now, that interest has returned with fervor!

I am extremely dismayed that the potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare?s requirement of a physician referral in order for beneficiaries to receive 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. I personally witnessed this in prior years.

My partner and I have delivered quality physical therapy services to patients in our community since 1977 in our private practice. We have been approached MANY times by physicians who wanted to entice us into 'arrangements' for exclusive referrals if we 'rented office space from them' or if we would accept some 'creative' referral contracts! I went to college to develop my skills to enhance the quality of life for my clients - not to enhance the financial schemes of unscrupulous physicians!

I earnestly implore you to see through this scam - how many more patients will be treated in physician?s offices by quasi-trained in-office ancillary services personnel - believing that what they received was 'physical therapy'! Worse - that is will be BILLED as physical therapy!

I apologize if my letter appears to be on the emotional side - for 37 years of my life - I have attempted to provide a professional service - it saddens me to believe that a noble program like Medicare - will now fall sway to additional fraud and abuse that is preventable!

I sincerely thank you for this opportunity to voice my concerns and hope that you will take action that best serves the Medicare program and its recipients.
Frederick B. Hahn, PT

Submitter : **Mr. Josph Farrell** **Date: 06/24/2004**

Organization : **Redwood Orthopaedic Physical Therapy, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have been a physical therapists for 28 years. I have owned my private practice in Castro Valley, CA for 17 years. As a practicing clinician and business owner, I would like to comment on the March 26 interim final rule on "Physicians Referrals to Health Care Entities with which they have Financial Relationships (Phase II)." My comments are intended to raise significant concerns about the interim final rule and I request that they be addressed and corrected in the subsequent "phase III" regulations.

Recently and over the past 10-12 years I have experienced on the local level a physician who owns his own Phyiscal Therapy (PT) clinic. Prior to the opening of the Physician owned clinic, this particular physician would refer patients to the 3 privately owned local PT clinics in town. Once the clinic opened, referrals to the independently owned (by physical therapists) PT clinics stopped. Over the past two years I am aware of two large Orthopaedic Physician Groups (Tri-Valley area of SF Bay Area) opening Physician owned PT clinics. The reason: they can control the referral patterns to there own clinic and significantly profit from the PT referral without regard to utilization. In fact, I have had patients articulate to me that they demanded(it is the patients' right) to come to my clinic rather then attend the Physician owned PT clinic. The "sales job" to attend the Physician owned varied from: it is "too far to drive" for care (15 minutes) or we communicate more consistently with our PT in our office. These are blatant examples of leveraging by the physician owned groups. Their referral patterns changed significantly after they established there own physician owned PT clinic. Why, because in my state the physician must provide a "referral" for most insurance companies to reimburse for PT services. Thus, the business playing field is not level and some (not all) physicians are finding loopholes in Stark II to legally refer to their "physician group owned PT clinic" which is a very obvious conflict of interest.

In-Office Ancillary Services Exception: The "in-office ancillary services" exception is defined very broadly in the regulations,therefore, it facilitates abusive referral patterns. Because of Medicare requirements, physicians have a built in referral base of physical therapy patients in their offices. In the physician offices, services are often provided by non-physical therapists and billed under the physicians provider number as physical therapy services. The delivery of so-called physical therapy services is performed by unqualified personnel (e.g. massage therapists, athletic trainers, on the job trained secretaries, exercise physiologists)which in most circumstances are NOT SUPERVISED. In addition, the patient is harmed because they think they are being treated by a physical therapists. How would the public feel if they discovered that their physician was not a licensed physician???? They would most likely be outraged and SO should the CMS be outraged about this practice of PT referral to the physician owned PT clinic. The delivery of this sort of care is very wasteful to the Medicare Insurance Program.

Physical Therapists in this country have a unique body of knowledge and skill that is acquired through 5-6 years of education with a Masters and/or Clinical Doctorate degrees from accredited universities and required state licensure. Clinical specialists and fellowship training are also available for practicing PT clinicians. Physical therapists have specific training and skill in evaluation, assessment, prognosis, diagnosis,patient management and treatment program design which are based on clinical expertise and the best clinical evidence. "Non PT's" providing care in physical owned PT clinics do not have the expertise to design a plan of care, assess the plan of care and communicate the treatment outcome. Thus the potiential for referral abuse and additional cost to CMS is escalated.

Submitter : **Dr. Paul Gaspar** **Date: 06/24/2004**

Organization : **Gaspar Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Paul Gaspar and I am a physical therapist practicing in Southern California. I graduated from the University of Southern California, earning a Doctoral degree in Physical Therapy. As a new graduate, I opened my own physical therapy practice. I have spent the past ten years building my business which now consists of three clinics and over 30 employees. The purpose of this letter is to provide you with feedback regarding the interim final Stark II regulations. I am asking you to give careful consideration to Physicians' referrals to health care entities with which they have financial relationships, as this situation threatens the health of thousands of privately owned PT clinics and jeopardizes the physical therapy profession.

Therapists such as myself who run rehab clinics and those who work for therapist-owned clinics are feeling threatened as an increasing number of physicians have taken control of referrals to physical therapy by opening up their own practices as a way to make up for lost reimbursement. Physicians who own clinics simply refer patients in-house, infringing on private practice. The two largest orthopedic groups in San Diego County have recently added physical therapy to their practice. I was asked to be an employee of one group and run the PT practice. In a meeting with the CEO I was told that the group of physicians would begin keeping all referrals in-house regardless of the area the patient lives or works. The CEO made it clear that if I were to take the position, I could not see the patients in any of my other clinics in North County that might be more convenient to the patient. This is a common practice of physician owned clinics. Patients are left wondering if they were referred in-house for financial reasons rather than medical reasons. The Stark regulations adversely affect patient access to care.

A health care professional should not profit from self-referrals. Studies provide evidence that medical costs are 40 percent higher in physician owned clinics. The physical therapy profession is being undermined by allowing medical professionals to abuse the health care system and increase costs for patients unnecessarily. Studies also show there is 18% less time spent with patients and the frequency of visits is severely inflated in a physician-owned setting versus private practice. Patients are given sub-standard care for longer periods of time at inflated costs.

My own practice has been devastated by physician owned clinics. Because physicians control the referrals, it has become impossible for me to compete for patients whose access to my services is controlled by the physician. I have spent over ten years building a practice where the patients, not my own financial interests come first. I have elected not to practice in a physician owned setting because I firmly believe ethics in business should come first. As a professor in the physical therapy program at the University of Southern California, I see the direct impact of this legislation on future physical therapists. The students are provided with no incentive to enter this field as the likelihood of them obtaining a job upon completion of a doctoral program is slim. Clinics are being closed left and right, and employees are being laid off in my area as a result of this legislation. Allowing physician owned clinics to operate accomplishes only one goal; to increase the pocket books of physicians involved in self referral. Creating legislation to ban physician ownership will preserve the physical therapy profession and eliminate unfair competition. Most importantly, it will assure that patients come first, a concept my clinic practices daily.

I thank you for your time and consideration on this important matter.

Submitter : **Dr. Brian Stone** **Date: 06/24/2004**

Organization : **Gaspar Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a licensed physical therapist working in an outpatient physical therapy clinic in Southern California. I am writing to express my serious concern with the trend I have seen with physicians in our area opening their own physical therapy practices. I have seen firsthand in other clinics that I have worked in, the impact of these practices. Other than the fact that there is a blatant conflict of interest with these types of set-ups, I feel that there are a lot of subtle impacts that go un-noticed by the general public.

It has been well documented in the literature that physicians historically have over-referred and over prescribed unnecessary treatment when they have a financial interest in regards to a patient?s physical therapy treatment. It as also easily foreseeable that the average person is completely unaware that they have a choice in where they can seek treatment for outpatient physical therapy. The other problem with these set-ups is the fact that the physician owned clinics are not held to the same standards as a privately owned clinic. I have seen in my experience many of these clinics in which there were unskilled, under-trained technicians with no formal training being loosely supervised by a physician who may or may not be anywhere near the place of treatment. As a result of this, the quality of care is significantly jeopardized and is questionable to whether you could really even call it physical therapy. This brings up the question of who suffers as a result of this. First, and most importantly, the patient suffers by being treated by an unskilled technician. The healthcare system suffers because these clinics drain huge amounts of money from insurance companies with little to no long term results to the patient. Lastly the skilled, hard-working, best educated, most qualified physical therapists who have the best chance of actually making a positive difference to these patients, are being forced to shut down their long-standing clinics due to the negative impact these inappropriate relationships are creating. I have already begun to see several smaller clinics shut down as a direct result of physician owned physical therapy clinics. If the current trend is allowed to continue I could easily foresee the majority of privately owned outpatient physical therapy practices going out of business.

Please consider these comments and concerns in regards to PHASE III of the STARK II Medicare regulations. There needs to be a ban on physician owned clinics and self referral. This is an unethical practice that continues to have a negative influence on us all.

Submitter : **Dr. Paul Gaspar** **Date: 06/24/2004**

Organization : **Gaspar Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Paul Gaspar and I am a physical therapist practicing in Southern California. I graduated from the University of Southern California, earning a Doctoral degree in Physical Therapy. As a new graduate, I opened my own physical therapy practice. I have spent the past ten years building my business which now consists of three clinics and over 30 employees. The purpose of this letter is to provide you with feedback regarding the interim final Stark II regulations. I am asking you to give careful consideration to Physicians? referrals to health care entities with which they have financial relationships, as this situation threatens the health of thousands of privately owned PT clinics and jeopardizes the physical therapy profession.

Therapists such as myself who run rehab clinics and those who work for therapist-owned clinics are feeling threatened as an increasing number of physicians have taken control of referrals to physical therapy by opening up their own practices as a way to make up for lost reimbursement. Physicians who own clinics simply refer patients in-house, infringing on private practice. The two largest orthopedic groups in San Diego County have recently added physical therapy to their practice. I was asked to be an employee of one group and run the PT practice. In a meeting with the CEO I was told that the group of physicians would begin keeping all referrals in-house regardless of the area the patient lives or works. The CEO made it clear that if I were to take the position, I could not see the patients in any of my other clinics in North County that might be more convenient to the patient. This is a common practice of physician owned clinics. Patients are left wondering if they were referred in-house for financial reasons rather than medical reasons. The Stark regulations adversely affect patient access to care.

A health care professional should not profit from self-referrals. Studies provide evidence that medical costs are 40 percent higher in physician owned clinics. The physical therapy profession is being undermined by allowing medical professionals to abuse the health care system and increase costs for patients unnecessarily. Studies also show there is 18% less time spent with patients and the frequency of visits is severely inflated in a physician-owned setting versus private practice. Patients are given sub-standard care for longer periods of time at inflated costs.

My own practice has been devastated by physician owned clinics. Because physicians control the referrals, it has become impossible for me to compete for patients whose access to my services is controlled by the physician. I have spent over ten years building a practice where the patients, not my own financial interests come first. I have elected not to practice in a physician owned setting because I firmly believe ethics in business should come first. As a professor in the physical therapy program at the University of Southern California, I see the direct impact of this legislation on future physical therapists. The students are provided with no incentive to enter this field as the likelihood of them obtaining a job upon completion of a doctoral program is slim. Clinics are being closed left and right, and employees are being laid off in my area as a result of this legislation. Allowing physician owned clinics to operate accomplishes only one goal; to increase the pocket books of physicians involved in self referral. Creating legislation to ban physician ownership will preserve the physical therapy profession and eliminate unfair competition. Most importantly, it will assure that patients come first, a concept my clinic practices daily.

I thank you for your time and consideration on this important matter.

Submitter : **Ms. Aliza Aro** **Date: 06/24/2004**

Organization : **Progressive Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

The potential for fraud and abuse exists when
physicians are able to refer
Medicare beneficiaries to entities in which they have a financial interest.
The situation affecting physical therapy is compounded by Medicare's
requirement of a physician referral in order for beneficiaries to receive
physical therapy services. Physicians who own practices that provide
physical therapy services have an inherent financial incentive to refer
their patients to the practices they have invested in and to overutilize
those services for financial reasons.

In a personal situation, I felt compelled to look for another therapy clinic when my boss, an orthopedic MD, abused his power to overutilize phyical therapy visits to his own physical therapy practice for his patients. Needless to say, I now work at a phyical therapist-owned facility that complies with all legal and ethical rules and regulations.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist, in private practice for the past 7 years. I am commenting to voice concern over the interim final rule regarding referral to facilities in which financial interest is held. The potential for expanding abuse and overutilization is exceptional in the current form. Instead of addressing the current abuse, the interim rule appears to provide a roadmap to navigate around Stark laws without looking over your shoulder or seeking legal council.
I wish to share some personal experience to support my concern:
I established an outpatient therapy clinic in a rural area where there previously was none. Over the next 5 years, I earned the respect and confidence of the local physicians, providing quality, and effective care to their patients and the community. Early 2003, another organization came to the area. They offered the local physicians an 'ownership / profit sharing' arrangement in a rehab hospital the organization would manage. The doctors formed a coalition of participation, assumed within the current Stark provisions. Suddenly, doctors who had referred 6-8 patients A YEAR for therapy services (I was the only provider in the area, and reviewed my referral records), were now sending every patient they could remotely justify through 10-13 days of inpatient rehab. Everyone from tinnitus to ingrown nails needed BID therapy- PT, OT and speech. Several went through more than once the first year, obviously with different diagnoses, but strangely similar problems. The personal financial incentives have now resulted in expansion into the outpatient and home health therapy services. The concept, as I have been explained, is to keep the patients in the loop, from hospital, to rehab, to home health, and then outpatient services, with more profit each step of the way. Once referred into the system, a patient is progressed (referred) through, likely until benefits are exhausted in each stage.
The effects on my facility have been profoundly negative, obviously. There is not much I can do at present, as all therapy patients must be referred by an MD, and all but one (to my knowledge) of the area doctors are members of 'the coalition'. I must make an important clarification; I had an excellent professional relationship with all of these doctors prior to this. The only problem was that I did not provide any financial 'rewards' for their referrals, and they have told me so. In fact, they desperately wanted me to be their therapist, but I declined. I am a patient care therapist, not a 'maximize profits and units/ patient' therapist.
This is but the brief history of an ongoing developement, and I have omitted the questionable ethics that have evolved due to length limitations of this format.
My concern in not limited to myself, but to many other facilities in similar predicaments, and the multitude of others that will be affected if the current interim rule is approved. I believe the Medicare system would best be served by promoting efficiency of care through direct access to therapy services, as physicians now hold a captive referral base, and thus the capacity to create profit for themselves. Each professional should be focused on providing the services for which he /she is trained. The capacity to profit from a referral pad and signature is too powerful for many doctors to resist, and the current Interim Final Rule does nothing more than simplify the means to get away with it.
Thank you for considering this comment.

Submitter : **Dr. Scott Levere** **Date: 06/24/2004**

Organization : **Resurgens**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

In-Office physical therapy is an integral part of the treatment regimen for Orthopaedics. This is the best way the physician can be sure that the proper regimen is being followed. Physical Therapy located in the office ensures that the patient receives the best treatment & returns the quickest to the pre-morbid condition.

Submitter : **Mr. Ryan Yolitz** **Date: 06/24/2004**

Organization : **Rehab Associates**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

June 23, 2004

Mark B. McMcClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
US Dept of Health and Human Services
Attn: CMS-1810-IFC
P.O. Box 8013
Baltimore, Maryland 21244-8013

Subject: Medicare Program; Physicians Referrals to Healthcare Entities with Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Dr. McMcClellan,

I am a Physical Therapist in private practice in the state of Georgia. I have been practicing Physical Therapy for 6 years. I am writing to you to comment on the March 26 Interim Final Rule on Physicians Referrals to Healthcare Entities With Which They Have Financial Relationships (Phase II).

Great potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to businesses in which they have a financial interest. Physicians who own Physical Therapy practices have an inherent financial incentive to refer and over utilize those services for financial gain. Physicians owning Physical Therapy practices is no different than physicians owning pharmacies. A great moral conflict exists with either situation.

Another issue affecting the Physical Therapy profession is the requirement of a physician referral for Medicare beneficiaries to receive Physical Therapy services. Patients in this situation will be funneled to Physical Therapy practices owned by the referring physician and Physical Therapists not employed by that physician will not have access to these patients.

Thank you for the consideration of my comments on this topic.

Sincerely,

Ryan C. Yolitz, PT
GA License # 006402

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Attention : Mark McClellan, MD, PhD Administrator
Centers for Medicare and Medicaid Services

Dear Dr McClellan:

As a practicing Physical Therapist for 20 years I have practiced in varied settings (hospital inpatient/outpatient, home health, and currently in private practice) and worked with a number of physicians and Physical Therapist colleagues.
I am gravely concerned about the abuse I have observed in a local clinic where a PT had worked for/in a Physician's office and the excess billing, overtreatment and poor care that the clients received as a result.
I would like to see the Phase III regulations address and correct the regulations so that this kind of conduct can not continue. Currently, under Medicare requirements, Physical Therapists require a physician's referral to evaluate and treat patients. Physician's who employ physical therapists in their practices have an unavoidable financial incentive to overutilize PT services and I have seen that exact case in my locale.
Also, the "in-office ancillary services" is such a vague loophole and defined so broadly that it fosters abusive referral practice. Unfortunately, many physician's use in house office personnel to perform "physical therapy" and bill as physical therapy practice; many times these are office staff or possibly Athletic Trainers. However, they do not have the training (currently a clinical doctorate level training) or licensure requirements of a Physical Therapist. This again, is happening in multiple medical practices in my locale.
I urge your commission to review these practices, tighten up the loopholes and allow licensed Physical Therapists to treat the public within our scope of practice unencumbered by the regulation requirement for a Physician referral, unethical use of ancillary staff to provide "Physical Therapy" and financial incentives to the physicians to overutilize these quasi rehabilitation services.

Thank you for your consideration of these matters and I look forward to your comments.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

On the subject concerning "physician owned physical therapy practices" it concerns me that it is legal for unqualified staff to perform "physical therapy treatment" to patients in physicians' offices. This can be harmful to the patient and it is wasteful of federal tax payor dollars.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a Physical Therapist and is a member of the SC chapter of APTA. I have been practicing for two years at a PT owned outpatient facility, local hospital, and nursing home. I would like to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (PhaseII)." On numerous occasions I have had conversations with my patients in which they were highly encouraged to receive therapy services from their doctors office. Most of our patient population are geriatric and most of them want to attend therapy clinics that are closer in proximity to them for personal reasons such as being on a fixed income and less traffic. Most of them feel guilty and torn between listening to their doctors and doing what is best for them. I have been told that doctors encourage their patients to stay at their facility so that they can keep a closer check on the patient but at our facility (and most facilities) we send a progress note with the patient everytime they see the doctor. These doctors who own theses practices that provide physical therapy services have an financial incentive to refer their patients to their own practice. Please do not let these physicians take advantage of the people contributing to medicare and this aging population. If we don't look out for them, who will? Thanks for this opportunity to express my opinion.

Submitter : **Mr. Michael Wisdom** **Date: 06/24/2004**

Organization : **Wisdom Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

There are few who speak against this practice because the doctors and the therapists both profit tremendously from it. The doctor gets a new revenue center without having to do any of the service to earn it. The PT is assured of a healthy referral base due to the physician's own incentives.

The only one hurt in the process is the patient public who wants to trust their physician . After all,too many of health care procedures are simply terrifying. Patients need to believe that they can trust the physicians doing and recommending them. Physician self referral contaminates that trust.

Issues 1-10

1. Financial Relationship-Definition

Any financial relationship of the physician and physical therapy contaminates the physician patient relationship. The patient has no idea whether they are getting medical advice or business referral. When the general public finally understands what is going on with conflict of interest they will be less likely to trust their physician and choose not to seek needed treatment.

6. Rural Providers Exception

This is the traditional justification for physician owned and certainly is not a new argument. I have never seen a situation whereby a PT would not provide care where a physician would. My experience when rural exceptions are given by county result in the physician owned practices moving to just over the county line and advertise and solicit patients from the urban areas contiguous.

8. Employment Relationships Exception

The problem is the unearned fee the physician derives from a medical service he does nothing to provide. The physician is paid for medical office visit already, there is no justification for paying the physician for PT. Therefore the employment status of the people actually doing the PT care is not worthy of exception.

2. In-Office Ancillary Services Exception

This simply allows the primary problem of the physician collecting an unearned fee to exist by exception. The patient is still getting charged for a physician profit that the physician does absolutely nothing to earn thus inflating the charge. It also allows the incentive of overutilization by virtue of the physician referring to his own profit center.

Issues 21-24

24. Impact

Physician owned PT services betrays the patient's trust. Patients believe that they are paying for and receiving medical advice from their doctor. In fact much of the time that patient is receiving self serving advice to refer services from the doctor's profit centers. The patient pays an unearned fee for that service, raising costs and/or receives a lesser quality of care. The marketplace is negatively impacted because competition is nonexistant. There is no level of care that a PT can provide that would convince that doctor to refer away from his own profit center. Patient trust is bound to erode eventually when the public finally figures they have been betrayed. That lack of trust translates ultimately in patients choosing not to have enough confidence in their medical advisors to follow through with legitimate medical advice. At some point patients simply will not know the difference between necessary medical advice and that which enhances the physician's profits.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a licensed physical therapist practicing since 1996. I am against physician owned practice and reerral for profit by physicians. Studies show that this leads to over utilization of Medicare funds. I also believe that Medicare patients should have the ability to have direct access to physical therapist as this, at least, would put the physical therapist on an equal footing. Please do not ignore the facts. Do not continue to allow abuse of the Medicare system.

Submitter : **Mrs. Chantal McDonald** **Date: 06/24/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I wish to raise concerns about the motive in physician decisions being made with regard to physical therapy referrals. In defining the rationale for a physical therapy referral, a physician should strictly be making decisions based on the patient's need for physical therapy services and the optimal place to refer them to. In my estimation, the patient's care should be the primary motive, not the financial benefit a physician may gain as a result of his referral. In an ideal world, one would hope that the financial gain would never enter into the picture. In reality, we know this not to be true. I am familiar with two physician practices who have recently added a physical therapist in their office in order to boost their revenue. The patients receive substandard care consisting primarily of exercise instruction and do not receive the benefit of having a space dedicated to providing the optimal care, with the appropriate equipment in a supervised environment to progress the patient through their rehabilitation.
Physical Therapists hold an expertise which cannot be duplicated and should not be abused by physicians who simply wish to increase their revenue.

2. In-Office Ancillary Services Exception

It should be made clear that Physical Therapy is an expertise requiring appropriate education (now a doctorate), ongoing skill development, space, equipment, and licensure, to provide the service without placing the patient at risk of injury. This service cannot and should not be duplicated by non-licensed individuals claiming to be providing physical therapy services. This is both a disservice to the patients and a dangerous practice to impose on consumers. There needs to be regulation to eliminate this risk and ensure that patients are receiving the utmost in care through all phases of their rehabilitation. We would not allow a scrub nurse to perform surgery, why allow personnel in physicians offices to perform and charge for physical therapy services? Please correct these problems in phase III regulations.

Submitter : **Mrs. Sofja Seymour** **Date: 06/24/2004**

Organization : **Mrs. Sofja Seymour**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist that has worked both in a private practice setting and physician-owned clinic. I feel that I have been able to provide the most quality care in the physician-owned clinic. We are able to take the TEAM approach to patient care to the highest level. We work side-by-side with our physicians, who respect and often seek our professional opinion. They support our profession and even provide substantial reimbursement for APTA membership and continuing education. I understand that there is the potential for fraud and abuse with this situation; however this potential exists in any setting. Infact I find that there were often unneccessary medicare referrals in the private outpatient setting. These patients continued to be seen so that the referring doctor would not be offended, but encouraged to keep the referrals coming. Our clinic does provide care to medicare patients, but this makes up less than half of our patient caseload. Our clients are informed that they are entitled to attend therapy at the clinic of there choice. We do not limit our physical therapy referrals soley to our own clinic. It is up to the professional, be it the physician or the physical therapist to maintain ethical standards. I feel you would be doing a great disservice to the healthcare community in not allowing physician-owned clinics to operate.

Submitter : **Ms. Kathleen Schaefer** **Date: 06/24/2004**

Organization : **Ms. Kathleen Schaefer**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. McClellan:
I work in an acute care rehabilitation setting and as such am not personally impacted by the Stark 2 law. However as a consumer of health care services, I am appalled that we would consider encouraging physicians to have a financial interest in physical therapy services. Although such in-office arrangements have only recently emerged, abuse is already rampant. Consider this: for many, the physician has a stature equivalent to that of a lawyer or priest. He or she is the person that we turn to when we encounter illness. It is only natural for a patient to accept a referral to the physician's own therapy staff, especially if the physician does not provide or even mention the existence of alternative sources. Even worse, I am aware of situations in which doctors have refused to write orders for therapy services unless the patient agreed to go to his or her own clinic.
There are many benefits to keeping therapy as an autonomous entity. First, the profession is regulated to ensure that only therapists and therapy assistants may perform any skilled training. (This is not the case w/physician practices.) Secondly, because it consists of one less layer of management, the private practice should necessarily have lower costs than the physician-owned clinic. Thirdly, the likelihood of Medicare abuse is lower for the private clinic in that therapists are required to obtain physician approval prior to treating. In the case of the physician owned therapy business, no such controls exist.
Thank you for allowing me to comment on the Start 2 legislation. I hope I have succeeded in making a case against physician owned therapy services. They not only restrict trade, they have the potential for increasing Medicare costs. Once private therapist-owned clinics have been driven out of business, the physican-owned clinics will have no competition. How can that benefit either the consumer or the benefit payer?
Best regards,
Kathy Schaefer, PT

Submitter : **Mr. Donald Kelly** **Date: 06/24/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have worked for therapist owned, corporate owned and physician owned practices over my 8 year career. Seeing all these aspects gives me a unique perspective on the issue of self refferals to physician owned physical therapy practices. I have found that about half of the physicians do not abuse the system, however half do. In many cases, the setup of having PT located on the MD premises is convenient for the clients and fosters improved communication with the physician(s). However, clients are rarely advised of their ability to chose the physical therapy provider of their choice. This can set up a non efficacious situation in which the client is inconvenienced to go to the MD office for therapy rather than a local clinic. I feel that most physicians are ethical about who they send to therapy in the orthopedic setting, but less so in family practice and general/internal medicine. Many of those referrals are not appropriate for physical therapy but are evaluated and breifly treated by the therapist at their clinic. I also have seen a fair amount of MD's sending patients back to therapy for continuation of care when they have plateaued in their care. These additional visits and overutilization is part of what reflects poorly on our profession and displays overutilization within the profession that has been shown to prevent increased reimbursment, or even lead to decreased reimbursement. The other concern that I see is lack of physician supervision during the course of care of Medicare clients. Frequently, MD's are not on the premises when services billed out under their Medicare number are being provided. Also, although Athletic Trainers and Aides that are not "Physical therapy" providers, are frequently utilized improperly in these physician owned practices. I feel that preventing self referral would be met with great objections and could create major shockwaves within the healthcare community. I feel that a start to making the process better would be to "force" Physicians to disclose on all their paperwork and referral forms that they have ownership in the anxillary services. I have even seen an ortho group list local privately owned PT clinics on their referral forms in addition to the disclosure to foster client choice and help them understand their options. I also feel that ultimately checks and balances are the best way to monitor self referrals. I have the ability to track referrals, visit numbers, Icd-9 coding, CPT billing and many others. I assume that Medicare has the ability to track these items and be able to compare these numbers for PT versus POP clinics to red flag any discrepencies in POPs or private clinics to identify abuse in either setting. I trust that Medicare will make an educated decision that has the client's best interest in mind. I thank you for this opportunity to speak my mind and support my profession whicj I love dairly because of the way we help people. Good Luck with the process!!
Don Kelly Clinic Director and Public Relations Chair of the Rhode Island APTA

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

As a contract therapist, I have had the ability to work in a variety of clinical settings, including POPTs. Though I can appreciate the convenience of being able to access the physician more readily in this environment, it concerns me physical therapists are not always the individuals providing "physical therapy". Not only is this misleading to the client, but, in some cases, may also be detrimental. Truly, the sooner intervention occurs in a condition, the sooner we are likely to anticipate recovery through conservative measures, like P.T. Nonetheless, if the the provider is not highly skilled, and able to readily reassess and adjust, appropriately, a patient's care secondary to the assessment, we may be delaying the recovery process and costing the healthcare mounds of medical dollars, which could have been saved if proper treatments were rendered. Please consider the liberal ability to allow unlicensed "physical therapists" to treat these patients the injustice it is!

Submitter : **Mrs. Kay Ahaus** **Date: 06/24/2004**

Organization : **American Physical Therapy Association, Oklahoma Ch**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 23, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
US Dept of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am a physical therapist and have been for 36 years. I wish to comment on the Physician's Referrals to Health Care Entities with which they have financial relationships. (PhaseII); Interim Final Rule with Comment.

I have worked hard in my profession to establish skills so I may provide quality care for patients needing physical therapy. In our community, I have seen local physicians insist their patients go to a clinic owned by these same physicians. Patients do not know they have a choice of providers. Whe the doctor says, "Go here", they think they must go there. Several of my patients had to insist they come to our clinic because the physician resisted sending them to anyone but "their own therapist". But, I have special certification in vestibular rehabilitation, something not many therapists in Oklahoma have received. Patients know where they want to go. But, they often have to insist over a physician's objection when the physician has a financial interest in the physical therapy clinic.

Several times patients treated in doctors' offices were seen by unlicensed technicians the physicians briefly trained on the job. The physician can bill for physical therapy, but the patient has not received physical therapy but a shabby second rate imitation "treatment". Sometimes these "treatments" can harm the patient.

Please consider eliminating such practice.

Thank you for allowing me to comment.

Yours truly,

Kay Ahaus, P.T., M.S.
12600 SW 31st St
Yukon, Ok 73099

Submitter : **Dr. Neil McKenna** **Date: 06/24/2004**

Organization : **Dr. Neil McKenna**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I have been an outpatient physical therapist for 4 years. I have earned the distinction of Doctor of Physical Therapy, am a board-certified specialist, and have completed a fellowship program in orthopedics. I believe this exception for "in-office" services fosters fraud and abuse in the form of over-utilization of physical therapy services which ultimately drives up health care costs. The following studies expose the ill-effects of referral to in-office physical therapy: (1)Mitchell JM, Scott E. Physician ownership of physical therapy services: Effects on charges, utilization, profits, and service characteristics. JAMA. 1992; 268:19-23. (2)Swedlow A, Johnson G, Smithline N, Milstein A. Increased costs and rates of use in the California Workers? Compensation System as a result of self-referral by physicians. N Engl J Med. 1992;327:1502-1506. Working as a physical therapist in a private practice setting, Medicare requires a prescription from an MD to initiate care for my patients. With physicians able to refer these patients to themselves, many of these patients will not benefit from my expertise. The physical therapy that is often provided in these physician-owned clinics can be billed under the physician's provider number. This sets up the possibility for physical therapy to be provided by "non-physical therapists" since they are not the ones who are conducting the billing. Unlicensed activity is referenced in the "Business and Professions Code of California" Division 1, Chapter 1.5 section 145 as a "threat to the health, welfare, and safety of the people of the State of California." I personally do not know of any specialist in the field of orthopedic physical therapy that is employed by a physician-owned clinic. This observation, as well as the possibility that the services may not be provided by PTs, can ultimately result in a lower-level of care. This will manifest as potential harm to a patient if the provider is simply unaware of one of the many precautions/contraindications that are affiliated with the myriad of physical therapy treatments. Besides this type of harm is another concern: the inability to provide effective treatment, which drives up therapy costs in the form of visits used and units billed for these services. In conclusion, the "in-office" exception has the potential to drive up health care costs and deter patients from receiving the best physical therapy services that they are entitled to. Thank you for your consideration on these comments.

Submitter : **Mr. Gil Schoos** **Date: 06/24/2004**

Organization : **Renton Highlands Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I would like to oppose any regulation that would allow Physicains to operate a Physical Tharepy Clinic to which they can refer patients. This would be the same as allowing them to own a pharmacy to dispense drugs.

Any situation that has a finacial incentive back to the referring source is going to be abused. Not by everyone but certainly this is going to happen.

There is no shortage presently of Physical Therapy delivery sites that are free from this compromise. Why would you even entertain the option of allowing this to happen when it clearly is wrong and clearly is not needed.

This isWRONG. It is an more than likely abuse and will result in increased costs to the system and inferior care for the patient.

There simply is no rationale reason to allow this to happen. It should be illegal and morally is wrong.

Submitter : **Mr. Hiten Dave** **Date: 06/24/2004**

Organization : **American Physical Therapy Association**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

In-Office physical therapy leads to fraud and abuse as physicians will utilize maximum number of visits even if the patient does not need them. This is because the physician makes money for every patient visit in his/her clinic. This is analogous to in a hypothetical court, the Judge and the Jury has no differentiation and therefore the accused would get an absolute biased trial. I have heard patients tell me that a particular physician uses "mind games" to entice the patient to go to his in-house physical therapy clinic by saying: "If you go to my clinic then I will be able to keep a close eye on your rehabilitation" Whereby another independent physical therapy clinic is only 2 blocks away. Many of the physicians do not have licensed physical therapy staff and have unlicensed medical assistants doing pseudo physical therapy and billing for it. There are physician continuing education instituitions which advertise to physicians to hire massage therapists and unlicensed staff to do in-house physical therapy. A physician is going to become morally and ethically challenged when a free reign is given over referral for profit.

Submitter : **Mrs. Ali Schoos** **Date: 06/24/2004**

Organization : **Bellevue Sports & Spine Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am attaching my comments regarding physician owned physical therapy.

CMS-1810-IFC-329-Attach-1.doc

I am a physical therapist in private practice. I have 22 years experience and I am board certified in orthopedics by the American Physical Therapy Association. I have presented to a variety of groups, including the National Osteopathic Surgeons Association, the National Athletic Trainers Association, the Washington State Physical Therapy Association (WSPTA), the Private Practice Special Interest Group of Washington, and others, on issues of physical therapy practice and reimbursement. I was named Physical Therapist of the Year in Washington State in 1993 for my efforts on behalf of the WSPTA. I am opposed to physician ownership of physical therapy for a number of reasons: 1) It diminishes the concept of a democratic and open marketplace; 2) It deprives the beneficiary of the physical therapy service of choice; 3) It increases the cost of care; 4) It allows for the increased potential of abuse of services.

I have seen physician ownership of physical therapy rapidly expand in my community and state since Medicare cut reimbursement levels to physicians, particularly orthopedic surgeons. There are "continuing education" courses for physicians geared specifically on how to increase their income by opening a physical therapy clinic, as if it were not a skilled service, but a retail outlet. When two large orthopedic groups in Bellevue that referred to me as well as to other clinics in the area, joined forces and opened a physical therapy practice, they told me it was specifically for the money. They recognized that quality care existed in the community, but they wanted to recoup the money they "lost" from Medicare. Since they largely control where their patients go for physical therapy, they have easy access to this income. I don't see how this differs much from a monopoly, except that it doesn't limit the money to one group of orthopedists, since all orthopedists can open their own clinics and receive the profits from their referrals. It does exclude the non-referring practitioner (the physical therapist) from deriving an income from the very practice he or she delivers, unless he/she works for the physician. So the very person who has studied to be the physical therapist, and who delivers the service (or should), cannot benefit as much as the person who controls the referral, but does not directly provide the service. One physician told me his group would have liked me to run their clinic, since I was "the best" physical therapist they knew, yet they didn't approach me as they knew I wouldn't do it. I lost 30% of my referrals the day they opened their doors. Why don't they use "the best" still? Isn't that what the patient deserves?

Since I have a long standing presence in this community, I continue to see patients who had seen me prior to the physicians opening their own practice, or others who have not felt the care they received at the POPTS (physician-owned physical therapy service)
was adequate, and looked elsewhere. I have been told, almost universally, that when a physician referred his patient to his clinic, he did not disclose his ownership status, as required by law. So the patient is misled into believing that the physician is only sending the patient to the physician's facility out of the patient's best interest. The patient usually doesn't realize he/she has a choice in where he/she may choose to have physical therapy provided, unless he or she has been a physical therapy client previously. When a physician does not own the physical therapy service, he will give the patient choice in terms of location, specialty of the physical therapist, and/or the quality of the service as known to the physician. When he owns a facility, he refers as many of the patients as possible to his facility. In a "free marketplace," my services must speak for themselves. If I am to be competitive, and receive the

benefit of referrals from physicians in my community, I must be the best I can be, in quality, cost, access, etc. None of that matters if the referral sources have a financial incentive to refer to themselves.

Studies have been done in other states that show the cost of care for an episode of physical therapy from a POPTS is higher then at a physical therapist owned facility. The incentive to monitor the visits, or even to determine who is truly in need of the service, is obviously lessened when the referring source is also the receiver of the profits. The incentive to the physical therapist in a POPTS, to provide the highest quality care, or the most efficient care, is lost as the referrals will come anyway. I have direct knowledge of an orthopedic surgeon who historically drastically limited his patients' visits to physical therapy, but now that he owns a physical therapy facility, sends patients for a length of stay he never would have done before.

Lastly, a physician is allowed to delegate "physical therapy" to non-physical therapists, based on his or her medical degree, regardless of the fact that the physician receives little to no education or training in physical therapy in medical school. The service that is rendered in that way is simply a delivery of modalities, or recitation of exercises, but not physical therapy as a licensed physical therapist would deliver it, nor as our practice act would define it. Medicare does require that the service it pays for be rendered by a physical therapist, but how well can it monitor this, if the service can be provided to non-Medicare clients differently?

I thank you for considering this issue, and ask you to be brave in the face of the stronger AMA (who supposedly recognizes that "referral for profit" has the great potential for abuse), and ban POPTS. Allow patients freedom of choice, a choice that they are AWARE of; allow them the economics of a less costly episode of care; allow them access to care that is driven by the market to be the best; and allow physical therapists to practice they way America has always stood for, in an open and free marketplace.

Sincerely,

Alice ("Ali") Schoos, P.T., O.C.S.

Submitter : **Dr. michael morris** **Date: 06/24/2004**

Organization : **Resurgens orthopaedics**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

In office rehab services are a win/win situation for everyone involved. The PT's have direct access to MD and vice-versa. The physician can monitor patients progress better and the physician has more control of the therapist's activities with the patient. My outcomes are better since having in-office rehab. Patient's love the convenience and one stop shopping concept. My referral patterns have not changed since starting this as well.

Submitter : **Mr. Thomas Moriarity** **Date: 06/24/2004**

Organization : **Rehabilatation Centers of Charleston**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dr McClellan,
I am concerned about physician refferal to PT clinics in which they have ownership. In my 14 yearsd of PT practice I have seen numerous MD owned clinics that were sold. The previous MD owners refferred less to PT when they divested themselves. Physician owned clinics also tend to use less qualified or unliscenced individuals to deliver PT services. At best this practice denies patients the best care and at worse it is fraud. Medicare pt's tend to have complicated medical histories and multiple musculoskelatal deficits. Only qualified Physical Therapists can provide an adequate PT exam, diagnoses, and administer a treatment plan.

Respectfully,
Tom Moriarity PT,OCS

Submitter : **Mr. James Porterfield** **Date: 06/24/2004**

Organization : **Mr. James Porterfield**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have been a physical therapist in Ohio since1974, and I have had the good fortune to experience and be a part of the positive changes in caring for patients.

Physician owned Physical Therapy services (POPTS) shifts the primary focus of care to dollars paid. History has shown us that the move towards POPTS sets is counter productive to the betterment of health care. This move towards POPTS is money driven and devised to counter the increasing expenses of clinical practice. It is also an attempt to hold on to the outdated paternalistic and ?top of the food chain? mentality of the past. The Physical Therapist of the future will be autonomous and yet be a part of a system that best provides care for patient. Physical Therapy is evidenced based and we have excellent descriptive data that profiles effective clinical practice.

Please assist us in strengthening the profession of Physical Therapy by amending the Stark Laws to disallow POPTS.

Submitter : **Mrs. Laura Marusich** **Date: 06/24/2004**

Organization : **Spine and Rehab Specialists**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

The number one reason that physicians should not own PT clinics is because they absolutely compromise patient care. They will and do not refer to the clinic that is known to specialize in their patients problem. Because of their vested intrest in their own clinic they will not refer out. They do not inform their patients that they have the right to choose a PT clinic. This is is especially detrimental when you live in a community that is under educated and afraid to go to a clinic that is different from where their doctor sent them. Often the physician owned clinics are so busy that a PT can only interact with the patient during the initial eval and reassessment phases of rehab. How can that be in the best intrests of the patient? I thought the original Stark law was to prevent this situation from occurring. It failed miserably. I hope that Stark II can accomplish this goal.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist who treats patients in their home. There are several groups of orthopedic surgeons in the county who have a financial interest in the physical therapy clinics in or near their office. Their protocol requires the patients to return to their office therapy clinics for 2 weeks of outpatient treatment after short term home health.

Many times this is a great inconvenience for the post op patient and their families. Many live in retirement communities several towns away and need to rely on friends for transportation to the physician's place of choice (20 or more miles away with no public transportation). Within a 1-2 mile radius there is a minimum of 5 corporate or privately owned therapy clinics, easier transportation and near the shopping centers the patient's and their friends frequent. Many of the patient's continue the out patient therapy locally AFTER the mandated 2 weeks at the doctor's. They have voiced the therapy is often more comprehensive at the local clincs, they went to the local clincs prior to surgery referrred maybe by their primary doctors and were pleased with the therapy. They are pressured to go the doctor's as requested and told they may not do as well post operatively.

This is a fnancial hardship, inconvience and at times more painful with accompmanying stiffness/ soreness in the operated joint with a 30 to 45 minute ride vs. 2 to 5 minute ride. One local clinic is actually owned by a PT who worked for many years for the physician owned practice. It also destroys any continuity of care with the therapist who has worked with the patient and knows them, their pre surgical functioning ability, prior injuries, and has established a working relationship with hte patient and their family.

Submitter : **Dr. Robert Jansen** **Date: 06/24/2004**

Organization : **Georgia South Carolina Society of Nephrology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

The Georgia South Carolina Society of Nephrology is a professional organization representing nephrologist in Georgia and South Carolina. Our organization is dedicated to maintaining the highest professional standards to assure that our patients receive the best care possible. We are writing to comment on the proposed provision on establishing safe harbor methodoligies for payment of medical directors of dialysis centers.

We are concerned that the proposed methodology based on hourly wage rate is inappropriate for medical directors of dialysis centers. The medical director responsibilites carry a degree of accountability which is inappropriate for hourly compensation. The medical director, under federal guidelines, is responsible for all activities within a facility and for quality improvement initiatives. The activities of a medical director are more comparable to a senior exectutive of a corporation rather than an hourly employee. To place an hourly rate on these activities will endanger patients by discouraging physicians from actively participating and managing dialysis centers.
Further, the hourly approach will likely result in essentilly fixing medical director fees regardless of the size of the clinic and result in a substantial reduction of payment to medical directors. This fixed, reduced payment will only serve to further discourage physicians from entering the field of nephrology and accelerate the loss of qualified nephrologist who serve as the advocates of quality patient care.
We welcome any opportunity to work with CMS and support the mission of CMS in assuring quality care to medicare beneficiaries.

Robert Jansen, M.D. M.B.A.
President
Georgia South Carolina Society of Nephrology

Submitter : **Mr. David Sabor** **Date: 06/24/2004**

Organization : **SunSpectrum**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern
I manage freestanding rehab Agencies and Corfs. I am starting to see an alarming trend of Physicians opening their own rehabilitation. The biggest problem seems to be that Medicare patients are losing their ability to choose their own providers. Certain physicians are "insisting" that patients go to their own facilities.
The next area of concern is obvious possibility of over utilization. I seems counter productive in trying to control health care costs to allow anyone to have financial interest to see patients in therapy and to see them stay in therapy as long as possible.
I am convinced that facilities that are privately owned or physician owned have significantly higher utilization than other facilities.
Your Sincerely
David Sabor PT 9370

Submitter : **Mr. FRANK SERATCH** **Date: 06/24/2004**

Organization : **NORTHEAST PT ASSOCIATES, INC.**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

As a physical therapy private practice owner and a practicing physical therapist, I strongly support the prohibition on physician self referral. I oppose the arrangements that create incentives to underutilize or overutilize services for personal or institutional profit, or that are in any way based on the financial interest of the referral source.

My wife and I have been physical therapists in the northeast PA region for 12 years and have owned our own practice for the past 3 1/2 years. We are concerned about the interim final rule on "Physicians' Referrals to Health Care entities With Which They Have Financial Relationships (Phase II). We feel that the potential for fraud and abuse existsw when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. This situationis compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices that they have invested in and to overutilize those services for financial reasons.

the "in office ancillary services" has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services.

I have had first hand experience with patients reporting that their doctor has referred them for physical therapy specifically to particular physician owned practices. When the patients have objected, instead choosing to receive therapy at my own practice, the patients are given reasons why they should attend the physician's choice such as, "I know the therapist and can better direct your care". This has a direct impact on our business and our reputation. I, my wife, and our staff are all professionals and are well trained therapists who work closely with all referring physicians to assist our patients in receiving the best care for their conditions.

Thank you for your consideration of our comments.

Submitter : **Mr. John McWilliams, Jr.** **Date: 06/24/2004**

Organization : **Member of Am. Physical Therapy Assoc.**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist and have been practicing since 1975. Since 1981 I have owned my own private physical therapy clinic. I am writing to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II).
I believe this rule has several shortcomings. When physicians refer to their own therapy office, the incentive is high to keep that office functioning. A "captive" referral base may lead to over utilization of services. This is certainly not in the best interest of the patient or Medicare. This over utilization does not promote the positive standards set forth by the American Physical Therapy Association. Quite often the physical therapy services are provided by non physical therapists. These services do not represent the professional stature or education required to become a physical therapist and thus misrepresents our profession. The patient is indeed captive to a financial program rather then being able to pursue an independent cooperatively guided program. These services severly limit the available therapy and therefore alter appropriate positive outcomes. This is nothing short of misrepresentation of the physical therapy profession of continual educational upgrades (Masters and Doctor of PT programs are the norm for education at this time).
A physician owned physical therapy office has the potential to screen and "pick and choose" patients according to insurance programs and diagnosis. They keep the desired ones and send out those with long term problems or less than preferred insurance benefits.
Please address these concerns. A phase III correction would ideally prohibit this practice.

Thank you for your consideration, Dr. McClellan.

Submitter : **Date: 06/24/2004**

Organization : **Medical Group Management Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

MGMA commends the Centers for Medicare & Medicaid Services (CMS) for attempting, and in some cases succeeding, to simplify the self-referral regulatory framework. CMS added needed flexibility and clarity to Phase II that will benefit group practices. MGMA supports the changes and clarifications made to the 'same building' test and group practice definition. We also applaud the creation of a 'professional courtesy' exception as well as the broadening of the 'compliance training' exception.

Despite the positive steps taken by CMS, MGMA recommends additional modifications to make the rule feasible and maximize its effectiveness. MGMA also contends that CMS should provide additional time beyond the current July 26, 2004 effective date to comply with any new provisions, including regulatory exceptions. This would provide group practices with sufficient time to review their current business arrangements, and in some cases, revise them to comply with the new requirements.

Linkage to Anti-Kickback Statute

MGMA strongly believes that it is distinctively unfair and unhelpful to link the self-referral exceptions to compliance with the anti-kickback statute. The self-referral law was intended to be a bright line test, not a facts and circumstances test. The law has become inordinately complicated, and the references to anti-kickback law compliance create even more uncertainty.

The intermingling of the anti-kickback statute with the self-referral rule appears more like an attempt to give the OIG authority to threaten civil fines for arrangements that might not meet the inducement standard for a criminal violation of the anti-kickback law, than a necessary element to prevent abuses under the self-referral law. If an arrangement otherwise complies with the self-referral statute, but the OIG believes it might violate the anti-kickback law, the government's remedy should be to prosecute the case under the anti-kickback law, not bootstrap it into the self-referral rule. Had Congress intended the two laws to rely on one another, it would have indicated so clearly in the statute.

Regulatory Citations to the Medicare Carrier Manual

CMS references several Phase II definitions to specific sections of the Medicare Carriers Manual. Specifically, these references are included in the definition of 'entity,' 'locum tenens' and 'physician in the group practice.'

In October 2002, CMS discontinued the use of the Medicare Carriers Manual and implemented a new online system of Internet-Only Manuals (IOM). Through the IOM, CMS has reorganized the carrier instructions and established a new organization system. Therefore, the regulatory references made in the modified definitions are outdated by the publication and implementation of the IOMs. MGMA recommends that CMS revise these definitions to refer to the new sections of the IOM.

Issues 1-10

3. Group Practice Definition

CMS states that 'incident to' services can be included in productivity bonuses under the compensation test. However, the rule uses the word 'services' without specifically mentioning 'items.' MGMA requests that CMS clarify whether 'incident to' drugs administered by someone in the office other than the physician may be directly factored into productivity bonuses.

Issues 11-20

11. Physician Recruitment Exception

It is important that hospitals are permitted to assist in physician recruitment. However, MGMA is concerned that the physician recruitment exception as currently written could prevent practices and hospitals from realizing its benefits.

The exception stipulates that hospitals may only pay the 'actual additional incremental costs attributable to the recruited physician.' This requirement could result in the unintended consequence of hampering hospitals' ability to replace deceased, relocated, or retired physicians. For example, consider the following scenario:

An obstetrician-gynecology practice consisting of two physicians is located in a small rural town. The practice is the sole provider of OB/GYN services in the community. One of the physicians passes away. With the assistance of the local community hospital, the remaining physician would like to recruit a new physician to replace the deceased one.

Policy considerations behind the physician recruitment exception would seem to dictate that under the aforementioned scenario the hospital should be permitted to assist the existing physician in recruiting a new physician by allocating to the new physician a pro rata share of the overhead expenses (i.e., office space, equipment, and personnel) previously attributed to the deceased physician. In situations involving the death, relocation, or retirement of a physician, no financial gain accrues to an established practice when a hospital assists to replace a physician. The practice is merely seeking to replace what they have lost. However, the restrictive nature of the 'incremental costs' language would prohibit the hospital from allocating to a new physician overhead expenses previously attributed to the deceased or departed physician.

Without this assistance from the hospital, the overhead expenses for the remaining physician would increase substantially. Consequently, it would be extremely difficult for the physician to replace the deceased physician. The inability to recruit a physician could jeopardize patient access to care.

In addition, MGMA believes that the exception's current structure discriminates against group practices. Under the interim final rule, a hospital could pay for any costs, including overhead costs, to recruit a new physician into a solo practice setting. However, the hospital could not pay the overhead costs to recruit that same physician into a group practice setting. Furthermore, the interim rule prohibits groups from imposing practice restrictions, such as non-compete clauses, in cases where hospitals provide financial assistance in recruiting physicians. However, groups are permitted to impose non-compete clauses when they recruit physicians without the assistance of hospitals. There appears to be no reasonable explanation for these inequities.

Therefore, MGMA requests that CMS revise the exception to permit hospitals to financially assist group practices, particularly small ones, in replacing a deceased, relocated, or retired physician. By permitting hospitals to allocate to the new physician a pro rata share of the overhead expenses once the hospital has identified the physician, the practice will be in a position to continue delivering care to patients without interruption. MGMA also supports a time limitation for the assistance, such as one year, to further ensure that the integrity of the self-referral statute is maintained.

Lastly, MGMA urges CMS to remove any prohibition against the use of non-compete clauses. Provided groups comply with the remaining regulatory requirements and state law, groups that employ the recruitment assistance of hospitals should be treated the same under the law as those groups that recruit physicians on their own.

Issues 21-24

23. Exceptions-Community-wide Information Services

MGMA is a strong proponent of increasing the utilization of information technology throughout the health care system. Both patients and physicians alike reap the benefits of information technology, such as improved patient safety, efficient delivery of care, and long-term cost savings.

The creation of the 'community-wide health information systems' exception will facilitate the adoption of information technology. However, MGMA believes the exception as structured in the interim final rule will prevent the type of widespread adoption of technology envisioned by MGMA and the federal government. Therefore, MGMA urges CMS to revise and clarify the exception's language as follows:

1. Definition of information technology

The interim rule refers to information technology as items or services 'that allow access to, and sharing of, electronic health care records and (emphasis added) any complimentary drug information systems, general health information, medical alerts, and related information for patients...in order to enhance the community's overall health.'

The use of the conjunctive 'and' above seems to imply that health care records must be provided in order to fall within the exception. There are various types of technology that offer great benefits to providers and the patients they serve. Therefore, MGMA contends that no one single type of item or service should be required. We recommend that CMS replace 'and' with 'or' to provide entities with the needed flexibility to decide which items or services they will provide.

Secondly, the rule focuses solely on the clinical aspects of information technology, such as drug information and medical alerts. While the clinical arena is an important focus, business and administrative functions (i.e., patient eligibility, medical necessity, and billing) are equally worthy of consideration. Health care institutions are seeking to integrate clinical and business functions through the use of new technology. Providing seamless and coordinated care will improve both the quality and efficiency of the entire health care delivery system. MGMA urges CMS to expand the definition of information technology to include business and administrative items or services.

Lastly, many physician practices do not have the expertise or resources to implement new technology systems. Therefore, MGMA requests that CMS clarify that free education and training directly related to the use and implementation of new technology is permitted.

2. Community-wide health information system

The exception stipulates that the 'community-wide health information system' must be available to all providers, practitioners, and residents of the community who desire to participate. MGMA contends that the current requirement that the health information system be available to all interested parties is impractical. Financial and other market constraints could limit an entity's ability to provide technology on such a broad scale as proposed in the interim final rule. As a result, this requirement could have the unintended consequence of deterring some entities from providing any information technology. Therefore, MGMA requests that CMS remove the requirement that the technology be available to all interested parties. Entities should have the flexibility to determine the scope of the 'community,' provided that the process does not take into account the volume or value of referrals generated by the providers and practitioners.

CMS-1810-IFC-339-Attach-1.doc

Community-Wide Health Information Systems (Section 411.357 (u))

MGMA also recommends that CMS clarify what constitutes a "community" for the purposes of a "community-wide health information system." It is imperative that CMS provide maximum flexibility to foster the development and distribution of information technology. Specifically, MGMA suggests that CMS provide guidance in the preamble outlining the following elements that can be considered in determining a community-wide health information system:

* A metropolitan statistical area;
* A health professional shortage area;
* A virtual community;
* A community of interest (i.e., specific disease states)
* A hospital's geographic area (defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75% of its inpatients); or
* Other communities that are either geographically or virtually connected.

Obstetrical Malpractice Insurance Subsidies (Section 411.357 (r))

MGMA supports the interim rule's exception pertaining to obstetrical malpractice insurance subsidies. However, we do not believe permitted subsidies should be limited to one particular specialty, such as obstetricians. Many specialties are facing skyrocketing insurance premiums, and therefore, should be entitled to receive subsidies. MGMA encourages CMS to work with the Office of Inspector General (OIG) to create a broader malpractice insurance subsidy exception as well as a corresponding safe-harbor under the anti-kickback statute.

Designated Health Services Identified in Medicare Physician Fee Schedule

Since 2001, CMS has published in the final Medicare physician fee schedules a list of Medicare services considered designated health services for the purpose of aiding provider compliance with the self-referral statute. MGMA applauds these efforts and fully supports the inclusion of these codes in Appendix E of each final fee schedule.

However, this list does not include 6 of the 11 designated health services categories. These categories are: durable medical equipment; home health services; parenteral/enteral nutrients, equipment and supplies; prosthetics, orthotics and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services. The table in which the Current Procedural Terminology, Fourth Edition (CPT-4) and Healthcare Common Procedure Coding System (HCPCS) codes for designated health services appear is entitled the "Updated List of CPT1/CPCS Codes Used to Describe Certain Designated Health Services Under the Physician Self-Referral Provisions (Section 1877 of the Social Security Act)." Believing that it is an exhaustive list, the name is misleading to providers who quickly reference it.

CMS should clarify that the list of designated health services appearing in Appendix E is not exhaustive

and indicate where providers can obtain more information on the remaining categories. We also suggest renaming the table "Updated List of CPT2/CPCS Codes Used to Describe 5 Categories3 of Designated Health Services Under the Physician Self-Referral Provisions (Section 1877 of the Social Security Act)."

1 CPT codes and description only are copyright 2003 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.
2 CPT codes and description only are copyright 2003 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.
3 This updated list includes codes falling into the following 5 categories of designated health services: clinical lab services; physical therapy; occupational therapy; radiology; and radiation therapy. The list does not include codes considered durable medical equipment; home health services; parenteral/enteral nutrients, equipment and supplies; prosthetics, orthotics and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services. For the full definition of designated health services under the physician self-referral provisions (Section 1877 of the Social Security Act), refer to 42 CFR 411.351. For more information, refer to http://www.cms.hhs.gov/medlearn/refphys.asp.
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Submitter : Laurie Kendall-Ellis **Date:** 06/24/2004

Organization : alliedhealthrehab@msn.com

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

With 26 years as a practicing physical therapist and 17 years of business ownership my greatest concern with Stark II is one of consumer protection and informed choice.

I have personal experience with consumer's who relate stories of how they were escorted down the hall by their MD to the "therapist", not knowing they had a choice. Consumers having to travel 30 to 40 minutes away to receive care that could be delivered locally, consumers not improving in the MD therapy office and not being offered alternatives, consumer's stating that their MD will not follow their case if they receive therapy services outside of his/her office, and MD's who will not send needed medical information to an outside therapy office in support of consumer choice. These and many other stories make me sad to be in this current medical environment.

I know this sounds like a cliche, but I entered medicine because I cared about people and wanted to rehabilitate them back to their previous level of function. Today, many practices are more concerned about monies and "owning" services beyond their scope of practice only because it offers added income at a time of declining reimbursement not, because it offers improved recovery.

Consumers trust and believe in the medical community. We jeapordize that trust when we do not fully inform consumers of their rights. We jeapordize that trust when we do not refer consumers to the most appropriate service site. The consumer needs to be treated by a licensed professional in the field of service they are seeking treatment in. The more we allow a closed system to thrive, the more fearful I am that consumers are not receiving proper care by the proper licensed professionals.

Let us not allow our national system to foster this behavior. Protect your constituents. Allow them to have the choice of where to receive their care. Protect those that don't know. Protect those who are not informed of their options due to financial considerations.

Sincerely,
Laurie Kendall-Ellis, PT

Submitter : **Dr. Jennifer Schreckenguast** **Date: 06/24/2004**

Organization : **Gaspar Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

to: Mark B McClellan, MD, PhD
Administrator
Centers fo Medicare and Medicaid

Subject: Medicare Program: Physician's Referrals to Halth Care Entities With Which They Have Financial Relationships (Phase II).

My name is Dr. Jennifer Schreckengaust and I am have been working as a physical therapist for the past 5 years. I am currently working in an outpatient setting in Encinitas, CA at Gaspar Physical Therapy. I received a BS from the University of Michigan in 1996 and a doctorate in physical therapy from the University of Southern California in 1999.

I would like to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)."

I believe the potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. This situation affecting physical therapy is exacerbated by Medicare's requirement of a physician's referral in order for beneficiaries to receive PT services. Physicians that own practices that provide PT services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.

In addition to overcharging and overutilizing PT services which increase the cost of health care, it also does not give the patient many options for their physical therapy care. Most likely, the patient will follow the advice of the referring physician. Hence, a number of smaller PT clinics will be effected and possible shut down. This lack of competition will further drive up the costs of health care for the entire population.

The "in-office anxillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. This loophole has created the expansion of physician-owned PT clinics. Due to Medicare referral requirements, physicians now have a captive referral base of PT patients in their office.

Also, in physician offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to patients and wasteful to the Medicare program. Patients expect and deserve to be treated by qualified physcial therapists who have extensive training and expertise to help improve their function and quality of life. The possible abuses that could stem from these "physical therapy" services by unqualified personnel place the patient will also harm the reputation of every physical therapist since they will be lumped in a category with untrained personnel who provide "physical therapy" services.

Thank you for taking your time for your consideration.

Sincerely,

Jennifer Schreckengaust, DPT

Submitter : **Dr. Robert Schulte** **Date: 06/24/2004**

Organization : **North Dakota**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

7. Space and Equipment Rental Exception

The argument to prohibit the practice fee splitting, financial relationships is a very strong argument and has been cited numerously as an issue for protecting the public. A physician can still have physical therapy services provided within his facility, however the relationship should only be based on a space / rental agreement only. Fee splitting and ownership of physical therapy services is highly inaapropriate and is not in the best interest of the consumer. In physicians offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The 'in-office ancillary services' provision does nothing to prevent this practice from occurring. The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. Having a rental agreement for space is one thing, owning the services is quite another and this practice has potential for abuse.

2. In-Office Ancillary Services Exception

I also have very strong reservations regarding the 'in-office ancillary services' exception because it is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. This exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. This is not in the best interest of the patient.

1. Financial Relationship-Definition

The obvious purpose of the Stark Law is the protection of the consumer against conflicts of interest. Such prohibition and protection is designed to guard against excessive health care costs, attempting to insure referrals are based solely upon the patient's best interest rather than a desire by a professional to increase profits. My concern is that the physical therapist (or any other health profession) should not engage in fee splitting or have a financial relationship with the physician who refers a patient to him/her. Increasing evidence suggests that physician owned physical therapy services (POPTS) are associated with over utilization and excess cost. While recognizing that this is not true of all physician owned practice settings, I support this provision which seeks to protect the consumer from a potential conflict of interest. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. As a physical therapist and acamedician, I strongly discourage this type of practice arrangement and respectfully ask that Medicare prohibits the practice of referring to health care facilities with which a provider has a financial relationship.

Submitter : **Mr. James Bartholomew** **Date: 06/24/2004**

Organization : **Mr. James Bartholomew**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

This definition should follow the M.D./pharamacist precedent

2. In-Office Ancillary Services Exception

A M.D. should practice medicine andm let physical therapist practice physical therapy! M.D.'s have non-qualified, on the job trained (by whom, because most M.D.'s have no clue as to what a P.T. does) people.

7. Space and Equipment Rental Exception

Who will over-see these contracts for possible kick-back?

9. Personal Services Exception

I know of M.D. "medical director" arrangements for clinics who then are the nearly sole referral source to those clinics.

Submitter : **Mr. Michael Mastrostefano** **Date: 06/24/2004**

Organization : **Bodies In Motion Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Dear Dr. McClellan,

I am a physical therapist and owner of a private practice in Falls Church, VA. I have personally witnessed the detrimental effects physician-owned practices can have on the quality of rehabilitative services. These "POPS" or physician owned practices are notorious in the industry for over-utilizing physical therapy, billing for physical therapy delivered by supportive, rather than professionally trained staff, and overscheduling patients in order to improve the fiscal outcome of thier business.

Each of these issues will ultimately raise the cost of rehabilitative care for Medicare recipients. This is an extremely important issue since the first of the baby boomers will become Medicare recipients in five years, flooding the system. Overutilization of physical therapy occurs when a patient will be served by attending PT once or twice per week, and the POS insist on 3 times per week. Physical therapists who work at POPS are obligated to follow the direction of the "boss", a physician. PT's at prviate practices have the freedom to disagree professionally and suggest alternative frequencies of attendence without fear of insubordination. This is a situation in which two professionals can work together toward managing a patient, rather than office hierarchy dictating patient care.

POPS also routinely use physical therapy aides to deliver physical therapy. Physical therapy aides are unskilled workers who do not have the knowledge base necessary to engage in appropriate clinical decisions. Inappropriate decisions can prolong rehabilitation.

Overscheduling directly impacts patient care. Rehabilitation works best when a physical therapist can treat not only the symptoms, but also the underlying causes of the problem. This takes time, and overscheduling forces a physical therapist to prioritize only the most pressing issues, rather than engage in holistic treatment. At our clinic we have fewer overall patient visits that we attribute to a more thorough evaluation and treatment plan. This reduces cost and leads to higher patient satisfaction. Our patients comment on the difference in the quality of our services over POPS.

Thank you for taking the time to consider my comments on this issue.

Sincerely,

Michael Mastrostefano, PT OCS ATC

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

6. Rural Providers Exception

I live in a small rural town. One of the local physician offices has entered into an agreement with a physical therapist to provide physical therapy services to their patients. The physical therapist who sought out the agreement befriended the primary physician in control of the practice. The two decided that it would be of benefit to the physician that the therapist enter the practice and provide physical therapy services to the medical practice's clients. Over time, the one physical therapist has increased his business to employ two other therapists.

Other therapists practicing outside of that medical group's practice have seen a marked decline in referrals. Therapists outside of the practice were told that all patients would be given a choice of therapists to see when a referral to therapy was given. However therapists outside of the practice have repeatedly been told by patients that the practice strongly recommends that patients see the therapists who work within the practice, that they are the best.

It's an interesting situation. It reinforces the idea of seeking out 'connections' and referral sources based upon charisma and favors. My own feelings, which I realize are naiIve, are that practices should receive referrals based upon how hard the practices work to provide great care for their clients, not how much they can 'shmooze' the local physicians. By allowing situations like this to occur, we are promoting this type of behavior to continue.

I realize that the physicians will respond with statements such as 'we know what the therapists are doing and we work together', etc, 'there is less turn over', etc. I understand all of those statements. I still feel that referrals should be given to patients and that patients should have a choice where to seek their therapy. If a therapist is unable to handle a referral, it is the therapist's responsibility to say so and to refer to someone who is able or to seek the needed mentoring/schooling/or education needed to provide the service.

I live in a very small town. If therapists are allowed to practice within a physician's office such as they are here, the results are devastating. Other therapists not in the 'office' are forced to practice without referrals from that group. Therapists outside of the practice have to work twice as hard to obtain referrals. The situation creates an unfair advantage for all of the therapists.

I thank the Administrator for consideration of my comments. Please do not grant rural providers an exception to the ruling.

I believe the potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial (or otherwise) interest. The situation affecting physcial therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services.

Submitter : **Dr. Stephen Fadem** **Date: 06/24/2004**

Organization : **Kidney Associates,**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am writing to provide comment on the provision establishing safe harbor methodologies for determining dialysis facility medical director reimbursement included in CMS-1810-IFC ? (Medicare Program; Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships ? Phase II)

I recommend that you take into account the concerns voiced by the leadership and counsel of RPA (Renal Physician?s Association). As a clinical nephrologists in practice I share these concerns and can sense that they could have a negative impact upon all of our efforts to deliver a product of high quality care.

My comments are divided into the following five sections:

Medical Director Compensation and Hourly Wage Rate,
Underfunding for duties provided,
Use of Safe Harbors as Fixed Market Value,
The Necessity of this Portion of the Provision,
Fair Market Value Methodolgy.
I would like to think you in advance for carefully reconsidering this provision and working closely with the leadership of the RPA on this very important issue.

Stephen Z. Fadem, M.D., FACP
Medical Director
Houston Kidney Center/Davita Integrated Service Network

Please see the attached Adobe PDF file.

CMS-1810-IFC-346-Attach-1.pdf

I am writing to provide comment on the provision establishing safe harbor methodologies for determining dialysis facility medical director reimbursement included in CMS-1810-IFC – (Medicare Program; Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships – Phase II)

I recommend that you take into account the concerns voiced by the leadership and counsel of RPA (Renal Physician's Association). As a clinical nephrologists in practice I share these concerns and can sense that they could have a negative impact upon all of our efforts to deliver a product of high quality care.

My comments are divided into the following five sections:

Medical Director Compensation and Hourly Wage Rate
Underfunding for duties provided
Use of Safe Harbors as Fixed Market Value
The Necessity of this Portion of the Provision
Fair Market Value Methodolgy

Medical Director Compensation and Hourly Wage Rate

The medical director of a dialysis facility is charged by federal regulation with a comprehensive list of duties and expectations. To perform these duties the medical director must continuously remain updated on and apply well knowledge relating leadership and motivational skills, legislative and regulatory events, as well as technical and clinical changes. This requires a great deal of after hour's time and effort above and beyond what can be charted, and thus the hourly wage model is not the best one to use. These duties are assigned a high level of accountability. The RPA has compared this role to that of a CEO. We also coordinate reporting to national and dialysis chain databanks, and have direct responsibilities for the implementation and success of clinical performance measures (CPM) programs within our facilities. We are heavily involved in ESRD network activities. The medical director must be available on a twenty-four hour basis. While a thunderstorm may be a minor inconvenience to many in a community, the potential for power outages, flooding and transportation difficulties can be nightmares that every medical director has experience with. Just a change in the weather can mean different chlorine levels in the potable water supply and delay dialysis treatments for hours. To these duties we respectfully add "damage control" and conflict resolution as we deal with the frustrations of patients, our colleagues and team mates on a daily basis.

The hourly wage model applies well to the emergency room physician. I worked in emergency rooms when younger and identify well with these sets of responsibilities, limited only to clinical activity, and only to the time spent in the facility.

Underfunding for duties provided

Imposing the CMS methodology for medical director reimbursement in this provision would seriously underfund the services provided. Aside from fairness, this is not to the advantage of CMS because the cost of care in a dialysis facility is much less than in a hospital. The dialysis facility plays a key role in controlling hospital utilization through the quality initiatives for which the medical director is responsible. Thus it makes economic sense to support those activities that lead to the best economic and quality outcome.

The medical director "compensation" is not compensation in the true sense of the word. It is reimbursement. From this reimbursement expenses (office staff payroll, taxes, rent, insurance, communication services, etc) are subtracted and compensation is made. Thus, if a methodology were applicable, it should not look at salaries paid, but revenue generated.

The medical director reimbursement is a huge percentage of revenue to our practices. This helps us meet our expenses and pay all our salaries. As nephrologists we must be competitive with the other medical disciplines who are vying for bright graduates. To seriously impact our profession financially would only serve to lower the quality of physician we could attract and directly impact the quality of service our patients will ultimately receive.

Right now, the medical profession at large must compete with other disciplines such as computer science for the brightest minds. In the long run, it is critical that funding for our services be appropriate.

Use of Safe Harbors as Fixed Market Value

CMS was wise in stating that *"we are not in a position--nor would it be appropriate--to set a fixed, industry-wide fair market value rate for ESRD medical directors."* However, granting a safe harbor is a strong incentive for a dialysis company to use the fair market methodology created by CMS, and that this would invariably fix the market value for dialysis facility medical director reimbursement.

The Necessity of this Portion of the Provision

Safe harbors are employed when the 'gray areas' of intent or state of mind are involved in determining the appropriateness of an arrangement or relationship. However, in the civil context of Stark regulation, a 'bright line' exists indicating an arrangement or relationship is either appropriate or not appropriate, and intent and state of mind are not an issue and not applicable.

Fair Market Value Methodolgy

The fair market value of a physician's block of time is determined by what alternate activities he/she can be doing in that time block, and what alternate candidates are also available. This varies greatly because we all bring to the table different skill sets and levels of experience. Thus, it is best to leave the negotiations for medical director reimbursement unencumbered by federal regulation with regard to pricing so that true market forces can come into play and provide a fair and just system of reimbursing physicians who provide this needed service.

I would like to think you in advance for carefully reconsidering this provision and working closely with the leadership of the RPA on this very important issue.

Stephen Z. Fadem, M.D., FACP
Medical Director
Houston Kidney Center/Davita Integrated Service Network

Submitter : **Date: 06/24/2004**

Organization :

Category : Physician

Issue Areas/Comments

Issues 1-10

3. Group Practice Definition

Physician Compensation ? Group Practice

Please advise/clarify the following issue related to productivity bonuses and profit shares for group practices.

The group practice compensation requirement permits physicians in the group practice to be paid a share of overall profits of the group, or a productivity bonus based upon services the physician personally performs, (including incident to ?personally performed services?), so long as certain requirements are met for either the productivity bonus or profit sharing .

In reality, to avoid adverse tax consequences to the physicians in the group, many group practices do not allocate ?profits? to the group members, but instead distribute ?bonuses? to the group members in the manner required and described by CMS under the group practice compensation ?profit sharing? exception.

If a group practice distributes what the group considers and describes as ?bonuses? to members of the group in a manner wholly consistent with what CMS describes under the ?profit sharing? requirement, has the group complied with the group practice payment requirement?

Issues 11-20

11. Physician Recruitment Exception

The interim rule requires that under the Physician Recruitment Arrangement exception, a recruited physician must relocate his or her practice to the hospital?s geographic area which is defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75% of its inpatients.

Please clarify the following:

1. What is the rationale for selecting contiguous postal zip codes as an element of the geographic area definition?

2. How is the contiguous postal zip codes element to be assessed or applied?
For example, looking at a zip code map, should the hospital move in a clockwise or counter clockwise manner?

Submitter : N. Blakely **Date:** 06/24/2004

Organization : N. Blakely

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Dear Dr. McClellan,

I'm writing to make comments on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." I have several concerns about the interim final rule that I would like to see addressed and ultimately, corrected in the "phase III" regulations.

I have been a physical therapist for sixteen years and have worked in private practice for the past eleven; the last seven years in my own practice partnership.

In my state as in many others, we are legally able to practice without a physician's referral. Unfortunately, Medicare as well as other insurers have not recognized this ruling and continue to require a referral for us to receive payment. This referral requirement is especially problematic in a situation in which the referral source has a vested financial interest. I am concerned about the potential for fraud and abuse that this system provides. Physicians with practices which provide physical therapy services have a financial incentive to refer their patients to their own physical therapy services. Any system that provides these opportunities could potentially be abused and services overutilized.

Our practice, and the profession of physical therapy, have worked diligently to provide the best and most appropriate care possible for Medicare patients under an often challenging system. We continue to be committed to the care of this important group of patients and we want to continue to promote the best utilization of appropriate physical therapy services. Policies that potentially compromise these patient's care and the system that supports them need to be scrutinized and corrected.

Thank you for your time and efforts Dr McClellan.

Submitter : **Mr. Daryl Menke, PT** **Date: 06/24/2004**

Organization : **Mr. Daryl Menke, PT**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Dr. McClellan:

My name is Daryl Menke, I am a physical therapist in Topeka, Kansas. I have practiced for 20 years, currently I am in a private practice. The purpose of this correspondence is to comment on the March 26 interim final rule on "Physicians' Referrals To Health Care Entities With Which They Have Financial Realtionships (Phase II)." My comments are intended to voice my concerns, pointing out the inequities of this ruling and request a correction in the subsequent "phase III" regulations.

Instead of progressing forward, the "in - office ancillary services" exception is defined so broadly that it will inevitably result in abusive referral arrangements. This loophole validates the real and potential fraudulent and abusive referral patterns because of the associated financial incentives.

This is further compounded by the following:
1) The Kansas Physical Therapy Practice Act requires a physician referral/order prior to intitiation of physical therapy treatment. In other words, one professional business (physical therapy) is dependent on another buisness (physicians) for their economic stability and growth. This inequity places the physical therapist at a distinct disadvantage and hints at restriction of trade.

2) Medicare requires a physician referral in order for beneficiaries to receive physical therapy services. The inherent financial incentives to refer to ones own entity facilitates the creation of abusive referral arrangements that will ultimately cost the already strapped Medicare system.

3) Paient choice is severely limited if not eliminated because of the "gate keeper" mentality. Although consumers have empowered their choices with the purchase of goods and services, when health care related decisons are involved the patient often goes along with the "establishments choice".

4) Secondary to loopholes in statutes and regulations, physicians often provide so-called "physical therapy" services by unqualified personnel, which is harmful to the Medicare beneficiary and wasteful to the Medicare program.

Standard of care begins with the education and training of the healthcare provider. There is only one legal and standardized process of Physical Therapy education and training in the United States. This is supported in research findings, legal precedents, and judicial findings. The public entrusts their health to individuals with the faith and conviction that these healthcare providers have the appropriate qualifications and competence that can be documented. Consumer payment for unqualified care violates the basic perceptions and rights of the public.

Competence is defined as the possession, application, and evaluation of requisite knowledge, skills, and abilities that meet or exceed standards of performance for a specific profession. Legal, regulatory and accrediting bodies expect that individuals whom provide health care services are able to integrate and apply knowledge, skills, and abilities in a manner consistent with the standards of the profession (Millette D. Badali: I. Canadian Alliance of PhysioTherapy Regulators, May 17, 1999).

Learned professions have autonomy because they have laws in place permitting control and ownership of the professional services. With this control and ownership, the surplus values are returned to the profession through re-investment, support of research, improvement of services, and the basic value of enhancing the lives of those whom rely on the services for the restoration and preservation of their health, safety, and welfare. Protection of the professional ethics, standards, and fiduciary responsibilities is paramount. The "in - office ancillary services" exception subverts the professional control, fiduciary integrity, and the ethical character of the professional practice of Physical Therapy.

Thank you for your consideration in correcting thses inequities.

Daryl Menke, PT

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I wish to comment on the March 26 interim final rule for Physicians' Referrals to Health Care Entities Whith Which Thay Have Financial Relationships (Phase II). The true art of medicine is to practice under the oath for which the field of medicine was founded. As seen in our medical market today, this is not always the case. Medicine is evolving into more of a business mans society than a patient care field. There is an enormous potential for both abuse and fraud when a physician develops in-office ancillary services such as physical therapy in which they have a financial interest. Physicians' have a captive referral base of physical therapy patients which increases the risk of the abuse and fraud seen in their offices. Physicians who own pratices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. These services are sometimes provided by non-physial therapists and billed under the physician's provider number as physical therapy services.The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

I am a private practice physical therapist owner with 3 outpatient centers in the surrounding community. The private practitioners in my community have seen the affect of physican owned physical therapy service on their practice. The reasons given to the patient in these cases by their physician is that he is able to keep a close eye on their rehabilitation and better monitor their progress. In this particular case, it was told the reason for setting up in-office physical therapy was to recoup some of the financial losses seen over the past couple of years in lost income from insurance contracts. Also, previous physical therapy service that was provided to the practices patients before setting up in-office services was excellent and of great quality for many years, enough so that many family members were treated during that time with great success. Patients that were previously treated in outpatient settings are now kept in-office and told that if you receive physical therapy with us that you will not have to pay any out-of-pocket expenses.

It is amazing that medicine, a profession set to such high standards, practices on the figures of a bottom line and not on the best needs for the patients. We all need to understand one thing, Success lies in not trying to be someone, but rather in trying to help someone.....

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr McClellan-As a physical therapist working in an outpatient physical therapy clinic, myself/my co-workers/and my organization have been impacted greatly from a physician owned physical therapy practice (POPTS)in our community. The primary referral source to an outpatient orthopedic clinic are orthopedic physicians. Our community has only one orthopedic physician office, and as such, when they opened their own PT/OT clinic our referrals have dropped significantly resulting in financial hardship for our organization. In calendar year 2000, we received 1893 referrals from the orthopedic group as compared to 648 referrals in 2003. This decrease of 1245 referrals per year has decreased our annual visits to the clinic by approximately 12,450. In addition, the members of the communtiy are not given an option as to where they may receive their PT/OT services when referred by this group. Most patients will go where their physician directs them and do not realize that they have a choice. As a result, the patient may not receive care from the most qualified and/or skilled therapist for their condition, but rather get referred to the clinic that the physician has a financial interest in. So while the physician is 'doing no harm' according to their oath, they are not necessarily doing what is in the best interest of their patients. The opportunity for excessive use of POPTS services also exists. Often times, not only are the physicians receiving financial gain from overuse, but often times the treating clinicians and clinic managers get bonuses and raises based upon the revenue they generate, this is clearly a conflict of interest. Thus,potentially establishing a system of abuse of services. As an example, a recent patient referred to our clinic approximately 5-6 months post-operative rotator cuff repair, reported being seen at the POPTS clinic 3 times per week for 6 weeks while he was in the passive range of motion only time frame. That same type of surgical patient seen in our clinic typically is seen for approximately 8 visits during that same time frame. It would be difficult to say the patients are receiving better services at the POPTS location. We offer 98-100% of our new patients an initial evaluation within 48 hours of their phone call. We have heard from clients that they can wait up to 2 weeks to get into the POPTS facility. It is widely accepted in the profession that the sooner you start treating individuals with musculoskeletal pain/injuries/dysfunction the better their outcomes and the faster their recovery. Also, an independent outside consultant surveys our discharged patients regarding customer satisfaction. We have always ranked in the 95-98% when compared to other clinics across the country. Again, not much of an argument that patients are receiving better care at the POPTS facility. This same orthopedic physician group has further placed financial hardship on our organization by opening their own outpatient surgery center and MRI.

I ask that you modify the Stark law to prohibit physicians from having a financial interest in physical therapy centers and in the interim disallow Medicare and Medicaid patients from receiving care in POPTS centers. Health care costs are skyrocketing and this represents an opportunity to reduce costs by eliminating the potential for excessive use and fraudulent practices. Thank-you for considering my comments.

Submitter : **Mrs. GAYLE SCHILD** **Date: 06/24/2004**

Organization : **Mrs. GAYLE SCHILD**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

To: Mark B McClellan, MD, PHD

I am a physical therapist in Cincinnati, Ohio practicing for nearly 30 years. I have owned my own practice for 12 years and employ only licensed physical therapists to evaluate and treat our Medicare and all other patients. Because of the interpretation of Stark II, the proliferation of physician owned physcial therapy has been nothing short of meteoric here as physicians attempt to find ways to increase their yearly paychecks.

Several of my fellow physical therapist/private practice owners have had to shut their businesses as a result of their referral sources opening their own in-office PT facilities. This obviously has the ramnification of both limiting patient choice for their physical therapy care as well as presenting oppportunity for physician self-referral abuse.

One of the studies cited by HCFA itself was the State of Florida Healthe Care Cost Containment Board which reported a 43% increase in visits to PT/patient and a 30% increase in revenue paid for PT services when provided in a physician owned facility. I believe this is fairly self-evident that if controlling costs and eliminating opportunity for fraud and abuse for medical care is a priority for CMS, you must act now to shut down physician owned physical therapy and joint venture arrangements.

Additionally, many of the physician owned physical therapists here in Cincinnati are employing athletic trainers, not licensed physical therapists to manage their physical therapy enterprises! Most schedule patients every 15 minutes and utilize unlicensed support personnel to treat patients, yet charge for skilled physical therapy care.

Please make this issue a priority so that we can protect patient choice, control health care costs and preserve the rightful scope of physical therapy for those of us who pracice ethically and with concern for the quality of our phsycial therapy care.

Sincerely,

Gayle Schild, PT and President SOSPT

Submitter : **Ms. Susan Price** **Date: 06/24/2004**

Organization : **AKDHC**

Category : **Physician**

Issue Areas/Comments

Issues 11-20

15. Anti-Kickback Safe Harbor Exception

See Attachment:

CMS-1810-IFC-353-Attach-1.doc

ARIZONA KIDNEY DISEASE & HYPERTENSION CTR.

June 23, 2004 Electronically Submitted
http://www.cms.hhs.gov/regulations/ecomments
REFERENCE CODE : CMS-1810-IFC

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: MEDICARE PROGRAM; PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS (PHASE II); INTERIM FINAL RULE

Dear Dr. McClellan,

This response is submitted to you on behalf of the 27 physicians of Arizona Kidney Disease and Hypertension Center, LLC. (AKDHC). AKDHC is a private practice medical group specializing in nephrology. The group is based in Phoenix, and serves the northern 2/3 of the state of Arizona. This practice has existed for nearly three decades. We provide care for approximately 1,400 patients with End Stage Renal Disease receiving dialysis therapy, in addition to 12,000 active patients with renal related disorders. Primary Medicare Beneficiaries constitute 65 % of our patient population.

The purpose of this letter is to provide comment on the provision establishing safe harbor methodologies for determining dialysis facility medical director fees included in the above referenced regulation on physician self referral, detailed on page 16092, 16093, and 16094 of the March 26, 2004 Federal Register. As active members of the Renal Physicians Association, we agree with their position, and wish to further stress an essential point, as follows:

MEDICAL DIRECTORSHIP DUTIES FOR DIALYSIS FACILITIES ARE MULTIFACETED IN SCOPE AND INTERMINABLE BY NATURE.

THESE RESPONSIBILITIES SHOULD NEVER BE COMPENSED BY A FIXED, INDUSTRY-WIDE MARKET VALUE, PARTICULARY ONE THAT UTILIZES A PREVAILING HOURLY WAGE OF A NON LIKE-KIND MEDICAL SPECIALTY.

Our nephrologists provide Medical Directorship via an Administrative and Consulting Agreement with a large dialysis provider chain. We are responsible for the oversight and direction of 32 Outpatient Hemodialysis Facilities in the state. In addition to this role we are charged with providing executive and medical oversight to the 17 Hospital-based Acute Dialysis Programs, the CAPD Programs, the Apheresis Programs, and Nursing Home/Extended Care Facility Programs. Consistent with the

magnitude of this scope of accountability, the practice provides administrative and consulting opinion and advice regarding the growth and development of the programs for this major dialysis company.

The Federal Regulations establish the base requirements of a Dialysis Facility Medical Directorship under the Conditions of Coverage. These duties are separated into two sections; Sub Part U, which is specific to facility guidance and responsibility, and Non-Sub Part U, which encompasses the additional multiple leadership tasks required to sustain dialysis programs. Attached for your perusal is an abbreviated version detailing the position description under which the group functions. Of further note is the fact that the nephrologists serving as Medical Directors are responsible not only for the contractual obligations, but assume the medical-legal liability as well.

There are currently methodologies in place in some areas between Medical Directors and Dialysis Companies to document and validate the actual hours spent on Sub Part U and Non-Sub Part U activities. This detailed accounting is done on an annual basis by Medical Directors, and submitted to the Dialysis Companies as an adjunct to their cost reporting to the government. It is the task of the Dialysis Companies and the Medical Directors to due diligence and ensure that the format encompasses all aspects of the time involved. Completed appropriately, this nullifies any compliance violations. These should be standardized in format within the renal community. We would be abdicating our joint responsibilities as service providers and physicians by expecting CMS and HHS to intervene and set these sub-specialty guidelines.

We sincerely respect the mission of CMS in general, particularly the workload associated with prioritizing the multiple agendas involved in the Stark regulations. We understand that the provision establishing the safe harbor methodologies for determining dialysis facility medical director compensation was conceived originally for the purpose of compliance with the OIG. We further understand that while CMS states in the ruling that the adoption of the safe-harbor is voluntary, the dialysis chains will select this methodology to eliminate the intensive federal oversight that currently exists in the ESRD program. These 400 words in the Interim Ruling have ramifications reaching far beyond what the Agency envisioned.

Please know that should this interim ruling provision be included in the final ruling, it will have devastating and long term consequences to the entire renal community. Both the merits of the provision itself and the haste with which it was promulgated are questionable. We urge you to delay the implementation of this provision to allow appropriate time for thorough review to prevent the downstream ramifications.

Sincerely,

Susan Price, CEO / Managing Partner
On Behalf of the AKDHC Physicians

MEDICAL DIRECTOR POTENTIAL DUTIES AND RESPONSIBILITIES

I. Subpart U In-Center Medical Director Duties

On Call Availability

.Medical Directors must be on-call, or must arrange for emergency coverage, to respond to any facility, patient or staffing problems, that might impact patient care. This occurs 24 hours per day. 7 days per week.

Clinical Management

.Assist in the development, implementation, monitoring, review and update of policies and procedures relating to:

-Patient care and the delivery of high-quality, safe and effective dialysis;

-Safe contact with patients with hepatitis and other communicable diseases;

-Standards and regulations including those issued by AAMI, OSHA and CDC;

-Timely and appropriate referral of patients for transplant evaluation;

-Disaster preparedness plan.

.Participate in CQI program, including:

-Preparation for, leadership of and attendance at, CQI meetings;

-Education of self and facility staff regarding CQI issues;

-Monitoring CQI goals;

-Assuring completion of CQI related projects.

.Evaluate Clinical Variance Reports. Determine and implement corrective action.

.Evaluate MDRs.

.Prepare for, lead and attend:

-Long term care plan (L TCP) and other patient care meetings;

-Patient/family meetings concerning the selection of treatment.

.Research and review of literature regarding dialysis delivery and/or facility management.

Physician Management

.Serve as chairperson of the medical staff of the facility:

-Conduct meetings of the medical staff at least twice per year.

.Facilitate physician compliance with facility rules and regulations, such as:

-Accurate updates to ensure complete patient medical records and other pertinent documentation, signing orders, participation in L TCP , STCP and CQI meetings.

.Assure that patient care meets acceptable standards of care:

-Assessment of the frequency and adequacy of visitation of medical staff;

-Assure physician coverage;

-Intervention when attending physician fails to respond to patient needs;

-Evaluation of CQI, PSP results and other outcomes data and other Company quality goals.

.Participate in the selection by attending physicians of a suitable dialysis treatment modality and setting for patients.

.Prepare for, lead and attend no fewer than two Medical Staff meetings per year.

.Participate in physician credentialing process including:

-Review of medical staff applications, interviews, recommendations and any follow- up, as required.

.Support and take appropriate disciplinary actions against a medical staff member when necessary .
Facility Staff Management
.Involvement in the management of staffing issues and problems, including:
-Coordinate with DON to ensure appropriate patient/staff ratios;
-Assist in staff recruitment and retention activities;
-Participate in the selection of candidates for key staff positions in the facility;
-Participation in the mediation of grievances;
-Assist in planning emergency coverage in the event of facility staff shortages.
.Serve as an educational resource for facility staff providing:
-Periodic review and revision of training materials;
-Development of inservice, other educational programs, and staff training;
-Review and assessment of vendor materials related to proper use of facility equipment.
.Coordinate emergency medical care to patients or staff suffering an urgent, life- threatening illness, including exposure to potentially contagious disease, needlesticks or sharps accidents.
Governing Body Responsibilities
.Serve as Chairman of the Governing Body and carry out the associated duties and responsibilities:
-Prepare for and attend Governing Body meetings;
-Facilitate communication between Medical Staff and Governing Body;
-Ensure response to issues brought before the Governing Body.
Communications with Outside Resources
.Participate in discussions with Skilled Nursing Facilities (SNF), Nursing Homes (NH), and Extended Care Facilities (ECF) to coordinate continued quality care for dialysis patients.
.Communicate with managed care organizations and other health plans to fulfill the specific administrative and documentation requirements of each organization.
.Participate in the administrative process associated with the transfer of patients to or from other dialysis facilities, including, for example, as a result of a change in patient insurance coverage.
.Participate in the administrative process associated with transient, temporary, or visiting patients.

.Communicate with transplant programs regarding transplant criteria and potential transplant candidates.
.Review medical records for the purpose of acceptance or rejection of transient patients seeking temporary dialysis services-
.Communicate with associated Surgical/Radiology Departments regarding availability and quality of vascular access services for all patients.
Facility Operations Management
.Provide oversight of facility operations, including participation in budget development and cost containment efforts.
.Ensure that dialysis equipment and other technical components and services meet clinical care standards.
.Oversee water analysis, including monitoring routine cultures and implementing remedial actions as necessary-
.Respond to facility systems problems or failures.

.Ensure that the clinic staff is prepared to respond appropriately and safely to emergency situations, i.e., fire or patient/visitor violence.

Knowledge of Regulatory Requirements

.Review with appropriate staff important changes in regulatory requirements including those issued by CMS, OSHA, and CDC.

.Participate in Corporate Compliance Program.

.Periodic review of Medicare Fiscal Intermediary's local medical review policies.

.Participate in state, local and federal surveys, assist in preparation of reports and plans of correction.

.Participate in ESRD Network activities, representing facility.

II. Subpart U Medical Director Duties for Other Dialysis Programs

Home Hemodialysis

.Assist in reviewing patients' suitability for home hemodialysis and family or caregiver support for home dialysis.

.Ensure that the patient has the proper equipment for home hemodialysis.

.Ensure proper staffing and backup support, including adequate in-center backup and on-call service-

.Oversee adequate training of home dialysis patients.

.Ensure availability of teaching materials.

.Ensure that all quality care objectives have been met for home hemodialysis patients.

CAPD/CCPD Programs

.Assist in reviewing patients' suitability for, and family or caregiver support of, CAPD/CCDP .

.Ensure that the patient has the proper equipment for CAPD/CCPD.

.Ensure proper staffing and backup support, including adequate in-center backup and on-call service-

.Oversee adequate training for CAPD/CCPD patients.

.Ensure availability of teaching materials.

.Ensure that all quality care objectives have been met for CAPD/CCPD patients.

Nocturnal Dialysis

.Assist in identification of patients' suitability for nocturnal dialysis.

.Provide support and oversight of nocturnal dialysis program.

.Ensure that the patient has the proper equipment to perform safe nocturnal dialysis.

.Ensure proper staffing and backup support, including adequate in-center backup and on-call service-

.Oversee adequate training for nocturnal dialysis patients. .Ensure availability of teaching materials.

.Ensure that quality care objectives are met for nocturnal dialysis patients.

Home Staff-Assist Programs

.Assist in identification of patients' suitability for, and family or caregiver support of, home dialysis.

.Ensure that the patient has the proper equipment for home staff-assist dialysis.

.Ensure proper staffing and backup support, in-center and on-call service-

.Oversee adequate training of home staff-assist dialysis patients.

.Ensure availability of teaching materials.

.Ensure that all quality care objectives have been met.
iii. Non-Subpart Medical Director Duties
Acute programs
.Oversee hospital inpatient dialysis program.
.Ensure adequate physician coverage for all acute programs including acute dialysis, intermittent dialysis, and Continuous Renal Replacement Therapy (CRRT), Absorption and Apheresis programs.
.Assist in selection of equipment and products.
.Review hospital technical considerations, including adequate water supply and quality.
.Assist in development and implementation of policies and procedures specific to the acute program.
.Participate on medical and hospital staff committee membership and involvement; as appropriate for acute program.
.Assist in ensuring adequate nursing services, backup support, and training for staff-
.Ensure that all quality care objectives have been met for acute patients.
.Participate in planning for subsequent chronic dialysis, if applicable.

Apheresis
.Oversight of apheresis program.
.Ensure adequate physician coverage for apheresis program.
.Ensure that the acute site has the proper equipment for apheresis program.
.Assist in development of policies and procedures specific to the apheresis program.
.Ensure adequate nursing services and backup support.
.Oversee training for apheresis program staff-
.Ensure that all quality care objectives have been met for apheresis patients.
Nursing Home Programs
.Assist in support for dialysis in the nursing home setting.
.Ensure that the nursing home has the proper site and equipment, including adequate water supply and quality.
.Assist in development of policies and procedures specific to nursing home dialysis.
.Ensure proper staffing and backup support, including adequate in-center backup and on-call service-
.Oversee adequate training for nursing home dialysis.
.Ensure that all quality care objectives have been met for nursing home patients.
IV .Non-Subpart U Consulting And Other Services
.Identification of under-served patient populations, new markets, growth and development, and new business opportunities.
.All pre-license activities associated with the organization and development of a new unit, including site location, staffing approval process.
.Utilization of practice resources, and compensation of practice administrative and other office personnel that support dialysis clinic related issues.
.Evaluation of new technologies, including Fresenius clinical trials.

.Other business activities related to improving cost-efficiency, productivity, and overall facility management in furtherance of Fresenius Medical Care corporate goals.

Submitter : **Ms. Julie Ellis** **Date: 06/24/2004**

Organization : **Center for Physical Rehabilitation**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist who owns two PT clinics in rural Idaho. Physicians are the gatekeepers for patients who may need physical therapy services. The problem is large if a physician owns and has a financial interest in a PT clinic. In my experiance the 'physical therapy' could then be performed by someone other than a licensed physical therapist. Please examine the use of codes by those physician entities that already exist. Coding errors and abuses will be certain to exist if the physician and their staff do not understand the 8 minute rule. In addition, the patient will not receive treatment by a licensed physical therapist in many cases. Our Idaho practice act directly prohibits anyone representing themself as a physical therapist but unfortunately the general public does not always know the difference. Please continue to define the Stark Amendments to eliminate physician ownership of PT services. Thank you, Julie Ellis PT,SCS,CSCS

Submitter : **Mr. Glen Gitterman** **Date: 06/24/2004**

Organization : **Allied Health & Rehabilitation**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern,
I am a private practitioner and partner in an out-patient physical therapy practice with concerns regarding Stark II. Specifically I am concerned that a physician practice referring to it's own therapy service will consider financial gain over patient benefit. I think my concerns are best illustrated via anecdotal occurrences.

One example of my concerns is illustrated by a recent patient who was evaluated by a physician specialist and told to see his therapist down the hall. This patient lives in a suburb and would have to drive into a city several times each week and pay for her parking (she is on a fixed income)in order to receive needed therapy services. If nothing else, an inconvenience. She was not given the choice of going to her local physical therapist with an office less than two minutes from her home, providing free parking, morning and evening hours, with treatment provided by licensed physical therapists.

Another recent example is that of a patient we recently evaluated. She was evaluated by her physician who referred her to his own therapist for ongoing neck pain. After several months of treatment without improvement, the only recommendation made by the physician was to continue therapy. Treatment options were not offered by the treating therapist.

While attending a community meeting, this patients husband engaged in conversation with a physical therapist. The result of that conversation was the husband decided that a second medical opinion was needed. The patient was seen by a neurosurgeon and found to have a cervical tumor. Upon taking this patients history during our post surgical evaluation, the patient insisted that the woman who treated her in therapy at her doctors office was a nurse, not a physical therapist.

When practitioners have financial gain and not the well being of their patients as the motivation for referral, the potential for abuse is enhanced.

Thank you for allowing me the opportunity to discuss this concern.
Sincerely,
Glen Gitterman PT,MS

Submitter : **Victor Vaughan** **Date: 06/24/2004**

Organization : **Victor Vaughan**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan MD, Phd
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention:CMS-1810-IFC
P.O.Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan

I am writing regarding the new phase II regulations on Physician referrals to health care entities in which they have a financial arrangement. I am a physical therapist with over 27 years of practice in a variety of practice settings including outpatient rehab, acute hospital and home care.
I am very concerned with the interim final rule and ask that corrections be made in the phase III regulations. These new regulations have escalated the potential for fraud and abuse with respect to the treatment of physical therapy patients enormously. Physicians who own practices have a significant inherents financial incentive to refer their patients to that practice. That often provides fertile ground for overutilization of services to help provide increased income for the physician owner.
In my area of Connecticut I have seen a rapid increase in the number of physician owned PT practices in the last 6 months as a result of the "in-office ancillary services" exception. Because Medicare requires a physician referral to initiate Physical therapy the physician controls both the entrance into PT as well as the length of stay now. If they own the PT practice to which the refer the Medicare patient they now essentially have a captive audience. Now supposedly patients have a choice but practically this almost never happens. In reality the patient relies on the physician to tell them what they need to do for a problem. If the physician prescribes PT often the patient doesn't know anything about the physical therapists in their area. The patient then is reliant on the doctor's recommendation. In most cases the patient will go wherever the physician recommends. It is easy to see that this sets up a situation that the physician makes a referral to their own PT practice, the patient attends for a number of visits determined largely by the physician-owner and the physician makes a profit simply from the referral.
In our area the therapists who do work in a physician owned practice often see 20-30 patients/day. In my practice we see 12-14 patients/day. This reflects on the quality of care being provided. Based on my 28 years of experience there is no way that a therapist could provide quality care to 20-30 patients/day. That mode of practice seems clearly designed to maximize incomd from the PT patients. In addition these practices often use only a few physical therapists and a larger number of unlicensed aides to handle the volume of patients. Since decisions are made on a daily basis regarding a patients treatment it is imperative that the physical therapist be the one making these decisions. They are the ones best trained in rehab. The aide is not trained to make the necessary decisions and alterations in care that a patient may require.Having this staffing pattern allows for very poor quality care and is clearly not in the best interest of the patients. This has the added advantage of keeping the salary costs down again to maximize profits.
I have also had patients tell me that they were coerced into attending PT in the MD's office. The physician will tell the patient they have to go the his PT or they will need to find another doctor. Likewise physicians will argue that they have better control over the care that the patient receives if the PT is done in his office. This is absolutely false. In my practice I can easily call a physician and will always honor their requests for any particular issue. I have never had a physician complain about the lack of control as an issue regarding his patients.
I ask that you address these concerns with corrections in the Phase III regulations by removing this clear and significant potential for abuse.
Thank you for your time and considerations.
Victor Vaughan PT MS ATC

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I have concerns regarding the interim final rule and would like them to be addressed and corrected in the subsequent "phase III" regulations. There is potential for abuse and fraud when physicians are able to refer to entities in which they have a financial interest. The "in-office ancillary services" exception in so broadly defined that abusive referral arrangements can be fostered. This exception has created a loop-hole that has resulted in the expansion of physician owned practices that provide physical therapy services. Many physicians who use to refer to private practice physical therapy offices, owned and operated by physical therapists are now refering to their own businesses. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy in their offices. The private practice therapists, who are small business owners and tax payers, are left out of the competition. Many physician-owned practices limit the choice of therapy providers for their patients to their own therapy practice. These services are often provided by non-physical therapist and billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provisions does nothing to prevent this practice from occuring and can provide waste to the Medicare program. Thank-you for considering my comments and taking them into consideration when addressing and correcting the interim final rule in subsequent "phase III" regulations.

Submitter : **Dr. Harold Millman** **Date: 06/24/2004**

Organization : **Bethlehem Rehabilitation Specialists**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Dr. McClellan,

We are a physical therapist group in private practice in Bethlehem Pennsylvania. I am a graduate of the University of Pennsylvania Physical Therapy and have been licensed to practice physical therapy since 1977. I have been Board Certified in Orthopedic Physical Therapy since 1995 and was awarded a Doctoral Degree in Physical Therapy from Arcadia University in 2003. I have owned and operated Bethlehem Rehabilitation Specialists, a private out-patient rehabilitation clinic for nearly 20 years.

Ms. Gallagher is a 1986 graduate of Arcadia University with a Masters of Science in Physical Therapy. She is currently a Doctoral candidate at Arcadia University. Over the last 18 years she has worked in multiple clinical settings providing services to a large Medicare population. She has over 13 years experience working in geriatric rehabilitation.

We are writing to you to express our concerns regarding the March 26th 2004 interim final rule on Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). There is no question that practice situations in which physicians own the entity to which they might refer patients for health care services have and will continue to create potential for excessive referral and utilization of services.
The specific situation as it pertains to the practice and provision of physical therapy services is compounded further when applied to the Medicare beneficiary. The Medicare beneficiary must receive a physician?s referral or prescription to receive physical therapy services. Clinically, the physician who owns practices which provide physical therapy services have an inherent financial interest and incentive to refer and recommend patients to their practices. Unfortunately, the financial reinforcement to self refer creates a situation for potential abuse and perhaps misjudgments.

Our practice has clearly been impacted by physician owned therapy practices. Since we opened our doors twenty years ago we have had relationships with and have been referred patients by hundreds of physicians. Many have encouraged their patients to contact us for physical therapy due to our reputation of providing quality individualized treatments. Many continued to refer to this office after they saw the results of our treatments and heard positive feedback from their patients. However, without exception, whenever a referral source engaged in a relationship in which they owned a therapy or rehabilitation facility the referral pattern to our practice essentially ceased.

Additionally, the in-office ancillary services exception is defined so loosely that the regulation itself facilitates the creation of abusive referral arrangements. The delivery of physical therapy services by non-therapist personnel is potentially harmful to the patient as well as a waste of Medicare dollars.

Again, we believe the language of these regulations creates the potential for situational abuse and waste of dollars. Only physical therapist should provide physical therapy and physicians should not be in the business of providing therapy services. Appropriate changes of these regulations will only be to the benefit of Medicare beneficiaries.

Thank you for your considerations.

Harold Millman DPT, OCS Brigid A. Gallagher, MSPT

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

This experience occurred at a different location - anonimity was requested....
Three years ago, I accepted a position in a physician owned clinic. The 'clinic' is one room modified to a PT gym in a doctor's office. In many ways, the position has been rewarding. The close contact with the primary(owner) referring physician and other's in the building(not fiscally involved) has been a boon to more comprehensive patient care. The one on one situation with patient's in the more intimate setting has also allowed me to be more thorough in my care and follow up of the patient's.

Recently, as I noted my employer gloating over the new stark law and dreaming of bringing on more PT's into a larger setting, my worst fears in this situation were becoming real. The situation is becoming more about money for 'my' doctor. This is in stark (no pun intended) contrast to his initial attitude which was primarily about patient care. Because of this change, I am looking for an alternate setting to practice .

My doctor has continued to refer to other therapists in town largely dependent on location, but shifts referrals to me when things are slow. Other doctors in town have expressed intent to follow 'my' doctor's lead for purely fiscal reasons. Recently, 'my' doctor expressed the ridiculous notion that he could do my job. He doesn't begin to know 1/2 of the knowledge and techniques that I use in my treatments and evaluations. Yet a looser stark law could potentially allow him to practice my profession with his limited knowledge. Isn't there enough of that going on with chiropractos, massage therapists, etc?

I do have mixed feelings about my situation though. After many years of practice, this set up has been the most satisfying in regards to patient care. I think the doctor-therapist interface my situation allows is part of that; yet, it makes me uneasy to be allowing another professional to profit from and have control over our profession through me.

Overall, I think our profession needs to move further out of the physicians shadow and not under it so I do support a stronger stark law.

Submitter : **Dr. Scott Quisling** **Date: 06/24/2004**

Organization : **Resurgens Orthopedics**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I feel in-office ancillary services are a very valuable asset in providing quality healthcare to my patients. The feedback from a therapist in office is much more detailed, more timely and more predicatable. The therapists can quickly and conveniently approach the physician about questions and concerns and this is a big advantage. There is no delay waiting for a progress note from the therapists. The therapists become very familiar with the physicians and their specific desires for post-op rehab and this minimizes the chance for error. Also, the patients find it very convenient to come to therapy at the same location as their doctor. These reasons are commonly repeated by the patients who are overwhelmingly pleased to have their therapy in-office. Patients very commonly are disappointed when they have to be sent somewhere else for their therapy. I feel in-office ancillary services are very important in improving healthcare. Thanks
Scott Quisling, M.D.

Submitter : **Mr. David Brewster** **Date: 06/24/2004**

Organization : **Mr. David Brewster**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am writing to voice my opinion about physicians having any ownership and/or financial interest in physical therapy practices, especially private practices. This is just not a good idea on several counts. Any physician who has any ownership in a physical therapy practice is facing the temptation to violate the conflict of interest agreement. This also encroaches on the physical therapist?s autonomy. Physical therapists have a much different education than medical doctors, osteopaths, and the like and therefore have a much more limited scope of practice in comparison to the latter. Given the fraud and abuse that has occurred in the medical field, why would the government actually approve a means by which MDs and others could legally overutilize a part of the medical system? Everyone has the right to go a physical therapy provider of their own choosing but if a physician has ANY financial interest in such a provider, I ask you, where do you think that physician is going to recommend his/her patient to go for such services?

Please consider why the APTA has a code of ethics and core values which opposes the ownership and other financial interests of physicians in physical therapy practices. Thank you for your thoughtful consideration in this matter.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist that is concerned about March 26 interim final rule on "Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." I believe that in this situation, PT services may be overutilized for financial gain. If the physician feels that physical therapy is important to his patients, he could certainly rent space to a physical therapist in his building. This would negate fincancial gain for more referrals. I feel it is important for patients to have a choice with their healthcare providers. If the physician has his/her own physical therapy services in house, they more than likely are not going to be given a choice. They have a captive referral base of PT patients in their office. I feel this situation is not good for the profession of physical therapy, not good for the patient, and sets up Medicare for possible overutilization.

Submitter : **Dr. Jarrod Post** **Date: 06/24/2004**

Organization : **Dr. Jarrod Post**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Patients must meet specific medical criteria before even being started on dialysis, and no financial incentive can impact those strict criteria.
There are limited available positions that can even accomodate a new dilaysis patient, and many patients are forced to go the the nearest open dialysis unit, and break their relationship with the doctor who has previously taken care of them. This limits also the possiblity of any financial incentive for a Director - their patient must get dialysis wherever an open position exists.

Submitter : **Ms. Diane Merkt** **Date: 06/24/2004**

Organization : **Ms. Diane Merkt**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

As a Licensed Physical Therapist of 19 years, I am commenting to raise concerns about this interim final rule and ask that they be addressed and corrected in the subsequent 'phase III' regulations. I have a concern that a physician has the ability to provide Physical Therapy services to a patient by a non-physical therapist and bill under his/her provider number for these services. I have clinically practiced in hospital systems as well as outpatient clinics. I do believe that the potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to an entity in which they have a financial interest. The 'in-office ancillary services' provision does nothing to prevent this practice from occurring. It is my belief that the delivery of any 'therapy' services in this manner which potentially may be provided by using unqualified personnel is wasteful to our Medicare program. A program which is already experiencing financial woes. It is also potentially harmful to the patient. If this non-qualified personnel provides the care, it undermines the required educational level of Physical Therapy which is moving to a Clinical Doctorate entry level by 2020 and currently is a Masters prepared graduate. I have personally experienced questions from the public asking me what the difference in service/treatment provisions are when they are referred to therapy. Finally, I recall that there were published studies that demonstrated overuse of services when this practice was allowed. Can we really allow this potential to reemerge? I thank you for your consideration of my comments.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

There is already widespread abuse going on in this area. Physician owned clinics are tellling the patients or are having the PT tell the patients that they cannot get physical therapy anywhere but at the POPTS clinic. Patients are scared to report due to "upsetting" the physician. I specifically have had a church member apologize to me because she could not come to "our" hospital clinic any longer as she had done through the years. When asked why she couldn't, she stated: "They told me I had to get physical therapy at their clinc!" She did not know she could go anywhere she wanted. These patients seen in doctor's office are not given a choice to go to a clinic closer to their home - they have to go to the POPTS clinic. In addition, POPTS clincs drain staff away from hospitals, healthcare centers, other clinics because they are promised bonuses and splitting of fees according to how many referrals they keep in their clinic. In addition, POPTS clincs do not provide treatment by licensed individuals for the most part.

Submitter : **Dr. Kent Raymond** **Date: 06/24/2004**

Organization : **Carolina Renal Care**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Dr. McClellan:
Carolina Renal Care, Inc. is an independent physicians association representing nephrologists who care for patients in private practices or one of the four academic medical centers throughout North Carolina.
We are writing to oppose the Interim Final Rule?s safe harbor definition of compensation for dialysis unit medical directors for the following reasons:
1. Use of published compensation survey data that reflects the salaries of physicians (i.e., actual physician payroll) does not consider the cost of operating a physician group practice (typically 40% - 80% of net revenue). Most Medical Director compensation is paid to group practices, along with patient care fee for service payments. After paying practice expenses (overhead), what is left is distributed to individual physicians as salary, bonus and/or dividends (analogous to profit in the business world). Why should any safe harbor approximation of fair market value compensation treat Medical Director payments for physician time and expertise any differently from other payments for his/her
time and expertise without consideration of practice overhead expenses?
2. An hourly pay rate system does not adequately reflect the expertise of physicians at managing dialysis units to insure their patients receive the best possible care. After all, the Medical Director is the one individual whose sole function is to maximize the quality of care provided by the dialysis facility, as opposed to facility owners whose motivation is often the highest possible profit for shareholder/investors.
3. In many cases, dialysis unit Medical Director contracts include non-compete clauses which prevent physicians from owning or operating their own units. The safe harbor does not reflect compensation for these non-competes, which have been widely recognized as having significant business value.
4. We believe that the safe harbors in the Interim Final Rule will lower quality of management oversight by physicians. In the end, dialysis patients will suffer and overall costs will increase.

Thank you for your consideration of these comments.

Sincerely,

Kent H. Raymond, MD, FACP
President

CMS-1810-IFC-366-Attach-1.pdf

CAROLINA RENAL CARE INCORPORATED

Carolina Renal Care, Inc.
928 Baxter Street
Charlotte, NC 28204-2847

Tel. 704.332.0370
Fax 704.334.3061

June 23, 2004

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1810-1FC
PO Box 8013 Baltimore, MD 21244-8013

Delivery Address:
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attn: CMS-1810-1FC

RE: Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule

Dear Dr. McClellan:

Carolina Renal Care, Inc. is an independent physicians association representing nephrologists who care for patients in private practices or one of the four academic medical centers throughout North Carolina.

We are writing to oppose the Interim Final Rule's safe harbor definition of compensation for dialysis unit medical directors for the following reasons:

1. Use of published compensation survey data that reflects the salaries of physicians (i.e., actual physician payroll) does not consider the cost of operating a physician group practice (typically 40% - 80% of net revenue). Most Medical Director compensation is paid to group practices, along with patient care fee for service payments. After paying practice expenses (overhead), what is left is distributed to individual physicians as salary, bonus and/or dividends (analogous to profit in the business world). Why should any safe harbor approximation of fair market value compensation treat Medical Director payments for physician time and expertise any differently from other payments for his/her

time and expertise without consideration of practice overhead expenses?

2. An hourly pay rate system does not adequately reflect the expertise of physicians at managing dialysis units to insure their patients receive the best possible care. After all, the Medical Director is the one individual whose sole function is to maximize the quality of care provided by the dialysis facility, as opposed to facility owners whose motivation is often the highest possible profit for shareholder/investors.

3. In many cases, dialysis unit Medical Director contracts include non-compete clauses which prevent physicians from owning or operating their own units. The safe harbor does not reflect compensation for these non-competes, which have been widely recognized as having significant business value.

4. We believe that the safe harbors in the Interim Final Rule will lower quality of management oversight by physicians. In the end, dialysis patients will suffer and overall costs will increase.

Thank you for your consideration of these comments.

Sincerely,

Kent H. Raymond, MD, FACP
President

Submitter : **Mr. Thomas Hoffman** **Date: 06/24/2004**

Organization : **American College of Radiology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Administrator McClellan:

The American College of Radiology appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services? Phase II interim final rule on physician self-referral. The College represents over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists.

I. General Comments

By publishing and enforcing this long-awaited rule, CMS has a critical opportunity to safeguard Medicare program integrity and, more significantly, enhance patient care. The College 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 impeded quality of care. The Medicare Payment Advisory Commission and Blue Cross and Blue Shield Association each reported in 2003 that diagnostic imaging is 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. 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. Such accelerated volume has almost certainly led to many unnecessary imaging procedures performed by non-radiologists. Thus, allowing this type of self-referral creates a structure that can easily place profit over patient. The College maintains that appropriate use of imaging services, competently performed and interpreted, will maintain quality of care and decrease health care costs.

For these reasons, the College urges CMS and the Office of Inspector General to more narrowly interpret the physician self-referral law both in issuing these regulations and in enforcing them. We acknowledge that the Congress enacted a broad and ambiguous statute that challenges CMS to draft a viable rule. We agree that CMS must balance regulating physician financial relationships and unduly inhibiting the practice of medicine. On balance, although certain parts of the Rule concern the College, we believe that CMS has moved closer to completing the 10-year effort to implement the Stark Law. Self-referral enforcement must occur to ensure quality patient care and program integrity.

Issues 1-10

2. In-Office Ancillary Services Exception

Perhaps the most troubling provision in the self-referral law is the statutory exception for in-office ancillary services. The College remains deeply concerned that the in-office exception has swallowed the self-referral rule, permitting financial and clinical arrangements that damage the Medicare program and United States? health care system. Physician self-referral in imaging has escalated in recent years primarily because clinicians have taken advantage of the in-office exception. They have built or purchased imaging centers and self-refer patients for MRI, CT, ultrasound and other radiologic studies. Despite claims that patients receive more convenient service from undergoing a study in an MR or CT scanner in their office suite, clinicians have incentives to more frequently order medically questionable studies and then fail to have a trained imaging specialist interpret them.

As the MedPAC and Blue Cross Blue Shield data illustrate, more physicians are responding to financial ? and regulatory ? incentives to send their patients ?where the money is.? The College urges CMS to evaluate the adverse impact that the in-office exception has on health care delivery and spending. By liberalizing the ?same building? requirement, CMS likely will create lucrative opportunities for self-referring group practices. That may well nullify CMS?s commendable decision to retain the full-time, exclusive ownership or occupancy provision that targets part-time MR or CT rentals. The College absolutely agrees with CMS that such off-site DHS arrangements may be abusive, but requests that CMS monitor carefully the other pathway for in-office ?building? referral arrangements.

Issues 11-20

13. Definitions

Radiology and Certain Other Imaging Services

Effectively combating self-referral hinges largely on the scope of designated health services that accurately reflect current medical practice and market forces. The College respectfully disagrees with CMS?s decision in Phase II to leave out of the DHS category of ?radiology and certain other imaging services? services such as nuclear medicine. As we wrote to CMS in March 2004, nuclear medicine is a key discipline in the radiology specialty. Physicians regard one of its most noteworthy procedures, positron emission tomography or PET examinations, as solely diagnostic. Additionally, as nuclear medicine technology perfects the fused imaging technique of PET/CT imaging, CMS must confront how it will regulate that hybrid service under the self-referral law. The College believes that PET/CT and other PET applications will increase at a high volume to offset their expensive costs. Blue Cross Blue Shield noted that PET equipment sales are expected to increase over 14 percent from 2000 to 2005, which foreshadows higher PET utilization.

Therefore, unrestricted self-referral of these procedures will inevitably result in significantly higher costs to the Medicare program. Congress intended that DHS categories cover services like nuclear medicine prone to abusive utilization. CMS should not compel patients and physicians to rely solely on the anti-kickback statute to prevent or terminate potentially unlawful arrangements that involve nuclear medicine. That law has a higher burden of proof and cases alleging anti-kickback violations require prolonged coordination between the OIG and the Department of Justice. Consequently, the College urges CMS to reconsider its decision and reinstate nuclear medicine, including PET procedures, within the radiology and certain other imaging services category.

Consultation

The College requests that CMS carefully monitor whether its decision to expand the consultation exemption to ?referral? will cause higher and potentially inappropriate utilization of ?ancillary and integral? diagnostic imaging services. This change will permit radiation oncologists to provide patients with a broader range of services. However, those services ? like many of the diagnostic imaging studies highlighted in the MedPAC and Blue Cross Blue Shield studies ? may exact a fiscal toll on the Medicare program that could merit watching.

Submitter : **Mr. PHILIP TYGIEL** **Date: 06/24/2004**

Organization : **Mr. PHILIP TYGIEL**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

IT HAS LONG BEEN RECOGNIZED THAT KICKBACKS FOR REFERRALS IN HEALTH CARE ARE BAD. THEY PROVIDE AN AVOIDABLE CONFLICT OF INTEREST THAT GIVES REFERRING PHYSICIANS INCENTIVES TO OVER-UTILIZE SERVICES OR WORSE ORDER UNNEEDED SERVICES . THESE ARE INCENTIVES TO EXPLOIT PATIENTS AND TO EXPLOIT PAYERS. THAT IS WHY OUTRIGHT KICKBACKS ARE ILLEGAL,PROHIBITED IN MOST PRACTICE ACTS. PROFESSIONAL ASSOCIATIONS STAND AGAINST THEM.HEALTH PROFESSIONALS AVOID THEM AS A MATTER OF PERSONAL PROFESSIONAL ETHICS.
KICKBACKS THROUGH A LOOPHOLE PROVIDE THE SAME INCENTIVES FOR EXPLOITATION OF PATIENTS AND PAYERS AS OUTRIGHT KICKBACKS. STARK II PROVIDES JUST SUCH LOOPHOLES IN ITS IN-OFFICE ANCILLARY SERVICES EXCEPTION. WHEN A PHYSICIAN HIRES OR CONTRACTS WITH A P.T. THE SAME PROBLEM ARISES AS WITH OUTRIGHT KICKBACKS. THE PHYSICIAN HAS VOLUNTARILY PLACED HIMSELF IN A CONFLICT OF INTEREST POSITION THAT IS NOT A NECESSARY PART OF THE BUSINESS OF HEALTH CARE. EVERY TIME THE PHYSICIAN SEES A PATIENT THERE IS THE EXTRA TEMPTATION TO REFER THE PATIENT FOR P.T. AND MAKE EXTRA MONEY.
WHILE THERE ARE INHERENT CONFLICTS OF INTEREST IN HEALTH CARE, SUCH AS A SURGEON MAKING MONEY BY RECOMMENDING SURGERY, THOSE CANNOT BE AVOIDED. VOLUNTARY CONFLICTS OF INTEREST, A PHYSICAN OWNING A P.T SERVICE, ON THE OTHER HAND CAN AND SHOULD BE AVOIDED. THEY SHOULD BE ILLEGAL. OUTRIGHT KICKBACKS ARE ILLEGAL. IN-OFFICE ANCILLARY SERVICES EXCEPTIONS ARE NOT BUT SHOULD BE. THEY ARE DEFACTO KICKBACK SITUATIONS.
PLEASE KEEP IN MIND THAT, ESPECIALLY IN THE MEDICARE POPULATION, THE PROBLEM IS INSIDIOUS. THE PATIENT PLACES UNQUESTIONING RELIANCE ON THE PHYSICIAN, ASSUMING THAT THE PHYSICIAN'S RECOMMENDATIONS ARE IN THE PATIENT'S BEST INTEREST. THE PATIENT IS UNLIKELY TO SUSPECT THAT THE PHYSICIAN ORDERED P.T. MORE FOR PERSONAL FINANCIAL GAIN THAN THERAPEUTIC VALUE. PATIENTS WILL NOT FILE COMPLAINTS BECAUSE THEY WON'T KNOW THEY'VE BEEN EXPLOITED. THE PAYERS,THE MEDICARE CARRIERS, WILL THEREFORE NOT KNOW OF THE EXPLOITATION EITHER. THEY WILL JUST GO ON PAYING.
STARK II, AS WRITTEN, DOES NOT ADDRESS THE PROBLEM AT HAND. IT PROHIBITS OUTRIGHT KICKBACKS FOR REFERRALS BUT THEY HAVE NOT REALLY BEEN A PROBLEM TO BEGIN WITH. THEY HAVE LONG BEEN ILLEGAL, PROHIBITED IN STATE PRACTICE ACTS AND ALL PROFESSIONAL CODES OF ETHICS. THEY RARELY IF EVER EXIST IN FACT. STARK II ADDRESSES ONLY THIS NON-EXISTENT PROBLEM.
THE REAL PROBLEM, THE REAL EXPLOITATION, IS SEEN IN THE IN-OFFICE ANCILLARY SERVICES EXCEPTIONS LIKE THE PHYSICAN OWNED P.T. SERVICES (POPTS). THESE ARE THE SITUATIOINS THAT STARK II NOT ONLY ALLOWS BUT ENCOURAGES. IN FACT AS STARK II HAS WEAKENED THE PROHIBITIONS AGAINST POPTS WE ARE SEEING MORE AND MORE PHYSICIANS OPEN THESE UNETHICAL FACILITIES AND PROFIT GREATLY AS A RESULT. THESE ARRANGEMENTS ARE EVEN MORE DAMAGING TO MEDICARE THAN OUTRIGHT KICKBACKS. WITH A KICKBACK,THE REFERRAL SOURCE MIGHT GET A NOMINAL FINDERS FEE. THAT'S BAD. WITH POPTS THE REFERRAL SOURCE WILL RECOGNIZE A SUBSTANTIAL PROFIT EACH AND EVERY TIME THE P.T. OR PHYSICAN'S TECHNICIAN SEES THE PATIENT. THAT'S MUCH WORSE. IT AMOUNTS TO EXTRA HUNDREDS TO THOUSANDS OF DOLLARS PER REFERRAL AND ULTIMATELY TO EXTRA HUNDREDS OF MILLIONS OF DOLLARS IN COST TO MEDICARE. STARK II DOES NOTHING TO ADDRESS THIS PROBLEM.
THERE IS NO NEED FOR A PHYSICIAN TO HAVE TO HIRE A P.T. THROUGHOUT THE UNITED STATES, EVEN IN RURAL AMERICA, P.T. IS AVAILABLE IN HOSPITAL AND OUTPATIENT CLINICS. THE P.T.s IN THOSE CLINICS WILL BE MORE THAN HAPPY TO WORK WITH THE PHYSICIANS ON BEHALF OF THEIR PATIENTS. PHYSICANS WHO OWN P.T. SERVICES ARE NOT PROVIDING ANY GREAT HUMANITARIAN SERVICE TO SOCIETY. THEY ARE MERELY FINDING ANOTHER WAY TO ENHANCE THEIR OWN INCOME.
I WOULD THEREFORE RESPECTFULLY URGE THAT STARK II BE REWRITTEN TO PROHIBIT ALL PROFIT FOR REFERRAL FOR P.T. SERVICES. AS CURRENTLY WRITTEN WITH REGARD TO IN-OFFICE ANCILLARY SERVICES EXCEPTION IT SERVES LITTLE IF ANY PURPOSE AT ALL.

Submitter : **Fred (Butch) Buchanan** **Date: 06/24/2004**

Organization : **Vaughn Buchanan & Shelley Phy. Therapists**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To: Mark B. McClellan, MD, PhD

Re: Medicare Program, Physicians referrals to Health Care entities with which they have financial Relationships (Phase II)
Interim Final Rule with Comment

Dear Dr. McClellan,
As a Physical Therapist who is licensed and has practiced in South Carolina for the past 33 years, I am writing to provide comments for consideration on the March 26th Interim final rule on physician's referrals to Health Care entities with which they have financial relationships (Phase II). My purpose is to raise concern and ask that my concerns be addresses in Pahse III regulation.

As a Physical Therapist in a preatice owed by several PT's including myself I have witnessed first ahnd the erosion of patient referrals created when our local orthopaedic group opened their own PT clinic. The most recent incident occurred last Sept. '03 - we were leasing space with an orthopaedic group at a rate of $12,000/month for ~6000 sq.ft. When the lease came to term, the grouprefused to renew and hired 3 PT's, cut the space in half and we relocated our clinic. We lost 50% of our new patient referrals.

Our pratice is able to compete with other PT owned clinics in the area, however, we cannot compete in the market place with a physician owned clinic because the patient must have a physician referral in order for the PT services to be paid under current medicare rules.

Also, the in office services exception allows physicians to refer patients to non-physical therapists for treatment and they still bill as physical therapy, Thus, unfair trade rules exist in the local market place.

My neighbor told me just recently that she was instructed to have physical therapy at her physician's PT clinic because they have better equipment and more qualified physical therapists. Last year we were the PT's who saw all their patients, so what changed?

Over the past 5-6 yearsall three multi-physician orthopaedic groups in our region haveopened their own PT clinics. This has created a sense that these physicians are driven by greed rather than the desire to offer their patients convienent, quality care.

Sincerely,

Fred S. Buchanan
Greenville, SC 29615

Submitter : **Mr. Gordon Eiland** **Date: 06/24/2004**

Organization : **Mr. Gordon Eiland**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-1810-IFC-370-Attach-1.doc

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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Submitter : **Ellen Nona Hoyven** **Date: 06/24/2004**

Organization : **In Touch Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan: I am a Physical Therapist from Oregon who has practiced physical therapy in both Oregon & California over the past 20 years. I have been fortunate to have worked 18 of those years in top quality physical therapist owned outpatient clinics; my first 2 years were in a rehab setting. Currently I am working in a clinic with a professional team that focuses on highly individualized patient care with excellent results and satisfaction for the patient.

My main objective in writing this memo is to voice my opinion and concern about the impact that "Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) will have on my profession. Also regarding the probable loss of quality and appppropriate care to Medicare patients as well as to Medicare overall. In the time I have practiced PT, the Medicare guidelines for PT have always been to preserve quality care and dollars for the treatment of Medicare patients. This is also a time when Medicare is watching every dollar spent in rehab. The potential abuses of physician-owned PT clinics that are motivated monetarily to refer or authorize excessive PT visits are not the optimum use of Medicare dollars.

Early in my career there was a prevalence of clinics that were POPTS, (Physician Owned Physical Therapy Services). It was my repeated experience that patients were not receiving the full benefit of professional physical therapy services in these types of settings due to various reasons: rushing patients through, non-degreed staff doing buld of treatment, non-specificity of treatment goals, etc. I would hear complaints from patients and family members. In most cases the patient had not known they had the right & option to go wherever their insurance covered them, since the physician would directly refer to his/her own PT clinic.

In our immediate area we have been impacted by two medical offices that have opened their own physical therapy services. In these cases the physicians in these medical groups notified us that they were no longer able to refer to our clinic. These physicians WANTED to refer to us since they knew their patients were getting excellent care, but they now had been DIRECTED specifically by their employers that they were to now refer only to these new POPTS.

I know that this situation is difficult for these professionals, the community physicians, to not have the choice to make THEIR best professional decision of where to send their own patients for physical therapy. There is definitely a problem for potential abuse and fraud when a physician is mandated to send a patient to a location where financial gain is a major incentive, not the quality of care for the patient.

Thank you, Dr. McClellan, for taking the time to listen to me in a small private physical therapist owned clinic who is concerned about all the aforementioned Medicare issues and consequences to my profession. I am grateful for your consideration in these matters.

Respectfully,

Ellen Nona Hoyven, PT

Submitter : **Mrs. Susan Bamberger** **Date: 06/24/2004**

Organization : **Mrs. Susan Bamberger**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Please be aware of the risks of overutilization of services in this sort of relationship. When the referring practitioner holds a financial stake in the patient's recovery, he may reccomend or require physical therapy way beyond what is needed.

Physical therapists are autonomous practitioners and are trained to judge the appropriate amount of therapy needed, and are required to reassess and discharge if they have met the goals or if they are not making adequate progress. This may take the number of visits suggested by the referring practitioner or may happen sooner.

Allowing a relationship established by dependency and financial gains on the referring pracitioner does not allow the physical therapist to work in their scope of practice, and does not allow them to maximize their skills to improve functional outcomes for patients. If you continue in your support of physical therapists as autonomous practitioners, you will continue to see excellent care provided to the public. Thank you very much

Submitter : **Dr. Robert Brown** **Date: 06/24/2004**

Organization : **Beth Israel Deaconess Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 24, 2004

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1810-IFC
P.O. Box 8013 Baltimore, MD 21244-8013

Re: Medicare Program; Physicians? Referrals to Health Care Entities With Which
They Have Financial Relationships (Phase II); Interim Final Rule

Dear Dr. McClellan:

This letter is to express my concerns with the provision establishing safe harbor methodologies for determining dialysis facility medical director fees included in the above referenced regulation on physician self-referral.

As a clinical director of an academic nephrology training program and the medical director of our dialysis facilities, my concerns are specifically addressed to the impact that the implementation of the safe harbor methodology will have to fix the market value for medical director services and the inappropriateness of basing compensation for these activities on an hourly wage rate basis. Clearly, the complexity of medical direction of the several dialysis facilities associated with an academic center provides many issues that don?t fit into the ?one size fits all? methodology that these rules are likely to produce. The presence of renal fellows in training and the dialysis care of many more new and ill patients make the assurance that we are providing quality dialysis a task for medical directors that cannot be easily broken down to the compensation scheme these regulations will likely cause. Other aspects of these safe-harbor provisions, likewise, need more full consideration before implementation.

I strongly urge delay in adoption of these provisions to allow a full comment and response period to better assess the ramifications of such changes. We must avoid the risk to quality assurance and continuous quality improvement efforts so crucial to the safety of our end-stage disease population. Without the strong input of medical directors, the least costly dialysis provision will result in much higher costs in the long run due to the well-proven effects that quality dialysis has been shown to have on patient morbidity, mortality, and hospital costs.

Thank you for considering these concerns specific to our academic training program.

Sincerely,

Robert S. Brown, M.D.

Clinical Chief, Renal Division
Program Director in Nephrology Training
Beth Israel Deaconess Medical Center
Boston, MA 02215

Associate Professor of Medicine
Harvard Medical School

Member, Board of Directors, and Past President
National Kidney Foundation of MA, RI, NH and RI

Submitter : **Ms. Linnea Comstock** **Date: 06/24/2004**

Organization : **Comstock Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Dear Administrator. I am a private practice physical therapist in Washington State. I know the high degree of service and information I provide to my patients. By allowing in-office anceillary services, one may be treated by a non-physical therapist and get billed for PT services, which would be poor value for the Medicare dollar. PT is more than just a use of modalities such as ultrasound. It is the detailed and comprehensive evaluation, and treatment plan development followed by implementation of the plan the patient receives. Patients will not benefit as much by an untrained tech giving people ultrasound and billing it as "PT."

Sincerely, Linnea Comstock PT

Submitter : **Date: 06/24/2004**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

In the proposed definition of a specialty hospital, the interim final rule states that a specialty hospital does not include any hospital for which the number of physician investors at any time on or after [November 18, 2003] is no greater than the number of investors as of such date. This requirement unfairly restricts a bona fide group practice who has invested in a specialty hospital prior to November 18, 2003 from increasing the number of its physician owners. It is common practice for a group practice to employ a physician with a promise of offering an ownership interest in the group practice after one, two or more years if certain conditions are satisfied. Additionally, it is typical for the number of physician owners of a group practice to fluctuate over time. We represent a group practice that employed a physician prior to November 18, 2003, and the physician was entitled by his employment agreement to purchase an ownership interest in the group practice after one year, which did not occur until after November 18, 2003. Because the group had previously invested in a specialty hospital it is unable to sell shares to the physician. This group practice has existed many years and was not formed for the purpose of investing in a specialty hospital.

We urge that CMS apply similar reasoning for counting physician investors that is used for counting investors for purposes of complying with securities laws. Under Section 501(e) of Regulation D promulgated under the Securities Act of 1933, a corporation, partnership or other entity is counted as one purchaser of securities offered in an exempt private offering, except if 'that entity is organized for the specific purpose of acquiring the securities offered . . . then each beneficial owner of equity securities or equity interests in the entity shall count as a separate purchaser . . . .' The requirements for satisfying the definition of a group practice under the Stark law and regulations are stringent, and it would be impractical for investors in specialty hospitals to try to organize as groups as a subterfuge to avoid the limitation on the number of investors in a specialty hospital. Moreover, the application of this interpretation could be limited to group practices that owned interests in specialty hospitals that were in existence or under development as of the date the moratorium was imposed in order to limit the opportunities for manipulation.

In summary, we recommend that CMS interpret the requirement related to 'no increase in physician investors' to provide that there has been no increase in physician investors if there is an increase in the number of physician equity owners in a group practice that owns an interest in a specialty hospital where (i) the group practice existed prior to November 18, 2003, (ii) it was not formed for the purpose of investing in the hospital, (iii) it meets the definition of a 'group practice' under the Stark law and regulations, and (iv) as of November 18, 2003, the group owned its interest in the hospital, which was either Medicare certified or under development as of November 18, 2003.

Submitter : **Mrs. Secili DeStefano** **Date: 06/24/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS ? 1810 ? IFC
P.O. Box 8013
Baltimore, MD 212244-8013

Regarding: Medicare Program; Physicians Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule With Comment

Dear Mr. McClellan,

I have been practicing outpatient orthopedics after receiving my Master of Science in Physical Therapy (PT) in 2001. In 2003, I was recognized as an Orthopedic Certified Specialist and a Certified Ergonomics Assessment Specialist. In 2004, I became a Certified Clinical Instructor and the Center Coordinator of Clinical Education for the Sterling, Virginia office of Physiotherapy Associates.

I wish to comment on the March 26, 2004 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? I have significant concerns about the quality of patient care, over-utilization, conflict of interest, and financial incentives related to referral for profit and PT. According to the Center for Health Policy Studies, billions of dollars are being wasted on referrals motivated by physicians? financial gains and not by their patients? medical need. California Workers Compensation reports that this phenomenon generates approximately $233 million in services delivered for economic rather than clinical reasons.

This is a conflict of interest and an important concern for Medicare beneficiaries. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest without regard to patient?s physical need. Florida?s Health Care Cost Containment Board found that patients treated at physician owned facilities received 43% more visits per patient than did patients treated at non-joint venture facilities. We are seeing the repercussions of this through the patients in our region. They are being impacted in a negative way by physician self-referral. Many patients have transferred from an area Physician owned practice to our clinic

making statements, such as ?that clinic wasn?t appropriate for me, but my doctor referred me there. I had a terrible experience. No, he didn?t give me any other options for physical therapy, but insisted I go to his clinic. Thank goodness I left.? Situations such as this increase costs for the patient and third-party payer due to additional visits with another more appropriate facility for the patient?s diagnosis and/or needs.

Some of the language in CMS ? 1810 ? IFC facilitates abusive scenarios. 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 practices that provide physical therapy services. In physicians? offices, physical therapy services are often provided by non-physical therapists and billed under the physician?s provider number as physical therapy services. As we have observed, this could be an administrative person without any medical training and more specifically physical therapy training.

Thank you for the consideration of my comments.

Sincerely,

Secili DeStefano MSPT, OCS

Submitter : **Date: 06/24/2004**

Organization :

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

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Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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Submitter : Robyn Dabell **Date:** 06/24/2004

Organization : Kitsap Physical Therapy and Sports Clinics

Category : Physical Therapist

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

The American public consumes 70% of all pharmiceutial drugs produced in the world. Many physician owned practices are so financially driven that they allow only 12 minutes per patient visit (just enough time to make a dx and write the perscription) This practise is turning the American public in mass to seek alternative medical practises many of which are unsafe and non scientifically backed. Physical Therapy is becoming more popular with increased support from 3rd party payers because -it works- but also because people are tired of the pop a pill mentality. The AMA is trying to rectify this skism by using therapy to subsidize failing practises. Please don't allow StarkII to clear the docket.

2. In-Office Ancillary Services Exception

The ?in-office ancillary services? provision does nothing to prevent physician for providing physical therapy services by unqualified persons. The delivery of so-called ?physical therapy? services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. In the past, Medicare rules have been careful to insure that only fully qualified physical therapists perform and are paid for therapy services. It is amazing the difference a thorough musculoskeletal exam done by a licensed physical therapist and followed by a specfic exercise perscription can make in the health and quality of life of patients. Like nutritional concerns, physicans are not trained in these areas and would levy undo power over this profession by this in-house association. This goes without saying the possible financial abuses. Please consider the comments of one who (like yourself) truly seeks to serve the needy. Robyn Dabell PT, MPT

Submitter : **Mr. Bart Hudson** **Date: 06/24/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist practicing in Lenoir City, TN and have witnessed a recent increase in physician owned physical therapy practices(POPTs). I would like submit my comments regarding the recent Stark II decision and attempt to increase awareness regarding current and potential abuses.

I have witnessed POPTs in this area where MD's have direct financial benefits from profit made from in house therapy. There have even been some in the past that bill PT services under the physician and no licensed therapist has provided care. This is certainly placing patients at risk when non-licensed individuals are treating.

Also, physician's who have ownership of in-house physical therapy have a conflict of interest when it comes to ordering therapy for their patients. Even the most well intentioned physician who has a financial interest in ordering PT may end up over utilizing therapy services. I have had patients tell me they have driven far from their own communities to have physical therapy within the doctor's clinic at the request of the physician. This is difficult for many patients to travel from a rural area into the closest city. Also, the only reason I see why physician's doing this is for financial gain.

Physical therapy is a discipline that is in and of itself. We are an improtant link in the health care field and work with physicians in treating many movement disorders.

I ask you to consider the conflict of interest that the current Stark Laws allow and the disservice it provides to the patient.

Thank you for allowing me to submit my comments,

Bart L. Hudson, PT, CSCS
Director, Physiotherapy Associates
Lenoir City, TN

Submitter : **Mrs. MELODY ABRAHAM** **Date: 06/24/2004**

Organization : **RESURGENS ORTHOPAEDICS**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Physicians should be allowed to have in office ancillary services where there is ownership. The first item to reflect on is that the therapist is in house available to patients that need care asap. The second part of this: We are in a world where everyone wants to be back to regular activities asap-physician referring to an in office based ancillary creates continuity of care and is an extension of quality service and time that is much needed in the express environment that we live in. A physician readily knows the quality of care his patient will receive from his own office based ancillary. Also, there is an insurance issue-not all therapy groups are on the insurance plans and quite often patients have to go out of their areas for care or may have to pay out of pocket dollars to stay close to home and the plan does not cover a particular group. Thank you.

still part of the continutity of care-to refer the patient easily and be able to monitor the rehab services,

Submitter : **Mr. Brian Emerick** **Date: 06/24/2004**

Organization : **Access Rehab Centers**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for this opportunity to discuss concerns regarding the effect of the most recent Stark II legislation.

As a therapist and a manager of a small therapy company I have serious concerns in regards to the impact of this legislation. I have enough faith in the system to believe that the effect that has occurred was not the one that was intended. I have recently seen severl of my therapy friends shut down their private practices, I have seen physician practies emboldened in regards to "capturing" therapy business and I have seen a visible change in the networking that is occurring by physicians who deal with patients who require therapy services. Unfortunately this is having a very chilling effect on the therapy profession.

I have had recent experience with physician-owned therapy practices. Our business allows therapists to treat 12-14 patients in a day, these physician-owned practices push therapists to treat 25-30 patients in a day. The money that they make must be dramatic but the worst part is that effectively the patients are not given any alternative to going to that Doctor's PT practice unless they don't accept that individuals insurance. As a therapist I dread some day facing the situation where I might have to treat three to four patients at the same time just so the physician can squeeze a little more profit out of me. I realize that this situation could be true of a therapist-owned practice but quite honestly if I treated patients with that degree of disregard they would go elsewhere. If a Dr. refers to his own practice the patients effectively have no alternative.

I can't believe that Stark II was designed to close down private practice clinics. I also find it hard to believe that it was intended to create an environment where PTs would be owned by Drs and ethical practice patterns would be thrown out the window. Please attempt to remedy the damage that is occurring as quickly as possible.

Thank You

Brian P. Emerick, MSOT,MBA
Executive Director,
Access Rehab Centers

Submitter : **Dr. Debesh Mazumdar** **Date: 06/24/2004**

Organization : **Milwaukee Kidney Associates**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

Dialysis is an integral part of Nephrology care, thus this is a continuity involvement rather than "self referral"

Submitter : **Mr. Todd Henkelmann** **Date: 06/24/2004**

Organization : **Mr. Todd Henkelmann**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

My comments are designed to express my grave concern that the Interim Final Rule (Phase II) for physician self-referral allows more abuse to occur, instead of reducing it. In these days when third party payors are reducing reimbursements to physicians for care given as never before, there would seem to be a strong financial incentive on physicians' part to find additional revenue streams. Owning a PT Clinic or employing a PT in their offices would be a good source of revenue and would invite abuse. How? The more a physician refers for 'in-house' PT treatment, the greater revenue the MD makes. The whole idea of the Stark bill was to eliminate this incentive for overutilization causing abuse of Medicare and other third party payors. It makes no sense whatsoever to weaken Stark as has been done in Phase II, and I fear this has been done on behalf of special interests.

As a specialist in the field of facial paralysis, having published a chapter on the PT role in treatment of facial palsies for Mark May, MD and Barry Schaitkin, MD, I can tell you first hand of patients who have been treated using electrical stimulation in MD's offices, both by PT's and/or unlicensed technicians, who have ended up worse and then referred to our Facial Nerve Clinic at the University of Pittsburgh Medical Center. There is no research evidence that electrical stimulation works in facial palsy conditions and yet they will still do it because they lack the specilialized training to properly treat this condition conservatively and because it is reimbursed well.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I have been a licensed Physical Therapist in the state of Georgia since 1992. For the first 9 years of my profession I worked in an academic/hospital setting where I had direct contact with physicians on a daily basis. This environment promoted both education and professional growth that enhanced patient care. For the past 3 years I have worked in a physician owned practice which functions under the guidelines of the In-Office Ancillary Services Exception. All of our PTs/PTAs honor our practice acts and practice ethically.

The initial physician practice did not include physical therapists, and therapy consults were referred to other areas. However, follow up visits with the physicians, especially surgical patients, were not satisfactory. There were issues of not advancing timely and adequately as well as not following specific protocols as instructed. It was at this time, they decided to hire physical therapists to be part of the group.

Working in this setting affords easy access to the physicians for patient problems that arise. Sometimes there are patient care issues that warrant immediate attention from a physician, and knowing that we always have them available expedites the proper course of treatment. It also promotes continuity of their care. It allows the autonomy for the PT to determine the course of treatment, the frequency, and discharge of services once the patient has achieved maximum benefit from skilled services. These are basic guidelines established by our code of ethics and state laws.

Education is also a component that strengthens our group whether this is through inservicing, surgical observation, or skill development. I have always been treated as an integral part of this health care team that provides a focused, service oriented program to our community.

There are very few practices in our area that are able to provide this type of multi-disciplined service. We receive many compliments from our patients regarding the team effort that we provide and the working relationship between the physicians and therapists.

I consider myself lucky to be respected by this group of physicians. I have never practiced unethically nor compromised the standards of practice set by the APTA, however, in regard to Issue #2 I strongly disagree with their stand against the type of practice that I am employed. This practice has challenged and supported my professional growth in Physical Therapy, and I feel I should be allowed to continue work in this setting. Thank you for your time in considering my views.

Submitter : **Jeffrey Shuert** **Date:** **06/24/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Though I can appreciate the "one-stop-shop" message a physician may preach to his patients, the reality I've experienced is that I often have better communication with the doctors from outside of the office than the therapists do who work there. Their relationship is definitely not colleague to colleague, but rather physician and "less-than-physician."

1. Financial Relationship-Definition

Working in a non-physician owned out-patient therapy setting, I frequently hear comments from patients who knew their doctor had therapy at his/her office, but didn't at all understand that the doctor whould make money off of each visit. I know we expect our patients to be educated about the healthcare system we've established, but it frequently appears that "transparency" by physicians who own their own therapy clinics is lacking.

Issues 11-20

15. Anti-Kickback Safe Harbor Exception

The reality is this: for every visit that a physician prescribes, they make money. To me, that's a kickback, easily abused, without checks and balances, and should have no safe harbor.

Issues 21-24

24. Impact

In my studies for my MBA, I did some research and found studies published in the AMA that had accumulated studies of utilization in physician self-referral settings (lab, radiology, therapy, etc). Since I am a physical therapist, I remember well that in a physician owned, self-referral setting for physical therapy, gross and net cost per visit, as well as the number of visits were all 30-40% higher than in non physician owned settings. Hmmm. I think we are all smart enough to know that this fact represents more than the mentality that "if you have it, you'll use it." The reality is that patients pay more, insurers pay more, CMS pays more and therefore myself, as a tax-payer in the country pay more for this conflict of interest to remain legal. The impact is simply more cost to everyone else and more "kicked-back" money to the doctors who practice this way. It should stop now.

Submitter : DeAnne Ferraro **Date:** 06/24/2004

Organization : DeAnne Ferraro

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

These comments come to you in regard to the impact of influx of POPTS facilities that have opened in this region in the past year. Never in the history of physical therapy, has there been such a large influence on the way we practice physical therapy, as the recent ruling of Stark Two Laws, revision number two. The most recent ruling allows all physicians, including medical doctors, podiatrist and chiropractors to all create a physical therapy clinic in their facility or near their facility and write prescriptions for their patients to have and fill their physical therapy service for a profit. This has had a dramatic impact on the community hospitals, private practice physical therapy clinics, and rural physical therapy clinics. The initial phase of Stark II Laws were powerful and effective in preventing physicians from referring to themselves for profit in any service. Over the years, however, particularly with the Stark II Laws, this referral patern of referral for profit has been weakened to the point where physicians not only refer patients for physica therapy or occupational therapy services, they also direct the patients to their facility. If Medicare can review the history of physical therapy services for this region, they will see a trend or a dramatic increase in referral patterns. Two clinics in this region are opened POPTS facilities that are more than a mile away from the primary office, which is a clear violation of "in-office ancillary exceptio". It is hoped that if Medicare makes changes, at least enforcement of these changes will occur.

It is disturbing to me that a visit to any AMA website will show that the number two form for profit for physicians behind diagnostic testing is physical therapy services. It is no wonder that physicians have found this as a means of profit for their company. At a time when Medicare has attempted to control costs with $1590 therapy cap rules and continued monitoring of the delivery of physical therapy at hospitals and private practice clinics, that they have ignored the significiant influx of POPTS facilities and its impact on Medicare funds. I still am unclear of when it became illegal for physicians to refer patients for pharmaceuticals for profit. Patients leave the physician's office with a prescription that should be filled at the clinic of the patient's choice, however, more and more, this is not becoming the case. Areas of medicine such as speech pathology, orthotics and prosthetics, nursing practices, ophthalmology and optometry practices and podiatry practices are independent entities that cannot be owned by physicians.

Unfortunately, physical therapy is not protected, and is not viewed by Medicare as an ancillary service. Where does the control of physical therapy services end? In this region, orthopedists, neurologists, family practice physicians, podiatrists and chiropractors all have ownership of physical therapy services and refer to themselves for profit. In the day and age of controlling costs, how does Medicare plan to deal with tis significant influx of POPTS facilities? Approximately three years ago, less than 10% of the physicians in this region had ownership in physical therapy services. Currently, over 50% of the physicians in this region have ownership in physical therapy services. Since insurance companies follow the lead of Medicare, I believe it is imperative for the future of our practice, and for the future of Medicare's funds, that the practice of POPTS facilities and the strengthening of Stark Laws to favor POPTS facilities be reviewed. Our own organization and the American Physical Therapy Association have made it clear to Medicare that the ownership of physical therapy by physicians, specifically POPTS facilities should be eliminated. I beg of you to please review the current Stark regulations. It should be what is best for the patient, not who holds the most political clout.

Submitter : **Mrs. Jennifer MacDonald** **Date: 06/24/2004**

Organization : **Whatcom Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am writing to comment on the March 26 interim final rule on "Physician's Referral to Health Care Entities With Which They Have Financial Relationships" (CMS-1810-IFC). I am concerned about the interim rule and ask that my concerns be addressed in the subsequent phase III regulations. The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiares to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicans who own practices that provide physical therapy services have an inherent financial incentive to refer patients to the practices they have invested in and to overutilize those services for financial reasons. Thank you for your consideration of these comments on CMS-1810-IFC. Sincerely, Jennifer MacDonald, PT Whatcom Physical Therapy Blaine, WA 98230

Submitter : **Mr. Jay Christiansen** **Date: 06/24/2004**

Organization : **American Bar Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1810-IFC-388-Attach-1.pdf

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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Submitter : Kathleen Mairella **Date:** 06/24/2004

Organization : American Physical Therapy Assoc of NJ

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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Submitter : **Mr. WILLIAM OETTING** **Date: 06/24/2004**

Organization : **OETTING STEBBINS P.T.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
US Department of Health and Human Services

Attn: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013
June 23, 2004

Dear Dr. McClellan:

I am a physical therapist in practice for 26 years. I have worked in a hospital setting, in a physician owned practice, and for the past 21 years in a private practice of which I am an owner. I am writing to comment on the March 26th interim final rule ?PHYSICIAN?S REFERRALS TO HEALTHCARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIP, (Phase II).? I am deeply concerned with the recent interpretation of Stark II, designed to minimize the potential for fraud and abuse by physician owned practices, will actually increase the potential by expanding the exceptions of self referral.

In my 26 years as a physical therapist, I have felt first hand the financial motivation behind physician self referrals. On three separate occasions, groups of orthopedists that were regular, steady, and satisfied referral sources of patients to my practice, opened their own practice to increase their source revenue. Each asked if I would join them as an employee, each voiced the need to increase revenue and each stopped referring patients the very day they opened their own physical therapy service. So hungry for revenues were they that they pulled the patients that I was presently treating regardless as to what consequences switching therapists in mid-stream might bring. On numerous occasions, the services delivered by the physician owned practices were described as ?inferior?, ?a mill? and not nearly as professional as my own.

I also feel that the ?in office ancillary services? exception is so broadly interpreted and so poorly understood, that the potential for fraud and abuse is great. We must tighten the interpretation, not loosen it in order to better ensure the delivery of services by physical therapists rather than by untrained, unlicensed individuals in the physicians? employ. The same services being delivered by unqualified personnel can be less than optimal at best and at worst extremely dangerous to the patients they treat. It can also lead to over utilization due to the motivation of financial gain, which has already been documented in several studies.

I again ask that you consider implementing a narrower, stricter interpretation of the self-referral regulations in order to minimize the potential for fraud and abuse. Monetary gain should not be the primary motivating factor in determining where a patient is referred for his therapy, nor should it be delivered by an unlicensed practitioner. Thank you again for your time and interest in considering my preceding comments.

Sincerely,

William A. Oetting, P.T.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Dept of Health and Human Services
ATTN: CMS-1818-IFC

SUBJECT: Medicare Program: Physician's referrals to Health Care
Entities with which they have financial relationships (PhaseII): Interim Final Rule with Comment

We are private practitioners in Central NJ. We have been in Private
Practice for over 16 years. We have treated patients who have first been treated at facilities that MDs have some financial interest in referring to. These patients have been dissatisfied by the quality
of care they received at these facilities or have realized they are not making significant progress. Once these patients have begun treatment with us, they are always more satisfied by the care we provide, and feel shortchanged by their previous treatment.

We feel quite strongly that physicians should not have a financial interest in entities (specifically P.T.) to which they refer patients. Patients put their trust in their physicians, and follow their advice. If a physician refers to a certain facility, the patient feels compelled to use that facility. Often, they are fearful of not going where the MD says to go. If a physician has a financial interest in a certain facility he or she would certainly be influenced by the monetary rewards of referring to that facility, as well as overutilization of that facility. Physicans write orders for medications, and they cannot own pharmacies.. Likewise, if they are referring patients to physical therapy, they should not be allowed to have a financial interest in the P.T. facility they are referring to. Medicare's physician referral requirements for P.T. provides an enormous referral base for MDs to capitalize on by providing physical therapy. It seems apparent that the physicians' desire to provide P.T. services would largely be driven by the financial reward for providing these services, and not out of concern for the needs of Medicare beneficiaries.

Likewise, the in-office ancillary services exception also has the potential for self-serving, and potentially harmful situations. Services provided in the physician's office can be provided by individuals with no qualifications to do so, simply because they are provided in the physician's office and billed under the physician's provider number. There is no reason why the Medicare program should pay for services provided by unqualified personnel when there is no shortage of licensed physical therapists who are willing and able to provide these services in other practice settings. It seems that having an unlicensed individual providing a skilled service only prevents the patient from receiving services from a more qualified provider. Physicians cannot dispense medication out of their offices and be reimbursed for it, why then, physical therapy.

Thank you for taking our comments under consideration. We appreciate your interest in these issues.

Submitter : **Dr. Jim Cotton** **Date: 06/24/2004**

Organization : **Texas Renal Providers**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues 11-20

15. Anti-Kickback Safe Harbor Exception

For the last 30 years the regulations governing dialysis facilities, and in particular Medical Director responsibilities, have increased to encompass a level of accountability and responsibility requiring Medical Directors to be on-call to respond to any facility, or staffing problems that might impact patient care. The Medical Director is legally responsible for all clinical and operational issues that occur within a particular unit. The scope of this undertaking is not comparable to any other role in medicine. Therefore we do not believe that using an hourly rate to establish compensation for the level of oversight effort and responsibility required is appropriate.

Submitter : **Mr. David Salem** **Date: 06/24/2004**

Organization : **Salem & Green, a Professional Corporation**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

Please See the attached letter.

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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Submitter : **Ms. Charlotte Hughes** **Date: 06/24/2004**

Organization : **Gentiva Health Services**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1810-IFC
P.O. Box 8013
Baltimore, Maryland 21244-8013

RE: Medicare Program; Physicians? Referrals to
Health Care Entities With Which They Have Financial Relationships (Phase II)

Dear Sir:

In reviewing the Interim Final Rule relating to physicians? referrals, we have identified what appears to be a conflict between the response to comments published with the Final Rule and provisions of the Balanced Budget Act of 1997 (BBA `97).

On page 16089 of the Federal Register notice published on Mach 26, 2004 the comment states:
?A commenter urged that a physician employed by a hospital should be allowed to refer to a home health agency owned by the hospital?

The response stated:

?As in the preceding comment, the commentor?s scenario potentially involves an indirect compensation arrangement between the employed physician and the home health agency However, the hospital can require its employees to refer to ts home health agency without running afoul of the restriction on compensation that reflects referrals if the requirements of Sec. 411.354(d)(4) are satisfied.?

While we understand that the primary purpose of this publication and responses to comments relate to whether or not physicians can refer to providers with which there may be a direct or indirect financial arrangement, we are concerned that the response to this particular comment may be taken out of context and used to justify non-compliance with BBA ?97.

BBA ?97 Section 4321(a) is intended to support patients? rights of choice of home care providers. Hospitals are required to provide patients lists of home care providers who have asked to be included on lists. Therefore, we believe that if hospitals can require its employees to refer to the hospital?s home health agency as indicated in the response to the comment above, it will be in conflict with the provisions of the Balanced Budget Act and Congressional intent that patients? rights to choose their providers be protected.

We thank you for consideration of this comment.

Sincerely,

AVP Regulatory Affairs
Gentiva Health Services
3903 Northdale Blvd,, Ste. 100E
Tampa Fl 33624

Submitter : **Mr. Anthony DeVinney** **Date: 06/24/2004**

Organization : **HealthSouth**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have been a Physical Therapist for 23 years. We have faced many challenges as a profession over those years. One of the greatest threats to our profession today is Physician Owned Physical Therapy Services or POPTS. Everyone knows that when a physician owns a physical therapy practice of any kind, his utilization of those services go up. Why does the law allow this type of abuse to occur? The physician has the ability to control business because he has the power of the pen with his signature on the referral pad. We have seen a dramatic increase in these type rehabilitation clinics over the past two years, as physicians try to off set their decreased revenue streams with alternate businesses. I have no problem with this as long as there is no chance for fraud or abuse. Nothing could be further from preventing this then the present situation in which we have to live in. This has dramatically cut into the business of freestanding rehabilitation clinics, where they are held to a much higher standard of care through CMS audits. What this does is create an environment of non-competition because the physicians are in control. We all know what happens when competition wans. Quality goes down and pricing goes up. Why has CMS allowed this to happen? They have stopped this in other arenas where physicians have proven their abusive past with diagnostic centers and labs. Why would therapy services be any different? I understand that it would apply if it was within the scope of the physican to practice physical therapy, but it is not. If they are a surgeon then I can see why they would be allowed to invest in a surgery center, it is within the scope of their practice of what they do. Therapy is not. There is no question or doubt in my mind that the heathcare industry as a whole will be much better off with physicians not being allowed to own physical therapy practices. The healthcare professionals have known this for years but powerful AMA lobby and special interest groups have derailed or weakened any legislation that would prohibit this from happening. I respectfully request that this be thoroughly investigated and that the government, "do the right thing" by stopping this abusive physician practice.

Submitter : **Jeff Day** **Date: 06/24/2004**

Organization : **Kitsap Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for allowing comments on this subject. I have enclosed a word file with comments.

CMS-1810-IFC-397-Attach-1.doc

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Sir:

Thank you for the opportunity to add my comments to this subject.

I am a physical therapist who has been practicing in therapist owned PT clinics for 22 years. I have been witness to the profession prior to the Stark law, during the time the law has been serving the public, and now during the time that the protection it provided the public is being eroded. I was also a constituent of Mr. Stark for a time during the 1980's. I hope my short comments can help you and CMS finalize rules that will best serve the public's interest, rather than be deleterious to it.

One of the rule changes that the Stark II law will make is to foster physician ownership of physical therapy practices. When the original Stark law was developed and passed years ago it served to help resolve multiple ethical dilemmas and lapses, as well as conflicts of interest that arose as a result of physician owned physical therapy services (otherwise known as POPTS). As part of the rationale for the law at that time were multiple citations of ethical violations such as excessive referral of patients by physicians to entities such as PT practices they had a financial interest in, as compared to the same physician's referral pattern prior to owning the PT practice. If the rationale applied then, it certainly applies now, so as a citizen, I don't know why the law should be weakened.

In an era of waste, fraud and financial chicanery and abuse such as we American citizens have seen over the past few years, such as Enron, Global Crossings, Arthur Anderson, Health South and multiple others, including several health care companies, why is a law that has served the public well for so many years being made impotent to do what it was intended to do? Rather than help protect the public, weakening the law will open the door to promote practices in healthcare, specifically POPTS, that will tempt a new era of waste, fraud and abuse on an unsuspecting public.

In recent years, all one needs to do to prove this point is to look at the proliferation of nuclear medicine services, including "PET" scans (positron emission tomography) prior to their being reclassified by

CMS as a non-Stark “designated health service”. Following the reclassification in 2001 physician ownership of nuclear medicine services was no longer prohibited, and as a result the number of has proliferated over the past few years, and not surprisingly the number of tests and the millions of dollars billed to insurance and Medicare has increased dramatically. Isn’t it ironic that in this case that once physicians have a vested financial interest in a referral based entity, such as the nuclear medicine centers, that the utilization soars, versus utilization prior to physician ownership? There is a limited number of health care dollars, and this is one example you can be sure will translate directly to POPTS. It is for the same reason as this that physician ownership of pharmacies has been, and should always be considered unethical and illegal. There simply isn’t any reason why POPTS should be any more ethical or legal than physician owned pharmacies.

One other factor that will harm the public, and citizen’s finances is the fact that POPTS use “ancillary” staff to provide and bill for physical therapy services.

Per Medicare rules and APTA guidelines, physical therapy services are only to be provided by, and billed through physical therapists and physical therapist assistants under supervision of a physical therapist. Allowing in office ancillary services billed as physical therapy would permit and promote treatment to unsuspecting patients by untrained, unlicensed and unqualified staff. This would allow staff ranging from a receptionist to a nurse, to a janitor to provide and bill for something that the patient would think was physical therapy. This will beyond a doubt lead to treatment ranging from poor quality at best, to potentially injurious or worse. This makes absolutely no sense, and people on the commission trying to make decisions on where to go with the Stark law must ask themselves, would they or one of their loved ones want to receive and be billed for PT services that were provided by a receptionist or a janitor?

As a PT in Washington State, I/we understand there is a limited amount of healthcare dollars, and by providing highly skilled PT services for which we are solely and exclusively trained, in a manner that provides the best possible results with as few treatments as needed to achieve those results. An untrained, unlicensed and unqualified ancillary provider, in addition to providing poor or potentially injurious services, simply can’t promote efficacious care that is cost effective and fiscally responsible.

One argument that is falsely put forth for justification of POPTS has been a claim of inability to find PT services in rural environments. There are many PT owned practices and networks of PT’s who would jump at the chance to open and run a practice in any setting if they were asked to do so by a hospital or referral source, so this argument falls flat and is just another means to justify weakening a law that has served the public well for many years.

In closing, I truly hope you will consider what is best for the public in this situation. Modifying this rule will render it impotent and will have serious consequences. I know you don’t want to do something that will lead to the scandals the American public has seen from organizations, which for lack of regulation and oversight have cost this great country billions of dollars over the past few years.

There simply is no good reason to allow changes to the Stark law that will foster physician owned

physical therapy services other than greed.

Sincerely,

Jeffrey P. Day PT
Kitsap Physical Therapy and Sports Clinics
Bainbridge Island, Washington

Submitter : **Mr. John Krug** **Date: 06/24/2004**

Organization : **ProCare Physical THerapy, P.C.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I believe there are very few instances where it would be necessary for a physician to refer patients to a physical therapist working either on that physician's staff, or in a facility that they have financial ties to. In my own geographic region, and I would guess in most others around the country, there are a number of therapist owned and independently operated entities that would graciously accept these referrals. It is the financial incentive that makes these physicians seek to control all aspects of their patients' care. I hope that CMS does not make it easier for these self-referrals to continue.

Submitter : **Mr. Ronald Grousky** **Date: 06/24/2004**

Organization : **Mayo Clinic**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

We would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to submit comments on the Interim Final Rule published on March 26, 2004 regarding Physicians Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II). Specifically, we wish to offer comments on the issue of Reporting Requirements section 1877(f) of the Act; Phase II; 411.361.

Section 1877(f) of the act sets forth certain reporting requirements for all entities providing covered items or services for which payment may be made under Medicare. The final rule requires that entities only report information that it knows or should know about in the course of prudently conducting business. We agree with the requirements that providers report information that is currently and routinely maintained for business purposes. This would include several of the items listed in the interim final rule such as:

Name and UPIN of each physician that has a reportable financial arrangement with the entity.
The covered items or services provided by the entity.
The nature of the financial relationship/compensation arrangement for each physician above.

However, the rule also states that providers need to report:

The name and UPIN of each physician with an immediate family member who has a financial relationship with the entity.

We have concerns with this requirement. The scope of information requested may be beyond that which would normally be maintained by many physician group practices for normal business purposes. There could be many potential relationships that may need to be identified. For example, a large group practice could have thousands of employees each with various relatives that may be subject to the reporting requirement. Section 411.351 has a very broad definition of immediate family member, which includes:

husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

This could potentially represent an overwhelming amount of information for large group practices to maintain and update within 30 days.

The rule states that reporting could be required even if an entity meets exceptions to the Stark rules. We believe that the first three items listed above may allow CMS to analyze an entity to determine if they comply with the basic requirements set forth in the rule. If CMS verifies that exceptions are met, it would not seem necessary to report the additional information related to immediate relatives who have a financial relationship with the entity. If the additional information is deemed necessary, we believe that a 30 day reporting requirement is unreasonable and would recommend that extensions of at least 90 days be available to providers.

Submitter : **Mr. Marc Meadows** **Date: 06/24/2004**

Organization : **Physiotherapy Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1810-IFC
PO Box 8013
Baltimore, MD 21244-8013

June 24, 2004

Subject: Medicare program; Physician?s referrals to health care entities with which they have financial relationships(Phase III); Interim final rule with comment

Dear Mr. McClellan,

I am a Physical Therapist in Northern Virginia who has been practicing for 17 years. I have been privileged to help numerous older Americans obtain the quality care whether following knee replacement surgery or restoring their function to allow a return to their livelihoods. I have operated in the private practice sector, initially my own practice, and then through an acquisition, as part of Physiotherapy Associates, a larger business entity. I have always believed that the patients should be entitled to the best care they can get in a free market environment.

I would like to comment on the March 26 interim final rule as it pertains to physicians referring to health care entities in which they have a financial interest. While I can understand a physician seeking to maximize the financial capacity of his power to refer, it is not just when gains are at the expense of patients restriction of choice. For instance, a physician, who is ? employed? as a Medical Director for a physical therapy practice has an inherent personal interest in referring to this practice secondary to his or her financial gain, irregardless of the quality of the care his or her patients receive. A physician takes advantage of the patient-physician relationship by referring to his or her own physical therapy practice. The patient choice is compromised by his or her physician?s self-referral.

I believe the potential for fraud and abuse outweighs the benefits where there is a financial arrangement. ? In-house? ancillary services, such as physical therapy, constitutes fraud and occurs at the expense of the patient when services are not provided by licensed therapists. Physical therapy services are being billed as such, but are being provided by unskilled personnel as ?physician extenders? to the unknowing, unsuspecting public. This prevents the patient from receiving quality physical therapy care, which the patient should be entitled to.

Thank you for your time and consideration of my comments.

Sincerely,

Marc O. Meadows, PT, ATC

Submitter : **Mrs. Lisa Ruttenberg** **Date: 06/24/2004**

Organization : **Over The Mountain Rehab**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a private practice owner I do not support physician owned physical therapy services. This has a direct impact on referrals to my clinic because physicians are required to keep referrals within their group for monetary gain. There is also the concern that referrals may be over utilized as a way to increase income. For these reasons I am strongly opposed to physician owned PT practiced and I encourage the self-referral ban.

Submitter : **Ms. Christa Perley** **Date: 06/24/2004**

Organization : **Over the Mountain Rehab**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a private practice owner I do not support physician owned occupational therapy services. This has a direct impact on the referrals to my own clinic because physicians are required to keep referrals within their own group. This was very apparent when I was employed by a local group in Birmingham who had in-house therapy. I felt that some of the patients we were seeing, did not need therapy services and they were only sent to me for making profit within the company. I strongly disagree with physician owned practices because I think they are very unethical and I encourage the self-referral ban.

Submitter : **Al Ahlman** **Date: 06/24/2004**

Organization : **St. Francis Hospital**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 11-20

16. Professional Courtesy Exception

Thursday, June 24, 2004

Mark McClellan, MD, PHD
Administrator
Center for Medicare & Medicaid Services
US Department of Health & Human Services
ATTN: CMS ? 1810 ?1FC
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sir,
I am writing regarding the interim rule on ?Physician Referrals to Health Care Entities Which They Have Financial Relationships (phase III).? I have been a PT for 30 years and have worked in six states. I find Columbus, Georgia to be a place that flagrantly utilizes referral for profit among certain groups of physicians. Every orthopedic group in Columbus has their own rehab unit and x-ray equipment. They do not give the patient a choice where they can go for rehab or for an X-ray. The present regulation is clearly not accomplishing CMS? previously stated intent to improve patient choice to quality services, decreased the opportunity to abuse self referral opportunities, and decrease the Government?s cost of healthcare. Studies have established that referral pattern and utilization of services increase when physicians have the opportunity to refer to services that they have financial interest.

Referral for profit runs up the cost to Medicare and Medicaid. It promotes an over-utilization of services. It often decreases to quality of the service, as there is no longer competition for the referral among the potential caregivers.

Please consider making it referral for profit a prohibited practice again.

Sincerely,

Al Ahlman MS, PT, ECS
205 Dogwood Trail
Fortson, GA 31808

Submitter : Alice **Date:** 06/24/2004

Organization : Alice

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

File Code CMS-1810-IFC
Issue Identifier: Rural Providers Exception (Section 1877(d)(2) of the Act; Phase II; Sec. 411.356(C)(1))

Certain existing hospital/physician joint ventures (specifically a jointly owned MRI) met Stark compliance under the "rural provider" exception when the joint venture was structured. Since that time, the county in question has been reclassified as "urban," as indicated by the Wage Index and Capital Geographic Adjustment Factor (GAF) for Urban Areas. The county in question is also currently designated as a "medically underserved area/population." There is only one hospital and one MRI in the county, and these are located at least 30 miles from the nearest metropolitan area. To reclassify this county as urban is inconsistent with reality, because the patients live in a sparsely populated and medically underserved area, regardless of the OMB "classification."

Question: Can CMS create different criteria for designating rural or urban counties which takes into account a county such as this, which for all practical purposes provides healthcare to rural patients, but which, due to urban sprawl, has been reclassified as an urban provider.

Thank you.
R at 78759

Submitter : **Mr. Bruce Toppin** **Date: 06/24/2004**

Organization : **North Mississippi Health Services**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

June 24, 2004

Center for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1810-IFC
P. O. Box 8013
Baltimore, Maryland 21244-8013

Re: CMS-1810-IFC

Dear Sirs:

The undersigned is Vice President/General Counsel of North Mississippi Health Services, parent corporation of North Mississippi Medical Center ("NMMC"). I am writing this letter on behalf of and at the request of the NMMC obstetricians ("OBs").

NMMC is the largest rural hospital in the country with approximately 600 beds and services a 22 county region. NMMC is located in Tupelo, Mississippi, a city with a population of approximately 35,000. Tupelo is situated in Lee County, a county of approximately 75,000-80,000 people. Contiguous to Lee County are several counties?Pontotoc, Itawamba, Chickasaw and Prentiss that do not have obstetrical units. In addition, there are several counties within 30-40 miles that also do not have a hospital or an obstetrical unit. NMMC has a Women?s Hospital that has 16 labor and delivery rooms, a 22 bed nursery intensive care unit and 13 obstetricians on staff.

The revised Stark II regulations 69 Fed. Reg. at 16115 provides an exception that allows a hospital to pay some or all of the obstetrical medical malpractice premiums for an OB physician who practices in a Healthcare Professional Shortage Area ("HPSA") provided certain conditions are satisfied. Unfortunately, because of the size of NMMC, it has attracted a sizable number of physicians to the area and, therefore, Lee County is not defined as a HPSA area. But, by the very nature of NMMC being the largest rural hospital in an area with many counties without a hospital or hospitals without OB services, NMMC and its staff OBs treat a significant number of patients from the HPSA areas. In fact, approximately 54% of the deliveries at North Mississippi Medical Center come from patients who reside in a HPSA area. We suggest that, because of the unique nature of rural healthcare, that the exception be revised to not only include the exception for HPSA areas but for those non-HPSA areas where at least 50% of the deliveries come from patients who reside in a HPSA area.

In the past 3 years, the cost of the OB malpractice premiums in Mississippi have escalated approximately 40%. This has forced more experienced and senior OBs to curtail their OB practice. This is unfortunate and, as the amount of Medicaid deliveries at NMMC has increased to 50% and the Medicaid reimbursement has not kept pace with malpractice expense, more physicians are considering relinquishing their OB privileges. The net effect will be detrimental to the patients in this rural area who will have less access to OB services.

For the reasons stated above, we ask that you consider and modify the exception for obstetrical malpractice insurance for those hospitals that treat a significant number of HPSA based patients.

Sincerely yours,

Bruce J. Toppin
Vice President/General Counsel

\jhm

pc: All Obstetricians

Submitter : **Mrs. Sandra Stryker** **Date: 06/24/2004**

Organization : **Mrs. Sandra Stryker**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Physician owned practices are not only an unethical way of providing physical therapy, but can easily be mismanaged clinically. Physicians do not have the training or expertise to own a physcial therapy clinic. Few controls would be in place to ensure that patients are getting the best possible care particulary when an internal medicine or family practice group owned the PT. In addition, physical therapists have direct access for see patients in 37 states without MD referral because PTs are trained with 7 years of college to do so. It is unethical for MDs to make referral decisions in which they have a financial stake. There is no way to separate one from the other. I strongly oppose the physician owned practice and will continue to support legislators who support my way of thinking.

Submitter : **Mary Jo Wagar** **Date: 06/24/2004**

Organization : **North Dakota Physcial Therapy Association**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am making comments as a physcial therapist who pracitices in North Dakota and as president of the North Dakota Physical Therapy Association. I have concerns about the interim final rule relating to 'Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships. It would seem that when physicians are able to make referrals to entities in which they have a financial interest that there is a great potential for fraud and abuse. The 'in-office ancillary servies' exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. Medicare recipients are especially captive because of the requirement for a physician referral for physical therapy services. Many times in physician offices services are provided by non-physical therapists and billed under the physician's provider number as physical therapy. The 'in-office ancillary services' provision does not protect the public from this occurring. This is potentially harmful to patients and an inefficient use of Medicare funds. Only licensed physical therapists should be providing such services.
Thank-you for your consideration of these comments.

Submitter : **Mrs. Connie McMillan** **Date: 06/24/2004**

Organization : **Therapy Solutions**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 24, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Identification: The staff of Therapy Solutions which includes: Joshua Woods, MPT (4 years experience), Connie McMillan, PT (38 years experience), Michael Bernd, MS, PT (30 years experience), Genie Ford, PT (22 years experience), Leigh VanTassel, PTA (5 years experience), Virginia Bevers, PTA (9 years experience). Therapy Solutions is a privately owned outpatient Physical/Occupational Therapy clinic in Casper, Wyoming.

Dear Sir:

As a part of the Physical Therapy community, we would like to comment on the interim final rule regarding ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? We hope the following will be helpful to address ?Phase III? regulations.

? Allowing physicians the ability to refer to physical therapy clinics in which they have a financial interest provides a situation in which financial interests will out weight the best interests of the patient in question. Opportunity for abuse of this situation is further increased by Medicare?s requirement that all Medicare beneficiaries must have a physician?s referral to receive Physical Therapy services.

Example: Patients coming to our clinic (a physical therapist owned clinic) complain they were told they would have more personal attention from the physician at the physician owned clinic in the same community. Patients state disappointment that they never saw the doctor at the clinic and frequently licensed assistants and/or technicians would provide their treatments.

? Many patients are unaware that they have a choice in where they receive Physical Therapy services.

Example: Numerous patients we see in this physical therapist owned clinic were instructed by their doctor to go to the Physical Therapy clinic located in the same building as the physician (physician owned). The patient was unaware she had the option to go elsewhere for rehabilitation services.

In a rural hospital in Wyoming, a physician brought a Physical Therapist into the examination room at the end of his visit with a patient. The physician did not introduce the PT, he instructed the therapist in what he wanted done, wrote a script and handed it to the patient. The physician then instructed the patient to follow the PT, giving the patient no choices. The Physician and Physical Therapist are both employed by the County Hospital. In this rural town there are two Physical Therapy clinics, one in the hospital and one physical therapist owned.

? The possibility for patients being treated by a physical therapy tech/aide with no degree and no training increases when a clinic is over utilized or administrated by people other than a physical therapist. This can be a problem for any clinic physician owned or not when financial interests outweigh quality of physical therapy services.

Example: Patient?s evaluated by the physical therapist and care turned over to the technicians. This has been observed in the past in hospital, nursing homes, outpatient clinics, etc. In these cases the patient is charged the same as time with the therapist. In situations as described a Licensed Physical Therapy Assistant can appropriately provide the care in most situations. The role of Technicians should be limited to no patient contact roles since they are not trained.

We are contributing this viewpoint in hopes of shaping the future of Physical Therapy.

Thank you for your time.

The Staff of Therapy Solutions

Submitter : **Caren Betz** **Date: 06/24/2004**

Organization : **Curative health Services**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I strongly support the prohibition on physician self-referral. It appears to create incentives to underutilize or overutilize services based on the financial interest of the referral source for personal or institutional profit.

Thank you.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mr. McClellan:

I am a physical therapist in Austin, TX and I want to comment on the March 26th interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? I have some concerns about the recent ruling and would ask that they be taken into consideration for the phase III regulations. Due to these changes I believe that it opens up an opportunity for abuse to take place when physicians are allowed to refer patients to clinics that they have a financial interest. There have been many studies done that show that services such as physical therapy are over utilized when physicians have a financial stake. Since Medicare requires that patients have a physician referral in order to obtain PT services this gives the doctor more incentive to send the patient to his own clinic. These types of set ups also largely decrease the options given to patients when it comes to PT services. Many patients are only informed of the physician?s clinic and are not told that they have the option of going elsewhere. For these reasons I believe that the March 26th ruling should be revised. Thank you so much for hearing my concerns.

Submitter : **Dennis Yutchishen** **Date: 06/24/2004**

Organization : **Blue Ridge Rehabilitation Associates, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am deeply concerned that the Stark II laws have the ability to lead to a conflict of interest for physicians and could lead to fraud of the Medicare system.

The Stark II self referral laws do not prevent a physician from referring patients to his/her own physical therapy practice if it is in the same building where the physician is practicing and if services are charged as incidental to his/her own medical services. This does not protect against a conflict of interest because the physician will benefit financially from the referral. If a physician refers his or her own patient to physical therapy services that he/she benefits from financially, it's a clear conflict and opens the door for abuse of the Medicare system.

Under the Stark law, a physician may bill Medicare under codes labeled ?incident to? other services instead of under a physical therapy billing code. The term "incident to" would imply that the physical therapy services being provided are "incident to" other medical services provided that day. This might make sense if a person in pain is evaluated and treated at the physician's office and part of the treatment included physical therapy for immediate pain relief. However, if continued physical therapy were needed, the patient should then be referred to an outside agency in order to avoid a conflict of interest for the physician as continued therapy would no longer be considered "incident to" the original services preformed by the physician.

Dennis Yutchishen
Physical Therapist

Submitter : **Mr. Karsten Blake** **Date: 06/24/2004**

Organization : **PTWA**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Physician referral to ancillary services such as physical therapy in which they have ownership should not be allowed. I worked in a physician owned clinic and experienced pressure from above to produce quantity of visits over quality of care. This practice avoided the Stark Laws by choosing not to treat Medicare patients in their medical practice as well as in there physical therapy clinic. It appears that if allowed to continue, Medicare patients may have fewer treatment options. I also heard from patients that they were strongly encouraged to go to the physician's physical therapy clinic over other physical therapy clinics that were closer to that patients home and work. Financial gain is definately a factor in these decisions as physicians attempt to diversify their income base as costs of insurance and overhead increase. I'm opposed to physician ownership of ancillary services. The potential for abuse is present.

Submitter : **Mr. Kevin McAnaney** **Date: 06/24/2004**

Organization : **Law Offices of Kevin McAnaney**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

The exception for ?in office ancillaries? should be tightened up. First, the regulation should require on-site supervision of ancillary services regardless of CMS billing requirements. The in office ancillary exception was intended to be limited to services that were required as ?stat? type services, such as some lab tests and x-rays. The current provisions, especially since CMS changed the reassignment rules to permit independent contractors to bill through groups for off-site services substantially expands the market for services that can be provided ?in office.? Supervision of ?in office ancillaries? by off-site independent contractors should not be permitted. Second, CMS needs to revisit the ?shared facility? in the same building. I have heard of hospitals and developers of medical office buildings developing new MOBs to include all varieties of diagnostic and imaging equipment. I cannot believe that CMS intended that result. The shared facility exception should be limited to certain kinds of lab or imaging equipment necessary to a practice on a stat basis.

CMS should also clarify when a physician ?personally provides? DME such that there is no ?referral.? I assume the physician must do more than personally hand it to the patient.

3. Group Practice Definition

CMS should both extend the ?stand in shoes? doctrine to physicians and group practices with which they practice and make it mandatory rather than elective. This would simplify application of the regulations and limit the use of the group practice as a shield to qualify for the more lenient indirect compensation treatment.

1. Financial Relationship-Definition

The indirect compensation definition should be tightened up. First, there should be a requirement that the payment from the DHS entity to the next link be fair market value for the services provided. For example, some lawyers argue that the physician recruitment exception can be circumvented by paying the fees directly to the medical group, notwithstanding CMS?s position that recruitment has no value to the hospital which would make the payment essentially a gift. Second, the knowledge element in the indirect compensation definition should be deemed met in any case that the DHS entity or the physicians or their representatives intentionally structure an arrangement to avoid requirements of an otherwise applicable exception. (Such restructuring should also preclude qualifying for the indirect compensation exception.) The indirect compensation definition and exception should be a protection against inadvertent, unforeseen, but harmless conduct.

CMS should clarify when a physician may hold an investment in a retirement plan. There are anecdotal reports of attorneys advising physicians to invest in DHS entities using their retirement plans. I don?t believe that is what CMS meant.

CMS should revisit the definition of ownership of a DHS entity. Many attorneys are counseling clients to invest indirectly in DHS entities by leasing or renting space or equipment or managing the DHS entity. One alternative would be to treat as a DHS ownership interest any investment interest in an entity that generates some percentage (50%) of revenues from services to DHS entities.

Issues 11-20

11. Physician Recruitment Exception

The recruitment exception should be liberalized to recognize that satisfying either the 75% new patient test or the 25 mile test should itself be sufficient to constitute ?relocation to the geographic area.? In addition, if those tests are met, I don?t see why the physician could not already be a member of the medical staff. The two tests seem sufficient to protect against abuse.

13. Definitions

Nuclear imaging should be a DHS service. CMS lost its view of the forest. These services are as much imaging services as ultrasound and the radiology services and are more and more interchangeable. The notable failure to include these services, especially PET scans, in DHS has led to numerous schemes to market the devices to referral sources.

Submitter : **Ms. Mary C. Sinnott, PT** **Date: 06/24/2004**

Organization : **Ms. Mary C. Sinnott, PT**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter. Thank you.

CMS-1810-IFC-414-Attach-1.doc

Mary C. Sinnott, PT
66 East Plumstead Avenue
Lansdowne, PA 19050-1432
msinnott@temple.edu

June 24, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am writing to you to offer comments on the March 26th interim final rule on "Physician Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II). As a practicing physical therapist, associate professor of Physical Therapy, and current president of the American Physical Therapy Association's Health Policy and Administration Section, my comments communicate significant concern about the loopholes in the current phase II Stark II regulations that allow physicians to own and refer to physical therapy practices.

Health care costs are on the rise again in the United States despite the fact that our outcomes do not justify the increased spending on health care services. In one of its reports the Office of the Inspector General provided evidence that physician-owned physical therapy practices demonstrated higher costs and higher utilization rates when compared with non-physician owned practices. There is also evidence in the health policy literature that physicians, challenged by high malpractice insurance premiums, are choosing to open other "health care product lines" to supplement incomes otherwise unrealized. As long as third party payer systems tie a physician referral to reimbursable services, the physician can control the flow of patients or clients to selected physical therapy providers. This compromises the patient's right to choose their health care provider. In addition, this process discriminates against other physical therapy providers who are at the mercy of the current health care system referral and payment strategies.

The irony of this situation is that most physicians readily admit that they do not know what "physical therapy" is – other than a service that can be billed. I have listened to many physical therapists report that, while employed by a physician-owned practice, they had to continue treating patients referred by the practice owners despite the fact that the patients had met their goals and were appropriate for discharge. I have personally notified the FBI on behalf of an APTA member to report fraudulent behave in a physician-owned practice.

Lastly, I ask that you seriously consider the financial impact of allowing physicians to bill "in-

office ancillary services" as "physical therapy". In order to practice Physical Therapy, an individual must have graduated from an accredited school, passed a licensure examination, and qualified for a license in 49 of 50 states. One of the basic tenets of licensure is protection of the public. The provision of services by non-educated or trained office personnel not only deceives the patients but also puts them at risk for harm. Physicians who bill these "services" to Medicare are out of compliance with the conditions of participation for physical therapy providers. Any and all physical therapy providers should have to meet the same conditions that exist to protect the beneficiaries and help to guarantee that qualified providers are rendering services.

In closing, thank you for your consideration of my concerns. It is my sincere hope that phase III of the Stark II reconsideration will place the well-being of beneficiaries before financial incentives of providers.

Sincerely,

Mary C. Sinnott, PT

Submitter : **Mr. Jeffrey Wright** **Date: 06/24/2004**

Organization : **St. John's Mercy, Sports and Therapy Center**

Category : **Other Practitioner**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Submitter : PT working in clinic **Date:** 06/24/2004

Organization : PT working in clinic

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing physical therapist that works in a private practice. I've noticed an increase in the number of physician owned physical therapy clinics in SW Florida. Not only does this mean a decrease in outside referrals to private practices which can be finacnially harmful to private owners, but it opens the door for potential fraud and abuse issues. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer patients to their own clinics, and often overuse or abuse those services for financial gain.

In physicians' offices physical therapy services can be performed by non-licensed and unqualified personnel. This can be dangerous to the patients being treated as well as wasteful to the Medicare program. Why are facilities such as rehab agencies and CORF's required to undergo stringent inspections, utilization review and audits by Medicare, but physician-owned clinics are not? And why are unlicensed personnel allowed to bill Medicare for physical therapy services in these types of clinics?

The loophole in the stark2 physician self-referral law needs to be addressed and corrected in order to protect the integrity of the physical therapy profession and to eliminate the incentives for utilization abuse. It harms the quality of care for patients as well as physical therapy private practioners and the Medicare system.

Thank you for considering my comments.

Submitter : **Ms. Carolyn Chanoski** **Date: 06/24/2004**

Organization : **Ms. Carolyn Chanoski**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir,

I am concerned that physician owned physical therapy practices constitute referral-for-profit. I encourage you to disallow any Medicare reimbursement for this fianacial arrangement between physicians and therapists.

Sincerely,

Carolyn Chanoski, PT

Submitter : **Mr. Bruce Stockburger** **Date: 06/24/2004**

Organization : **Gentry Locke Rakes & Moore**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

June 24, 2004

Direct Dial: (540) 983-9366

bruce_stockburger@gentrylocke.com

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

Re: File Code CMS-1810-IFC
Physician Recruitment Exception (Section 1877(e)(5) of the Act; Phase II; Section 411.357(e)

Dear Madams & Sirs:

As health law practitioners, we write to comment on the above-referenced section of the Interim Final Rule relating to Physician Recruitment. We direct our comments to two specific provisions which need to be reconsidered from our perspective.

I. Income Guarantee by a Hospital Under Interim Final Rule ? The Phase II regulations indicate that in the case of an income guarantee made by the hospital to a physician who joins a group practice, the costs allocated by the group practice to the recruited physician may not exceed the ?actual additional incremental costs? to the practice attributable to the recruited physician. From our standpoint, the ability for any hospital or group practice to comply with this requirement is completely unlikely, impractical, if not impossible. Taken literally, this language requires an absurd result. For example, if a hospital and existing cardiology group practice recruits an interventional cardiologist and the practice was able to accommodate the additional physician within its existing physical premises, we interpret the literal result to be that no items of expense related to rent utilities, premises insurance, etc., would be attributable to the new physician since all of these expenses were being paid prior to the arrival of the recruited physician. In a real world, this makes absolutely no sense. If you use a large multi-specialty group practice as another example, where traditionally the expense of the operating of the group practice is allocated on the basis of full-time physician employees, the addition of one new physician may not cause any incremental cost directly tied to the recruited physician. To take that position would ignore reality. If the group practice had a nurse with more capacity as a result of a physician collapsing from a heart attack, and recruited a replacement physician...again, no incremental additional expense, and again... no common sense result. We would agree that it makes sense to require the expenses to be allocated to the new physician on an objective basis. To require a literal accounting for the dollar amount of incremental costs will require absurdly burdensome efforts. The results are predictable and discussed below.

II. Non-Compete Agreements -- In many group practices, the interests of the group practice to protect its enterprise value leads many groups to include non-competition agreements in employment agreements with its physicians. Under the existing recruitment protocol, when a hospital assists in the recruitment expenses of a physician to a group practice, it is normal for the group practice to guarantee the repayment of the hospital?s financial assistance if the individual physician leaves the practice area before a period certain. The Phase II regulations prohibit this arrangement if a non-competition provision is included in the physician employment agreement. In many market areas, multi-specialty group practices are very important parts of the health care delivery system and are very logical places for a recruited physician to begin a practice. The group practice sets up a physician, creates a busy practice from group referrals, undertakes the financial outlay (including capital outlays for additional equipment in many cases) during the period it takes to ramp up the practice. If the group practice is not allowed to protect its interest by utilizing a non-compete agreement, there is very little financial and practical incentive to undertake the recruitment. Group practices have historically been leaders

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a licensed physical therapist, and I spent 7 years on my education to arrive at my professional status.

I find it absurd that any physicians, including those without specific rehabilitation/physical therapy training, are allowed to direct NON-physical therapists in the arena of physical therapy. Not only is this a disservice to patients, but why should ANY insurance cover this? Also, as a licensed physical therapist, I can't (and should never)direct such unqualified personnel to perform "physical therapy." This is a waste of tax payer dollars, at least; and potentially harmful to patients, at worst.

Physical therapy is a SKILLED PROFESSION, and should not be subject to these issues. It would be unheard of for a dentist to direct an employee in general medicine to raise the dental practice income. Why should physical therapy be any different? I have not even touched on the "hot topic" of the potential for fraud and abuse related to self-referral practices. Again, why should my tax dollars pay for such a system? Answer: They shouldn't.

While trying to avoid redundancy, I can't help but dwell on how offensive it is that physicians would feel the need, or have the right, to practice outside their area of expertise, all while being reimbursed by MY tax dollars.

I urge fairness and common sense on this issue. Let physicians practice in their field, and if they want to go back to school for 3 more years to become physical therapists, then, and only then should they move into my field of expertise.

Thank you very much for allowing my comments on this issue.

Submitter : **Dr. Edward Holliger** **Date: 06/24/2004**

Organization : **Resurgens**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

In office PT is benefical for patient convenience as well as PT/physician communication. Therapy is timely, and ends when treatment is complete. Earlier discharge from PT happens more in our PT than an outlying units where therapy goes on script expires.

Submitter : **Mr. Lynn Garrison** **Date: 06/24/2004**

Organization : **Mr. Lynn Garrison**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir,
I am concerned about the Stark amendment proposal to allow physicans to own physical theray practices. If physicians are allowed to own a physical therapy practice the physicans would have the incentive to refer every patient that they could to their physical therapy practice. In that case the physicians may refer patients who really don't need physical therapy and the Medicare program would be paying for unnecessary care. As a result, I would encourage the Medicare program to implement regulations that would disallow Medicare reimbursement for physician owned physical therapy practices.
Lynn Garrison

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am a physical therapist and owner of a private physical therapy practice. I have been a PT for 10 years. We provide quality cost effective physical therapy to our patients. Our ability to do so is threatened by the March 26 interim final rule.

I am writing to comment on the March 26 interim final rule on ?Physicians? Referrals to Health Care Entities in Which They Have Financial Relationships (Phase II).? I would like to express my concerns about the interim final rule and ask that they be addressed and corrected in the subsequent ?phase III? regulations.

The potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. This situation regarding physical therapy is compounded by Medicare?s requirement for a physician referral in order for beneficiaries to receive physical therapy services. Physicians owning 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 worked for a corporate owned physical therapy practice previously that had a contractual arrangement to provide physical therapy services within a physician?s office. I left this position due to being encouraged strongly by the physician to over utilize modalities for patients beyond what was medically necessary. Recently, the only orthopedic practice in our city brought physical therapy services in house. I understand that there is only one physical therapist on staff in an office of over 10 doctors. I don?t see how this therapist could handle this load without seeing many patients at a time. I would be interested to know how they are billing for these services, whether the group code is being used or if they are charging for one on one care of a therapist that the patients are not likely getting. There is no incentive for the therapists in a physician owned practice to remain competitive regarding their knowledge and skills as they have a guaranteed referral source.

I would prefer to get a patient referral because I am the best therapist for that patient to go for therapy vs. financial incentive of the MD. I also believe that MD should refer patients for therapy because they need it, again not for their financial gain.

Competition is a good thing, resulting in better care and more choice for the patient. When a referral from a physician is required for physical therapy and the physicians have financial incentive to provide in house physical therapy, this creates an unfair playing field. The private practitioner, who by current statistics provides better outcomes and more cost effective care than any other setting, is at , is at a great disadvantage and may not be able to remain in practice. Often the condition in which the patient needs therapy would be better served by another therapist in the area that may specialize in treatment of the patient's condition. These patients are not being referred out to the therapists that would provide a higher level of care, as there is no financial incentive for the physician to do so.

The ?in-office ancillary services? exception is defined so broadly in the regulations that it facilitations the creation of abusive referral arrangements. The exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In physicians? offices, services are often provided by non-physical therapists and are billed under the physician?s provider number as physical therapy services. The ?in- office ancillary services? provision does nothing to prevent this practice from occurring. So-called ?physical therapy? services by unqualified personnel is harmful to the patient and a waste of $.

Submitter : **Tony Hernandez** **Date: 06/24/2004**

Organization : **Rascal Creek Physical Therapy**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

My name is Tony Hernandez and I'm a physical therapist practicing in central California. I've been in practive for over 8 years and my comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent "phase III" regulatiions.

The potential for fraud and abuse exist when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive 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.

The "in-office ancillary services" exception has created a loophole that has resulted in the expansion of physician-owned practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In these offices, services are often provided by non-physical therapist and billed under the physician's provider number as physical therapy services. The "in-office ancilary servies" provision does nothing to prevent this practice from occuring. The delivery of so called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare program.

In closing, please address and assist in correcting the subsequent "phase III" regulations. Thank you for consideraton of my comments.

Sincerely,

Tony Hernandez, MPT

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

June 24, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Physician?s Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Dr. McClellan,

I am a licensed Physical Therapist currently practicing in a small rural, non-profit, hospital in Homer, Alaska. The population of Homer is 5,000 and the service area for this hospital is 10,000. The hospital has 20 Acute Care Beds and 25 Long Term Care Beds. As a Physical Therapist I serve Acute Care, Long Term Care, Outpatient Rehabilitation, Outpatient Orthopedics, and Home Health. Of the 15 years I have practiced, the last 8 have been here. There is one Orthopedic Surgeon in our local area, and he plans on offering Physical Therapy services out of his office in the future. Currently there are two private practice physical therapy offices in addition to our rehabilitation unit here at the hospital.

I wish to comment on the above mentioned March 26 interim final rule (Phase II). I am very concerned that the potential for fraud and abuse exists in our small town if this orthopedic physician opens a physical therapy office. As you know Medicare patients are currently required to have a physician?s referral in order to receive PT. Physicians who own their own services have an inherent financial incentive to refer their patients to their own practice and to over-utilize those services for their own financial gain. Currently this MD has radiology services in his office, and hence does not refer his radiology needs elsewhere.

The ?in-office ancillary services? exception is defined so broadly in the regulations that it has fostered the creation of such abusive arrangements. This same exception has also created a loophole that has resulted in the expansion of physician-owned practices that provide PT services. Often these services are provided by non-physical therapist practitioners and billed under the physician?s provider number as PT services. This is both harmful to the patient, and wasteful use of Medicare dollars. It also ensures that the physician receives financial gain for services he did not personally provide. In short if this physician offered physical therapy in his office it would not be in the best interests of Medicare beneficiaries and would negatively impact the hospital as well.

Thank you for your consideration of this situation.

Sincerely,

K.N., PT, MS

Submitter : Lee **Date:** 06/24/2004

Organization : Lee

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

CMS-1810-IFC-425-Attach-1.pdf

June 24, 2004

Mark B McClellan, MD, PhD
Administrator
Center for Medicare and Medicaid Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dear Dr. McClellan,

My name is Lee and I am the administrator in an independently owned physical therapy practice in northern Wisconsin (zip 54501). Our clinic has been serving the people of this community for over ten years.

I wish to comment on the March 26th interim final rule on "Physician's Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)" and the impact it is having on our business. We continue to have great concern over the Phase II rules themselves let alone how they are actually put into practice.

In our society, much weight is given to the area of finance in the measurement of one's success. I do believe that most physicians have sufficient integrity to comply with the law and keep their patient's best interest in mind when referring patients to outpatient therapy. However, in today's economy and with the rapid build-out of new hospital facilities, I am concerned that there will be significant pressure for physicians to refer directly to the outpatient therapy facility in which they will reap the greatest financial reward or "guilted" to refer "in-house" to protect the investment of the duplicated services.

Over the past few years, we have heard from many patients about the abuses to which they have been subject, a number of which we have documented. These abuses range from merely not providing alternative choices for the patient's outpatient therapy options to refusal to provide a referral to any facility other than the one associated with their organization.

It is our feeling that the only way to truly eliminate this abuse is to require and strictly enforce the ownership of physical therapy services by physical therapists. Ownership by physicians and physician groups presents the strongest temptation to direct refer for direct and indirect financial gain. Likewise, ownership by a hospital organization can result in pressure on the physician to refer in exchange for access to facilities.

As indicated above, we have a number of documented abuses. We occasionally remind administrators of the physician groups about the requirement that the patient be given a list of choices. However, due to the requirement by Medicare and many insurances providers that a physician referral is currently required for coverage under their policies, we are hesitant to push the issue in fear of being left off of any list that might be provided to their patients.

Direct access to physical therapy services by trained and licensed physical therapists will decrease the problem. Tracking of incident too and investigation of the same will also help. Peer review within the APTA will also help to control abuses.

I would have liked to have put more thought into this comment and cited more hard facts. Unfortunately, a short fuse in getting this out prohibits me from doing so. Please contact us at lalappin@newnorth.net with any concern or need for explanation / extrapolation on any of the above.

Thank you for your consideration in this matter.

Submitter : **Mr. Joseph W. Rusinowski, Jr.** **Date: 06/24/2004**

Organization : **Therapeutic Resources, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

The physician ownership of physical therapy services is improper. Just as physicians can not own a pharmacy that they then could steer their patients to. They should not be allowed to do the same with referrals to their own physical therapy services. Many of these so-called physical therapy services are back office staff inappropriately and indiscrimminately applying treatment modalities to patients to run up charges, incident to the physician visit, in hopes of offsetting the cost of the office. Time and time again I hear from patients that come to me and say that the physical therapy provided by our clinic is nothing like what they recieved at the doctor's office.

CMS will be doing a tremendous disservice to the Medicare beneficiaries if they allow any physcians to own and operate physical therapy services. The patient will not recieve adequate treatment, funding will go to waste and costs will be driven up. Most of the time CMS is paying for physical therapy and it isn't even being done by a licensed physical therapist or physical therapist assistant. The plan of care developed in these offices are not by any means worthwhile other than to generate visits and billables to CMS and other third parties.

We need to wake up and realize the impropriety to this arrangement and stop it now. CMS sets the pace for all reimbursement. Please do not allow for such a bad precedent to continue.

Thank you for allowing for us to provide you with input on this issue.

Submitter : **Ms. Elizabeth Scarpelli** **Date: 06/24/2004**

Organization : **Scarpelli and Kakehashi**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Medicare Program: Physician's Referrals to Health Care Entities With Which They Have a Financial Relationship (Phase II): Interim Final Rule with Comment>
My Name is Elizabeth Scarpelli. I am a practicing physical therapist for 27 yearts. I am a Board Certified Orthopedic Clinical Specialist, a senior faculty member of the Kaiser Hayward Physical Therapy Orthopedic Physical Therapy Residency Program and a Fellow in the American Academy of Orthopedic Manual Physical Therapists. I have been a consultant for the APTA's cervical spine manual and have taught physical therapy con-ed courses throughout the US. I am co-owner of a physical therapy practice in San Francisco, CA where I treat patients.
My comments are as follows: I have seen many changes in health care delivery over 27 years of practice. None have concerned me more that this latest assault on independent physical therapists. Independent physical therapists have by their education and practice, expertise in treating musculoskeletal dysfunction. Their ability to treat patients efficiently and effectively is their weapon against this assault, but they don't have the ability to self refer patients to their clinic. Physical therapists must obtain a physician's referral to treat most insurance and all Medicare patients. It is rare that a doctor who has a financial interest in a physical therapy practice would refer a patient elsewhere. Why should he? This poses a huge conflict of interest for a number of reasons:
1. We have experienced doctors who have employed their wives, secretaries, or assistants to perform ' physical therapy.' These 'practitioners' had neither the credentials nor expertise to do so. That poses a serious risk to patient health.
2. Anyone who thinks a doctor stands over any of these 'practitioners' while they are laying their hands on a patient, instructing them in exercise, or using a modality etc. is either naive or blind. It doesn't happen. Just as a patient.
3. In the managed care arena, physician's barely have time to see their patients let alone superivse physical therapy services.
4. Physician's are not experts in delivery of physical therapy services, physical therapists are.
5. We have treated patients who have left physician owned practices and come to our office because they were unhappy with their treatment. They often commented that they initially felt compelled to go to the doctor's PT for reasons such as,'I didn't want to cross him,' 'He insisted I go there. I was afraid to say something because I thought he'd get mad,' 'I didn't want him to retaliate, he was going to be doing my surgery,' and 'I didn't want to hurt his feelings!'
6. Physician's are looking at physical therapy services as a new revenue streams in a managed care market. They would have compelling financial reasons to keep all referrals inhouse. A physician who has a financial interest in a physical therapy practice, stops the competition from flowing to the community of private practioners.
7. These private practice physical therapists compete for patients based on their expertise and efficiency in delivering services and have already suffered a loss of their referral base since the onset of Stark II. This new ' in office ancillary services' would be devastating to us as well as our patients.
8. The Florida Cost Containment Study, I believe it was around August 1991, showed that physician owned practices billed over $40 million dollars to Medicare but unfortunatley Congressman Bill Thomas bullied both the researcher, Jeanne Mitchell PHd., stating that he didn't believe her statistics, and the Congressional committee itself, to disregard the numbers.
Please do not let this injustice to patients and Physical therapists pass.

Sincerely,
Elizabeth Scarpelli, PT,OCS,FAAOMPT

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

Thank you for the opportunity to comment on Physician Self-Referral. We are a Private Out-Patient Physical Therapy Practice that has existed for 10+ years and our professional staff average over 20 years in our field. In the past, we have all worked in various settings including a Physician owned practice.

We are very concerned about the potential for fraud & abuse that exists when Physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest and several of us have witnessed it first-hand!

Like all Healthcare providers, we have seen a decline in our reimbursement rates & an increase in our expenses. Any astute business person will look for other ways to compensate for these changes & we have noticed that a lot of Physicians in our area now own Surgery Centers, MRI's, and Physical Therapy clinics in order to increase those profits.

All of these services lend themselves to fraud & abuse because historically, patients have listened to their Physicians & taken at face value what care they require. We find this particularly true with the "Geriatric population". They tend to ask fewer questions & don't generally know that they have a choice as to which facility they can attend.

Several of our Physical Therapists have worked for a Physician Owned Practice at one time and left as one realizes that one is told how & what to bill regardless of the services rendered. At one facility, charges on the HCFA were not consistent with the treatment rendered or the charges the P.T. had put down on the "billing sheet". Services were often rendered by an aide/tech & not by a Licensed Physical Therapist resulting in poor and wasteful care. And, patients were often returned to P.T. even after Discharge in a "slow month".

One of our Therapists quit the day she realized that her name and license number were attached to HCFA's even though she never treated those patients. When she brought it to the attention of the department head, they just changed it to another person's name.

Now, in private practice, we often see the Physicians refer to some clinics depending upon who gave the "biggest" gift. One Physician has asked us "What's in it for me?", never checking on the progress or quality of care for his patients.

When a Physician uses a Private Physical Therapy Practice, a patient has two professionals (the M.D. & P.T.) that can help monitor their care & answer questions or trouble-shoot. By eliminating the self-referral, the financial incentives are out of the pictures & the patient receives better care & has better outcomes.

Please address the "in-office ancillary services" exceptions as Physicians are now "getting around" these in creative ways.
Thank you for your concern to provide the best quality care for your Medicare recipents, as well as allowing them a choice to choose.

Submitter : **Dr. george cierny III** **Date: 06/24/2004**

Organization : **Resurgens Orthopaedics**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

In office Phys. Therapy allows physician confirmation of orders, on-sight patient encouragement, strengthens doctor-patient relationship, eliminates treatment errors. George Cierny, MD

Submitter : Sandra **Date:** 06/24/2004

Organization : American Physical Therapy Assoc.

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am a Physical Therapist Assistant, and I also hold a bachelor's degree. I would like to comment on the March 26 interim rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)".

Physician referral is already required in order for medicare beneficiaries to receive covered physical therapy services. When physicians own PT practices, they have a built in incentive to refer their patients to their own PT practice, and have total control over the referral process. There is a great potential for fraud and abuse with this situation.

I treat many seniors in my out-patient orthopaedic clinic. They almost invariably say that they wish to do exactly what their doctor wants, and that they want to please him/her. That tendancy among the current medicare population, would allow the physician to have a "captive", referral base, even if they do post in their office that patients have a right to choose their health care providers. If a physician refers patients to a PT practice based on their skill, professionalism and results, that is appropriate. But, to receive financial gain in that situation is morall, and professionally inappropriate!

It is also inappropriate for PT services to be provided in a physician's office by non-physical therapists. A physician is a licensed medical doctor, not a licensed physical therapist. Just as a physician has a scope of practice defined by licensing law, so does the physical therapist. It is as inappropriate for a PT to provide medical services performed by non-medical personnel within their clinic, as it is in the reverse. If a PT takes a continuing eucation course instructing in medical techniques, this does not autorize that PT to perform as a physician, or to authorize anyone else in their office to act as such. Why then would it be OK for a physician to allow an ATC, LMT or medical assistant to perform physical therapy interventions, with continuing education but no license as a PT?

Many of the referrals that I see from physicians don't present any indication that the physician actually has diagnosed the musculoskeletal problem/pathology. They read: "back pain", "shoulder & neck pain secondary to an MVA", "knee pain". Or, they say "status post RC (rotator cuff) repair, but they fail to provide a surgical report, or any specifics as to other repairs (a bicep tear for example,) that is medically necessary information for the PT to appropriately evaluate and treat the patient. I would certainly be fearful of one of those doctors providing "in-office ancillary services", when their referral actions have displayed a blatant disregard for their patient's best interest; both by their apparent inability to diagnose, and by their omission of medically necessary information pertaining to that patient!

I thank you for taking the time to consider my opinion in this matter.

Sandra

Submitter : **Date: 06/24/2004**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The introduction of POPTs facilities in our region has had a profound,negative effect on the outpatient rehabilitation centers both from a private practice and a hospital setting stand point. Staffing of hospital outpatient therapy centers are diminishing and private practice facilities are having to shut down businesses due to the unfair and unethical advantage that these physicians have who own their own outpatient rehabilitation centers. Referral for profit is supposed to be illegal based upon the original Stark Law; however, now with the Stark Law II amendment, physicians are now finding loop holes to refer their patients to their own physical therapy clinics for profit. Obviously, this is a conflict of interest and unfortunately only a few insurance companies thus far have realized the high risk of overutilization this proposes. These same insurance companies have now taken steps to not allow POPTs facilities to provide physical therapy services for their clients or not allow the POPTs facilities in network.

We know that Medicare is trying to control medical costs for their clients such as with the prior $1590 Rule. Now, with these POPTs facilities exploiting patients with insurance coverage, there is no doubt that health care costs will rise for Medicare clients. We would hope that Medicare regulations would look into the disastrous effects of allowing these physicians to refer their clients to their physical therapy centers. We have recently had a physicians group who have been a referring source to our company explain to us that by having their own physical therapy service, they would be '...making an astronomical amount of money!' Where is the concern for quality of care? These same physicians have explained to us on several instances that our quality of service was excellent. They also felt that we were '...the best physical therapists in town.' Unfortunately, they just couldn't turn down such an '...enormous amount of money.'

Medicare is the agency in which other insurance companies follow regarding reimbursement issues. We hope that Medicare will implement clear rules that will deny physicians the ability to abuse the physical therapy profession for profit. I have practiced for 12 years in the field of physical therapy and am very proud of our profession. The resurgance of POPTs facilities are not only harmful for physical therpists' jobs, but also for the long term outlook for our profession. Now is the time to take a stand against this act of abuse by the physicians. Please implement changes to stop this corruption.

Submitter : **Date: 06/24/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a physical therapist (PT) of 20 years experience, I would like to express my concerns regarding the March 26 interim final rule on the physicians referral to physical therapy practices in which they have financial interest (Phase II). For more than 12 years I worked in a successful private practice setting treating patients with back &/or chronic pain. I enjoyed a broad referral base of excellent specialists who, recognizing me as a specialist in areas many therapists preferred not to treat because of the skill level, knowledge & extensive one-on-one time required to treat these patients, invited me to speak to groups of physicians as well as multi-disciplinary groups.

In February 2004, the private practice clinic I worked in closed due to decline in patient referral over a several-year period. Referrals began to decline when a large physician-owned medical complex opened near my clinic. One physician who expressed his appreciation for the improvement he saw in the patients he referred to me called to apologize, explaining that he was obligated to support the P.T. practice services owned by the physicians (POPS=physician-owned physical therapy services) who owned the building to which he & his partners had moved their practice. Likewise, his partners sent fewer referrals. Another specialist called, stating he was extremely pleased with my work, however the physicians who sent patients to his practice required that patients needing rehabilitation be referred to the PT practice that they owned. I treat some of these MDs? patients after they responded poorly to services provided through the POPS.

I often run into former patients who express frustration that they are unable to return to me for current problems because they must receive treatment through a POPS. These patients share that they are either unaware of the right to choose &/or indicate they are apprehensive about going against their physician?s wishes. Neither time nor space will allow me to list the many instances in which patients sought treatment through me, after failing to respond to or experiencing increased symptoms in response to inappropriate in-clinic ?physical therapy? services provided by untrained staff (billed under the physician?s provider number) in a physician?s office. The provision of in-office ancillary services does nothing to protect the patient from abusive medical practices & excessive or inappropriate treatment.

I fear by continuing to allow physicians to profit from the provision of P.T. services, not only will many highly skilled physical therapists will lose their jobs & Medicare funds will continue to be wasted on services that are potentially abusive & fail to meet patient?s needs. I ask that you carefully consider these concerns, address & correct any related guidelines in the Phase III rulings. Thank you for your time.

Submitter : **Mr. Albert Armendariz** **Date: 06/25/2004**

Organization : **El Paso Physical Therapy Services**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

El Paso Physical Therapy Services
6151 Dew, Ste 300
El Paso, TX 79912
(915) 581-9606

June 24, 2004

Mark B. McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P O Box 8013
Baltimore MD 21244-8013

Subject: Medicare Program; Physician?s Referrals to Health Care Entities with which they have financial relationships (Phase II), Interim Final Rule with Comment

Dear Dr. McClellan,

We at El Paso Physical Therapy feel compelled to comment on the March 26 ruling regarding ?Physicians? referrals to Health Care entities with which they have Financial Relationships (Phase II). The interim final ruling compounds the present practice by which physicians who have inherent financial incentives to refer to practices they have invested in will do so without regard to the patient?s best interest. As private physical therapy practitioners in Texas, we have experienced the practice of self-referral for financial gain into clinics that are often poorly staffed and supervised. Patients previously treated in these facilities often comment on lacking supervision despite being convinced that they were being referred to those clinics to be better supervised and treated by persons that knew the physician?s protocols.

Under the present referral system, the majority of patient?s from practices that service ?physical therapy? are referral based on insurance type. Patients that are private pay; worker?s compensation and private insurance are often directed into entities that are physician owned. Medicare patients are referred to other facilities offering physical therapy services to avoid conflict under the present Medicare guidelines pertaining to physician self referral.

It is our experience, having been in private practice for 18 years, that the lack of specific and strict regulations to physician self-referral will lead to abuses that have a negative impact on the public welfare.

We urge that our concern be addressed in the subsequent ?Phase III? regulations

Thank you for your considerations of our comments.

Sincerely,

Albert Armendariz, P.T.
El Paso Physical Therapy Services

Submitter : **Date: 06/25/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Physician self-referrals for physical therapy services should be prohibited. I have over 13 years experience as a licensed physical therapist in a variety of settings, including private practice for nearly 6 years. I have seen numerous cases in which patients come to my office after having received 'treatment' in a doctor's office with the same cookbook treatments of hot packs, ultrasound and maybe electrical stimulation modalities. Patients often report having received months of the exact same treatment without any resulting benefit because they weren't appropriately evaluated and treated by a licensed physical therapist. But because Medicare was paying for their treatments, the patients didn't balk. They trusted their doctors to give them effective treatment without questioning the qualifications of the person(s) administering their treatments. After having received appropriate treatment from me or other physical therapists with whom the doctors had no vested interest, patients more often than not had satisfactory outcomes and usually within 12 visits. The Medicare system is strapped financially because doctors are permitted to take advantage of it, without recourse or concern for the patients welfare. Not to mention the fact that Medicare takes into consideration the lousy statistics that doctors contribute to the efficacy of the quasi-treatments that they bill for, which adversely affects the livelihood of licensed trained physical therapists who attempt to operate their own practices. Medicare has significantly reduced their reimbursements due to overutilization of such modalities by physicians' 'ancillary staff' because the outcomes for those treatments have not shown to be beneficial to the patient in the manner they were administered to the patient. Medicare then thinks that ALL physical therapy is ineffective or, at best, not worth the money paid out, because patients have not benefitted consistently when treated in physicians offices. Getting referrals from those physicians who have 'physical therapy' in their offices is nearly impossible, except for the most difficult cases, which again doesn't fairly represent the potential outcomes resulting from quality physical therapy. The most difficult cases, by their nature, require more effort and time in the way of services provided and therefore cost more. This practice makes it appear that physical therapy outside a doctor's office is more costly than that in a physician-owned physical therapy office. Furthermore, doctors do not inform the patients of their financial interest in the physical therapy services that are provided in their offices, nor do they advise the patients that they have a legal right to receive therapy at any facility of their choice. Instead, doctors simply dictate that the patient have their therapy in their office under the premise that they can keep closer tabs on the patient. That is a common practice reported by countless numbers of patients who have been through those 'treatment mills' and learned the hard way. Most of them get very angry when they learn of these injustices and borderline malpractices, and rightly so. It's time that the federal government take a closer look at who's providing physical therapy services and billing for it when a physical therapist isn't anywhere to be found in the offices providing those services. Strict regulations and penalties need to be instituted for this illicit practice of unscrupulous billing of unqualified physical therapy services. It's only hurting the patients and licensed physical therapists who have trained long and hard to give the most effective treatments in the shortest amount of time to allow patients a better quality of life.

Submitter : **Karl Gibson** **Date: 06/25/2004**

Organization : **Karl Gibson**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a practicing physical therapist, I am concerned that these regulations create an expanded opportunity for fraud and abuse by physicians who are able to refer Medicare beneficiaries to entities in which they have a financial interest. This situation is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Many years ago physician self-referral was very common, but through the efforts of our Association and the passage of the Stark bill, physicians who owned practices that provided physical therapy services came to a realization, in consultation with their attorneys, that self-referral would no longer be legal, and for the most part sold off or just closed those business entities. Now, there are numerous companies marketing to physicians to get back in the PT business and use this passive income to supplement their regular income. This is clearly not what was expected from the regulations enforcing the act. Once they create this business entity, physicians have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial gain.

I am aware of physical therapists who have been advised by physicians who referred to them that they either share revenue, or they would receive no referrals and the physician would open their own service. When the therapist refused, the referrals ended.

Additionally, the 'in-office ancillary services' exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements or the expansion of existing ones. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices, and almost invariably a patient who has faith in their physician will go for whatever service is recommended and wherever the physician directs them to go.

In many of these cases, the physicians' offices are actually providing services by non-physical therapists and billing under the physician's provider number as physical therapy services. The 'in-office ancillary services' provision does nothing to prevent this practice from occurring. The delivery of so-called 'physical therapy' services by unqualified personnel is harmful to the patient and wasteful to the Medicare program, as it is often lower level palliative services that are not likely to efficiently and effectively achieve the outcomes desired by the patient.

I urge you to consider these issues as you proceed through the process of approval of these regulations. Thank you for the opportunity to comment.

Submitter : **Date: 06/25/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule with Comment

Dir Sir,

I have been working as a physical therapist for 1 year in the private outpatient orthopedic setting. I am writing to you today to comment on the March 26 interim final rule on ?Physicians? Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).? I am commenting on this ruling to report my concerns in the hope that they are addressed and corrected in the upcoming ?Phase III? regulations.

I enjoy the outpatient setting due to the improvement in the quality of life that a patient receives when provided with a high standard of physical therapy. I am very frustrated when patients report that they are provided with unsatisfactory physical therapy services by non-physical therapists simply because these ?clinicians? work in the physicians? office. I also get frustrated when I am informed of physicians who do not give patients a choice of where to receive their physical therapy services and refer them to clinics the physicians own to receive a financial gain. I feel that this impedes on a patients right to choose a clinic based on the quality of care provided.

Physician referrals to physical therapy clinics in which they have financial interest is a potentially fraudulent act. Since Medicare beneficiaries must have a physician referral to receive physical therapy services, it is evident that there is a financial incentive for physicians to send patients to physical therapy clinics that they own. These patients are referred to these clinics for financial reasons and not for the quality of care that the clinic provides. Thank you for taking the time to read my concerns.

Sincerely,

D.B, MSPT 92107

Submitter : **Mr. Andrew Moriber** **Date: 06/25/2004**

Organization : **Renal Care of Rockland, Inc.**

Category : **End-Stage Renal Disease Facility**

Issue Areas/Comments

Issues 11-20

19. Exceptions-Dialysis Drugs

We have a three page letter in PDF format which we are attempting to submit.

CMS-1810-IFC-437-Attach-1.pdf

Renal Care of Rockland, Inc.
131 Route 303
Valley Cottage, New York 10989
Telephone: 845-268-2777
E-mail: Amoriber@aol.com

June 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1810–IFC
P.O. Box 8013
Baltimore, MD 21244–8013.

Via electric submission

Subject: Comments regarding Stark II, Phase 2, regulations published 3/26/2004, Outpatient Prescription Drugs-Exceptions Dialysis Drugs
File No: CMS-1810-IFC

Dears Sirs:

On behalf of a dialysis facility whose medical staff includes physicians who hold a financial interest (as defined in the Regulations), we wish to submit these comments. Historically, physician owned dialysis facilities have been among the leaders in providing the highest quality of care. The purpose of these comments is to request changes to the regulations which will allow that history to continue, without placing a financial burden on the physician owned unit which is not placed on other dialysis facilities.

First Comment:

Intravenous Antibiotics used to treat access site infections and systemic sepsis should be added to the list of drugs excepted from the self referral prohibitions. - Our reasons are:

- Infections at the access site are not uncommon in hemodialysis patients. Intravenous antibiotics are commonly used to treat these infections.

- The actual potential profit on those antibiotics currently is not significant, and does not create an incentive to over-prescribe.

- Upon transition to acquisition cost reimbursement, beginning in 2005, there will be no financial incentive for over-utilization.

- The costs to Medicare if the facility does not furnish IV antibiotics, but refers the patient to a hospital outpatient department or home health agency, will be significant. In the dialysis facility the labor costs of drug administration are deemed included in the composite rate. In the hospital or home care setting, reimbursement will include a labor component as well as an allocation of other costs of the outpatient department or home care provider, such as rent, utilities, malpractice insurance, etc.

- The patient is already spending twelve to fifteen hours a week in dialysis and travel to and from the dialysis clinic. The burden of additional time traveling to a hospital for antibiotic therapy, waiting, and receiving the care should be considered. One of the goals of the ESRD program is rehabilitation. If the patient is spending over one half the week on their treatment, that doesn't leave much time for work or school.

- Patient comfort should be considered. Dialysis patients are already being "stuck" with large bore needles three times a week. They should not have to endure "extra" sticks. In the dialysis facility, we administer IV drugs through the medication port of the dialysis tubing, typically towards the end of the treatment.

- If the facility is able to administer antibiotics, it is in a position to assure that the ordered antibiotic regimen is (a) started timely and, (b) completed. Patients may delay or skip home healthcare treatment or outpatient hospital treatment, out of indifference or due to legitimate problems such as scheduling or transportation. Starting IV antibiotic therapy at the dialysis unit also provides the opportunity to attack these infections earlier. Early treatment is likely to be more effective than treatment which is delayed. In some instances when patients develop fever during the course of the treatment, the facility would have to discontinue treatment and send the patient to a hospital for intravenous antibiotic therapy if it could not administer the antibiotics.

  In our unit, the nephrology group which admits the great majority of our patients, usually rounded on every shift, weekdays, and most of the time on Saturdays, even before the new "G code" scheme was implemented for nephrologist payment. The dialysis facility, thus effectively became the site of primary care for most of our patients. With the G code rules in place, most dialysis clinics will probably also find that the dialysis facility will become the site of primary care for their patients. Allowing administration of these drugs in that context makes sense from the standpoint of efficient delivery of quality health care.

- If IV antibiotics are not excepted, dialysis facilities in which some or all of the medical staff has a financial interest will be forced to choose between not administering those drugs or administering and not billing. Non-administration at the facility, creates patient inconvenience since the patients will have additional encounters with the health care system. Not billing puts a financial burden on the physician owned dialysis facility, greater than the burden on other dialysis facilities. Not billing also puts the facility at risk of being accused of giving the patient a kickback ("free" drugs). Since there are almost no private pay patients in dialysis, we believe there is no kickback to the patient. Most patients do not care what their insurers pay. However there is a theoretical risk of being accused of a kickback

violation, with attendant legal expense and aggravation involved in responding to even a preliminary inquiry. If we decide not to charge, we would not mention it to the patient, unless they asked directly.

Second Comment:

A mechanism should be provided to add "new" drugs to the list of excepted drugs at the time a "J code" is issued. This could be addressed in the process through which J codes are issued. Alternatively, the listing of excepted drugs could be expanded by language creating limited exceptions for drugs issued a J code since the last update, if those drugs are approved to treat the same condition/symptoms as another drug already on the list. This should apply to dialysis drugs, as well as vaccines.

- Currently the regulations contemplate an update of the excepted drugs list, annually, as part of the Physician Fee Schedule Update. J codes may be issued at any time of the year. In the worst case a drug might be issued its J code in the month following publication of the Fee Schedule Update. That drug would not be reimbursed for as much as one year. The dialysis facility should not be forced to give "free" drugs for one year, or limit its formulary in a manner different from other dialysis facilities.

- With the anticipated change in dialysis drug reimbursement to "acquisition cost" in accordance with the Medicare Prescription Drug, Improvement and Modernization Act of 2003 the opportunity to profit by over utilization will have been removed from the system.

- We submit that there is reason to create both mechanisms. The dialysis facility owned by referring physicians should not be limited in its therapeutic options differently from other dialysis facilities. Sometimes, newer is better.

We respectfully request that you amend the regulations to address our concerns and comments.

Very truly yours,

Renal Care of Rockland, Inc.

By:
Andrew H. Moriber
Chief Executive Officer

Submitter : **Ms. Mary Beth Geiser** **Date: 06/25/2004**

Organization : **Wisc. Physical Therapy Assoc., Reimbursement Chair**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I have held the position of Reimbursement Chair for the WPTA for approximately 5 year (voluntary). I have been a practicing clinician for 14 years, many of those years have been in the field of orthopaedics and sports medicine. I feel the "in-office ancillary services" exception creates a protected pathway for physicians to abuse Medicare's payment system. I believe these regulations are too broad and not stringent enough. There is an unpoliced opportunity for physicians (who have a full or partial investment in the referring health care entitiy) to refer beneficiaries to "physical therapy" for financial gain vs. actual medical necessity. The financial incentive to earn a profit can lead to overutilization and the processing of fraudlantclaims to the Medicare system. There is potential for physicians to abuse the established "trust" their clients have in them as decision makers and bias the beneficiary to receive "physical therapy" at a health care entity to which they have a finacial investment in. It frustrates me to learn that many of these beneficiaries are unaware of the physician's finacial ties to the referring entity or are misinformed of the faciliy's ability to generate revenue for its owners.

In addition to the rapid expansion of physician-owned practices, this exception also has promoted the delivery of "physical therapy services" by unqualified personnel. A beneficiary who places trust in his/her physician and recommendations could be unknowingly coaxed to receive "physical therapy" from a facility owned by the referring physician, yet never once see an actual physical therapist. This misconception of receiving "physical therapy" is harmful to the beneficiary. It puts the client at risk for injury and can cause confusion over what is truly "skilled care." Potential injuries to the beneficiary can range from a simple muscle strain suffered during a misguided stretching exercise to a life changing event such as a crimpling low back injury (to an otherwise healthy eldery person) or fracture (to a women diagnosed osteporosis). These injuries could become realities if a the wrong intervention was adminsitered by an unskilled individual hired as an ancillary staff member to the physician.

Part of my role as WPTA's Reimbursement Chair is to educate local payers on "standards of practice." Having an aide or ancillary staff member vs. physical therapist administer medical care such as physical therapy to a beneficiary, is not an accepted "standard of practice" for our profession. Physical therapy services should be rendered by a Physical Therapist. There is no substution.

As a member of both the Wisconsin CAC and our Fiscal Intermediary -UGS Provider Outreach Advisory Committee (PCOM), I can speak from experience that there is known abuse of "physical therapy" services on a state and national level. CMS can take an active stand and begin curbing abuse and fraud in this arena. I am hoping that my comments are examined closely and all loopholes associated with this "in-office ancillary services exception" be closed.

With limited health care dollars available for physical therapy and the rising percentage of individuals utilizing the Medicare program, it frustrates me to see an enormous amount of money wasted on services rendered by a non-physical therapists. On both a national and statewide level our profession continues to educate its members on providing skilled and evidenced-based physical therapy services to Medicare benficiaries. Many states have passed local laws that protect the term "physical therapy" to avoid public harm to clients and beneficiaries seeking "physical therapy" from non-physical therapists.

I thank you for the appotunity to comment on this issue.

Submitter : **Date: 06/25/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To: Mark B. McClellan, MD,PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1810-1IFC

I would like to comment on the Medicare PRogram; Physician's referrals to health care entities with which they have financial relationships (phase II); interim final rule with comment.

I am a Physical Therapist and owner of a private practice in Anchorage, AK. I have been practicing for approximately 15 years. There are several large physician owned PT clinics in Anchorage. many I have personally seen many instances in which patients, including medicare beneficiaries, have been advised that their only PT option is the physician owned practice. Obviously there is inherent financial incentive for these physicians to refer to their own clinic, regardless of whether they believe it is in the patients' best interest to attend there. There are geographical as well as clinical (specialty and experience of outside practitioners) reasons why it may benefit the patient to go elsewhere. I have , on several occasions, been told by physicians or their patients who have requested us, that they feel practitioners at our clinic are superior in several specialty areas, yet they continue to refer those who don't request us to their own clinics. This is very frustrating for those of us who would like to compete on a fair level with other practices.
Several of these offices have PT assistants treating patients, they bill for physical therapy and the patients do not see a PT. Delivery of services by unqualified personnel is harmful to the patient, and gives them the impression that they have tried PT and it is not effective, when in fact they may have never been treated by a skilled PT.
Thank you for considering these comments.

Submitter : **Mr. Michael Danford** **Date: 06/25/2004**

Organization : **Kitsap Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have been a PT in independent private practice for over 26 years. I started on my own without any financial backing and struggled to survive for many years. Eventually, by educating physician's and the public about how PT could be beneficial, my business grew and became successful. We now have over 30 PT's at 7 locations and we encourage the PT's to become partners in the business. We routinely work with a wide variety of physicians. Over the last 2 years, 3 physician groups in our county that regularly referred patients to us have decided to hire their own PT's and open their own PT clinic. They are not doing this to provide any kind of PT service that we were not providing; they are doing it only as a source of additional revenue. They are doing it primarily to generate profit either directly to themselves or indirectly by using the PT revenue to pay some of their overhead and increase their profitability. Because of this, they often hire less experienced PT's, do not invest as much in PT equipment, do not pay as well, and do not offer as many career advancement opportunities as PT owned clinics do. They are not opening these to better serve the public's interest; they are doing this to make more money for themselves.

I would like to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." My comments are intended to raise concerns about the interim final rule and ask that they be addressed and corrected in the subsequent "phase III" regulations.

My main point is that the potential for fraud and abuse exists when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. The situation affecting physical therapy is compounded by Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons.

-As an independent clinic, we are constantly under pressure to provide as effective a treatment program as possible and keep costs down or the physician will not continue sending the patient. The physician owned clinic has exactly the opposite incentive. There is no check and balance; they benefit from having the patient need more PT sessions. I see it happen repeatedly that patients are allowed to continue much longer at the physician owned clinic than at an independent clinic.

-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 practices that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

-Additionally, in physicians offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. The PT profession has gone to great lengths over the last 10-20 years to raise the accademic level of new PT's. We want to be more cost effective providing care, but allowing this abuse in the name of "physical therapy" is wrong. It is resulting in a much lower standard of care, it is hurting real PT clinics, and the only ones that are benefiting are the physicians. There is no way to compete with this.

Thank you for consideration of my comments.

Submitter : **Ms. Kendall Alway** **Date: 06/25/2004**

Organization : **Ms. Kendall Alway**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist (PT) who has been working at a PT owned clinic for two and a half years. Several physician-owned physical therapy clinics have recently been opened in the area. Independent physical therapy clinics have been hurt by physician-owned PT practices. I have noticed that the my clinic (which is PT owned), has seen an overall drop in the number of referrals from physicians who have newly opened their own PT clinics. However, our clinic still gets the 'difficult referrals' on more complex patients from these same physicians. I am at a loss to explain this unless it is because the physician ultimately feels that a clinic owned by PT's is providing more skilled service. If this is the case, why isn't the physician referring all of their patients to us? It must be the financial incentive, and their patient's care must be suffering.

I believe that the experts in physical therapy should control physical therapy. The experts in this case are not physicians. Referrals to physician-owned PT clinics are in essense coming from the physician to the same physician's financial investment, opening the door to unintended abuse very, very, wide.

Because physicians often do not know exactly what we do or what our skill level is, they may feel free to use the 'in-office ancillary services' exception to use unqualfied staff to 'exercise the patients' instead of actual skilled care. An example of this is the use of unskilled PT aides in the treatment of patients. PT's are the only providers qualified to administer skilled physical therapy services, based on the physical therapy diagnosis (which is often different from the physician's diagnosis) for the entire duration of the care.

Thank you for allowing me to comment on this important issue.

Submitter : **Dr. Michael Shoemaker** **Date: 06/25/2004**

Organization : **Michigan Phydical Therapy Association**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a physical therapist, I am writing in response to the March 26 interim final rule of the Physician's Referrals to Health Care Entities With Which They Have A Financial Relationships (Phase II). Please consider these comments before implementing phase III.

The issue of physician ancillary services, self-referral, and physician ownership of physical therapy practices is several separate but related issues, but in all cases there is great concern for abuse/fraud, poor quality care, and limited consumer choice.

CMS should consider redefining 'physical therapy' as that service which is provided by a licensed physical therapist. When 'physical therapy' services are provided as an ancillary service in a physician office, it is often provided with poor supervision and by relatively unskilled, untrained personal such as massage therapists. If physicians would like to provide services/procedures that fall within the 97000 series of the CPT codes, they should be allowed to do so. HOWEVER, that service should NOT be called 'physical therapy.' It is erroneous to believe that anyone who is not trained and licensed as a physical therapist can provide physical therapy. When in-office ancillary services are provided in a physician office as 'physical therapy' by non-physical therapists, consumers are lead to believe they are being treated by physical therapists, when in reality they are receiving substandard rehabilitation care and have not been given any choice where to receive this care.

Another arrangement of concern is that of physician ownership of physical therapy services, whereby a physician or group of physicians owns a physical therapy practice. While this legislation attempts to address arrangement, the scope of the legislation is much too narrow and allows too many exceptions. There is obvious concern when there is a strong financial incentive for physicians to refer patients to their own entities (limiting consumer choice) and a temptation to overutilize services. Additionally, a broader question exists as to whether it is even appropriate for a physician to own a physical therapist practice. In some states, professional corporation law prohibits such arrangements.

Finally, another related arrangement of concern is the scenario where a physician practice employs physical therapists to provide physical therapy as a part of their practice. While this is more desirable than having non-physical therapists provide care, the concerns for inappropriate referral, overutilization, and limited consumer choice still exist. At minimum, physicians should be required to disclose their financial interest to patients and should be required to provide patients with an unpressured choice for where to go to receive physical therapy.

In summary, any of the arrangements described above all jeopardize the quality of care and choice that Medicare beneficiaries receive related to physical therapy. Additionally, these arrangements result in increased cost to the Medicare program due to poor quality and overutilization of services.

Thank you consideration of these comments.

Sincerely,

Michael J. Shoemaker, PT, DPT, GCS
Co-Chair, Federal and State Legislative Affairs Committee
Michigan Physical Therapy Association

Submitter : **Dr. Keith Osborn** **Date: 06/25/2004**

Organization : **Resurgens,P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

In-office physical therapy promotes close contact between the surgeon who performed the procedure or diagnosed the patients problem and the therapist performing the rehabilitation instruction. Patients make faster progress with fewer setbacks and are generally happier with their care. Having been involved with both alternatives over the past 17 years of spine practice, in-office PT has been the most effective and reliable at the lowest cost to the patient.

Submitter : **Mr. Patrick J. Monahan II** **Date: 06/25/2004**

Organization : **Connecticut Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter

CMS-1810-IFC-444-Attach-1.pdf

CONNECTICUT HOSPITAL ASSOCIATION

June 25, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1810-IFC – Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) *(69 Federal Register 16054)*

Dear Dr. McClellan:

The Connecticut Hospital Association, on behalf of its members, appreciates the opportunity to comment on Phase II of the Centers for Medicare and Medicaid Services' (CMS) final rule on physicians' referrals to healthcare entities with which they have financial relationships (Phase II). We support many of the regulatory modifications implemented by CMS in Phase II, and applaud CMS's efforts to provide appropriate exceptions. Several issues remain problematic.

Below we have outlined our most significant concerns with the Phase II rulemaking and make related suggestions. In general, these concerns relate to: 1) the exceptions for recruitment and retention; 2) issues involving the strict liability nature of the Stark Law and the possible imposition of sanctions that are disproportionate to the noncompliance; and 3) the exception for remuneration unrelated to DHS.

Physician Recruitment Exception

The ability to recruit physicians to practice medicine in particular geographic areas is of critical importance to hospitals in meeting the healthcare needs of their communities. Hospitals typically conduct community needs assessments on a periodic basis, looking at both short-term and long-term needs.

In today's environment, the predominant practice setting for physicians is a group practice. As CMS recognized in the preamble to the new regulation, "many new or relocating physicians prefer to join existing practices rather than set up a new practice for legitimate reasons." A group, rather than solo practice, offers the recruited physician mentoring, professional education, back-up coverage, and economies of scale.

Phase II made significant modifications to the physician recruitment exception. We agree with the clarification that relocation of a physician's medical practice is more relevant than the physician's residence, and we also support CMS's decision to exclude residents and new physicians from the relocation requirement.

However, we have concerns about certain requirements included in the provision for recruitment payments made through an existing practice. Specifically, the new provisions on income guarantees and practice restrictions (*i.e.*, non-compete agreements) present problems with respect to hospital recruiting efforts. Our primary concerns relate to the application of these new provisions to existing arrangements entered into in good faith reliance on the law and guidance at that time, and the potential inability in some areas to meet community need.

Income Guarantees

The relevant new provision in Phase II states: "In the case of an income guarantee made by the hospital to a recruited physician who joins a physician or physician practice, the costs allocated by the physician or physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician."

This requirement presents a significant obstacle for hospitals and group practices that wish to jointly recruit. As a practical matter, it would be very difficult, if not impossible, to track "actual additional incremental costs" attributable to the recruited physician with any degree of precision. This rule would impose an unnecessary and serious administrative and accounting burden that many physician practices are not equipped to handle. Under a literal reading of the rule, groups would be required not only to measure easily identifiable incremental costs (such as additional staff or equipment), but also such details as additional supply costs and staff overtime that are attributable to the recruited physician. Moreover, without specific standards for measuring incremental costs, a group's calculation methodology invariably would be open to question (and methodologies undoubtedly would vary from group to group). In light of the strict liability nature and enormous penalties associated with the Stark Law, the Phase II requirement leaves physicians and healthcare entities vulnerable to potential liability despite their best intentions to comply.

Permitting groups to allocate costs on a pro-rated basis among the total number of FTE physicians in the group is a fair, equitable, and practical way of solving this issue. This type of proportional allocation is used today by group practices, and it would be difficult to imagine a situation in which proportional allocation would result in the kind of abusive cost-shifting about which CMS is concerned.

Practice Restrictions

The relevant new provision in Phase II states: "The physician or physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to the quality of care." The preamble indicates that practice restrictions include non-compete agreements.

This provision raises significant concerns. First, other than non-compete agreements, it is unclear what would qualify as a "practice restriction" for purposes of this rule. For example, it is unclear how the following types of provisions would be treated under the regulation since they could be viewed as not affecting a practice's quality of care: 1) a "no moonlighting" provision that applies while the physician is an employee of the group; 2) a prohibition on soliciting patients of the group; and 3) a prohibition on soliciting employees of the group. The lack of specificity in the rule makes it impractical and puts hospitals and physicians at unreasonable risk of violating the law.

Perhaps more importantly, the use of non-compete agreements is a standard, legitimate business practice in many communities. The threat of competition from the recruited physician may well present a real business concern for the existing group. If non-compete agreements were to be prohibited, then hospitals in some areas could have a very difficult time convincing groups to help them recruit needed physicians. If existing groups are not willing to take on new physicians without the safety of a non-compete, then hospitals could find themselves unable to attract new physicians, and certain healthcare needs of their surrounding communities could go unmet. The reality of physician employment agreements is that they typically include non-compete agreements (negotiated by the parties for legitimate business reasons), and for CMS to deny that contractual right in this context could severely limit the utility of this exception (and thereby curtail important recruiting activities).

This is a particular problem in the context of existing arrangements. A great number of hospitals, groups, and recruited physicians have entered into arrangements that include non-competes. Relying in good faith on the statute and existing CMS guidance, the parties typically assumed that such provisions would not present a problem under the Stark Law. Requiring groups to renegotiate, amend, or terminate these agreements would be highly disruptive and problematic. First, hospitals may not be party to agreements between groups and recruited physicians, and therefore have limited ability to affect (or even to know the details of) those arrangements. Further, existing noncompete provisions may contain certain "safeguards" that are worth noting. For instance, many noncompete provisions include reasonable geographic limits associated with the practice restrictions. Also, some of the arrangements require the group to reimburse the hospital for payments made under income guarantee provisions in instances where a group exercises the noncompete.

Finally, in cases where groups declined to revise their agreements to comply with the new regulatory requirements, hospitals would be in the difficult position of either: 1) continuing to fund recruitment arrangements that do not comply with the regulation; or 2) ceasing the funding and risking a breach of contract suit from the group and/or recruited physician.

Geographic Area

Another area of concern in this exception involves the new regulatory definition of the hospital's geographic area. The relevant provision in Phase II states: "The 'geographic area served by the hospital' is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients."

We have two primary concerns with this new requirement. The requirement could prevent hospitals from recruiting into "outreach areas" (areas outside of the new definition of geographic area, but still within the hospital's service area), where the community need for physicians may be greater than in areas closer to the hospital. Other sites not proximate to the hospital may be the ones most affected by this new restriction. Often it is these "outreach areas" that have the greatest need for additional physicians.

Our other concern involves the application of this provision to existing arrangements that do not meet the new definition. For hospitals that have recruited physicians into what was reasonably considered to be the hospital's geographic area, but where such area does not qualify under the Phase II definition, the parties' options are limited and include: 1) requiring the physician to relocate (again) into

the defined geographic area; or 2) terminating the arrangement. Either of these options could have negative effects on the community's healthcare needs. For instance, the requirement could result in moving physicians away from areas where they are currently serving patients and meeting a community need. As long as the arrangement satisfied the requirements of this exception that were in place at the time of the recruitment agreement, the parties should not be forced to make either of the choices noted above.

Requested Action

For the reasons outlined above, we urge CMS to amend the exception for recruitment by: 1) revising the provision at §411.357(e)(4)(iii) to permit pro-rated allocation of costs among FTE physicians in the group; 2) deleting the provision at §411.357(e)(4)(vi) relating to practice restrictions; and 3) deleting the definition of geographic area at §411.357(e)(2).

Alternatively, we ask that CMS take steps to ensure that existing arrangements, which the parties entered in good faith relying on the statute and prior CMS guidance, are not disrupted. At a minimum, CMS should permit existing arrangements to run their course or be permitted until a specific period of time, and it should not take into account the new requirements when assessing compliance with such existing arrangements.

We ask that CMS make clear that the new requirements in the physician recruitment exception will, under no circumstance, apply to arrangements that meet all of the following criteria:

1) the existing agreement is set forth in writing and was executed prior to March 26, 2004;

2) the terms of the existing agreement reflect a good faith reliance on prior guidance from CMS regarding recruitment arrangements;

3) the recruited physician has relocated and started work pursuant to the recruitment agreement; and

4) the payment, guarantee, and/or loan forgiveness aspects of the agreement will be in effect no longer than four [4] years from the effective date of the agreement.

If the regulation were to be implemented as currently drafted, hospitals would find many of their arrangements to be outside of the exception, despite having entered into such arrangements based on a good faith reliance on the law and CMS guidance that existed at the time. This result is contrary to good public policy and past practice.

Exception for Retention Payments in Underserved Areas

We support the inclusion of an exception for certain retention payments by hospitals and federally qualified health centers. However, we are concerned that one of the requirements of this exception would greatly restrict its utility. Specifically, §411.357(t)(1)(iii) requires that the physician have a "bona fide firm, written recruitment offer from [another] hospital or federally qualified health center." In practice, hospitals often do not provide written recruitment offers to physicians. We urge

CMS to amend the requirement in the provision cited above. Specifically, we recommend that CMS delete the word "written" from the provision. With that modification, the provision still would require the existence of a bona fide offer, but the offer could be either verbal or written.

In addition, we urge CMS to revise the requirement that the hospital be located in a HPSA. As discussed above in the section on recruitment, outreach areas often have the greatest need to retain or recruit physicians. Whether the hospital itself is located within a HPSA should not be the relevant factor; the more important issue is whether the physician is located in an underserved area. We ask CMS to revise this requirement accordingly.

Disproportionate Penalties (and Related Issues)

The strict liability nature of the Stark Law can lead to disproportionate penalties, potentially imposing significant liability for even minor or technical violations. For instance, a personal services agreement between a hospital and a physician for $500 (*e.g.*, for consulting services), if unsigned or otherwise not in compliance with every technical requirement of an exception, could result in an obligation by the hospital to repay the total value of all services furnished to patients admitted or referred to the hospital by the contracting physician. The issues discussed below relate generally to the concerns caused by this unfortunate aspect of the law.

Exception for Temporary Noncompliance

We are pleased that CMS has addressed this issue, to a certain extent, with the new exception for certain arrangements involving temporary non-compliance. However, we have concerns about the strict limitations on its applicability as currently drafted. First, non-compliance must result from "reasons beyond the control of the entity." This phrase is unclear, and the examples provided in the preamble (including the conversion of publicly-traded companies to private ownership and the loss of rural or HPSA designation) are highly unusual.

Further, according to the rule, the problem must be rectified within 90 days of the date on which the arrangement became noncompliant with an exception. We agree that 90 days is a reasonable period of time, but for the exception to have any significant value for providers, the relevant starting point must be the date on which the noncompliance was discovered (or reasonably should have been discovered).

Although this exception is encouraging, to have its intended impact, we request that CMS delete the requirement that noncompliance result from reasons beyond the control of the entity, and that the 90-day cure period begin on the date that noncompliance is discovered.

Compliance with Antikickback Law

There is no reason for CMS to expressly require compliance with the antikickback law for purposes of the Stark Law.

Significantly, by including this requirement, CMS effectively negates the "bright line" nature of the tests that it otherwise tried to achieve in Phase II. The antikickback law is an intent-based statute, and interposing this degree of subjectivity in the Stark regulations potentially leaves physicians and health care entities with a great deal of uncertainty about their compliance under the Stark Law. We

strongly urge CMS to remove the references to the antikickback law as an element of the regulatory exceptions.

Exception for Remuneration Unrelated to DHS

In Phase II, CMS significantly narrowed the scope of this exception. The preamble commentary even withdrew the prior interpretation that general administrative or utilization review services are not related to DHS (as stated in the 1998 proposed rule preamble). CMS apparently based its revised reading of the rule at least in part on the expansion of the Stark Law in 1995 from clinical laboratory services to "designated health services," including all hospital services. If such a reading were necessitated by the statutory history, then presumably CMS would have adopted this narrow interpretation in the proposed rule in 1998. Also, when Congress expanded the Stark Law in 1995, it specifically retained this exception. Clearly, Congress could have decided to delete the provision if it had so chosen. Although the provision remains in the statute, CMS has narrowed the rule so extensively in Phase II as to make it of questionable utility.

We strongly urge CMS to reconsider its position on this exception. Specifically, we recommend that CMS adopt the interpretation taken in the 1998 proposed rule, including the examples included in the preamble to that rule. At the very least, we ask CMS to provide additional examples of when this exception could apply.

Conclusion

CHA appreciates the opportunity to comment on the Phase II interim final rule. Thank you for your consideration of these comments. If you or your staff have any questions regarding CHA's comments please contact me at (203) 294-7285 or at monahan@chime.org.

Sincerely,

Patrick J. Monahan II
General Counsel and Vice President, Patient Care Regulation

PJM:ljs
By e-mail and mail

Submitter : **Dr. John D'Avella** **Date: 06/25/2004**

Organization : **Hartford Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am a Medical Director of an inner city dialysis unit. I am responsible for the indirect care of 180 hemodialysis patients and 40 peritoneal patients. If anything goes wrong I am responsible. My title not the primary nephrologist is on all state and federal statutes. The responsibility and liability is huge. I am responsible for all compliance issues, all quality issues, all unit protocals,all technical issues and technical staff, all reporting to the network,state and federal inquires and semi annual care plans on all patients and acute care reviews on all unstable patients.In addition I get the opportunity to be on call for all medical director issues including patient disasters, water issues,technical issues, MD/unit issues and infectious issues among other issues 24hours/7days/365days a year. To reduce this to an job paid by the hour or to average out the pay scale is unfair and will have a negative impact on the quality of patient care. If a primary nephrologist does not do his/her job in puts individual patients at risk. If a medical director does not do his/her job the whole unit population is at risk. John D'Avella MD

Submitter : **Mr. Britt Smith** **Date: 06/25/2004**

Organization : **SOAR Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a private practice physical therapist who has lived through the first blush of physician owned physical therapy services(POPTS). I have practiced for 23 years in hospital based physical therapy services and private practices. I am currently the owner of SOAR Physical Therapy in Grand Junction, CO. I was in a private practice in Oakland, CA, from 1987-1994. When we opened our practice every orthopaedic physician group i the East Bay owned their own physical therapy service. We only received orthopaedic referral from outside of our geographical region, despite being an excellent group of physical therapists. We served Michael Dillingham MD (team physician for the 49 ers), Art White MD and his group at Spinecare in Daly City, Brad Delong MD, neurosurgeon in San Francisco and many more, when they had clients in Berkeley or Oakland; however, we didn't receive a single referral from Berkeley Orthopaedics or any of the other orthopaedists in our area. Steve Isono MD, an orthopaedist who served the US Olympic Committee, broke the trend when he moved to Albany, CA. Steve strongly believed that POPTS were unethical and he supported independent physical therapy practices. He appreciated the service, time and expertise we gave to each client.
For example:
Our clinic opened across the street from a major sports medicine POPTS owned by 2 orthopaedic groups. The chief PT at the clinic came by our clinic one day after we opened. He said he saw between 35-40 patients a day, himself, and he and the 2 other PTs saw 90+ patients a day. You do the math...they weren't providing individualized care. The PTs at our clinic would see patients every 30-45 minutes through the day (14-16 patients a day). My experience with POPTS is that they are 'focus factories' for the physicians. The need to crank patients through their facility is driven by minimizing cost and maximizing their income.
Theoretically, a POPTS could be the best situation for the patient because of easy communication and an inter-disciplinary approaches, but I don't see either happening in these situations. Everyone appears to be too busy for communication (time crunch)and I never had a patient say they saw the PT discussing their case with a physician. Furthermore, why can't physicians partner with a physical therapy group as a peer relationship and not an employer-employee relationship? Clearly, the drive to diversify revenue drives the move towards POPTS. I haven't read a serious rationale yet for the redefining of the Stark II legistation. Clearly this deal is bad for my profession, it is bad for consumers and it is bad for medicine. Thank you.

Submitter : **Date: 06/26/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist practicing in Austin, TX. I have been practicing for 5 years in various settings. Currently I work in an outpatient clinic. I have been a member of the American Physical Therapy Association (APTA) for 8 years.

The purpose of my letter is to comment on the March 26 interim final rule on "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)." I hope my comments raise concern about the final rule and I ask that they be addressed and corrected in the subsequent "phase III" regulations.

There is a huge potential for Medicare fraud when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest (physician-owned physical therapy practice). This greatly affects physical therapy practices because of Medicare's requirement of a physician referral in order for beneficiaries to receive physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial gain.

The "in-office ancillary services" exception is defined too broadly in the regulations. This broad definition will only 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 practices that provide physical therapy services. Because of the Medicare referral requirements physicians ahve a captive referral base of physical therapy patients in their office. Again, this is a huge potential for Medicare fraud.

In physicians' offices, services are often provided by non-physical therapists and billed under the physician's provider number as physical therapy services. This should be considered fraudulent billing and illegal. The "in-office ancillary services" provision does nothing to prevent this practice from occurring. The delivery of so-called "physical therapy" services by unqualified personnel is harmful to the patient and wasteful to the Medicare program. There are many techniques and modalities that if performed by an unqualified person could seriously injure a patient. Physical Therapists' are properly trained and licensed to perform these tasks without doing harm to the patient.

In closing I would like to thank you for taking the time to consider my comments. I hope they help you in changing the regulation to prevent Medicare fraud and protect all Medicare beneficiaries from harm.

Submitter : **Date: 06/26/2004**

Organization :

Category : **Occupational Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I am an employee with a large healthcare therapy provider and we participate in a management contract with an orthopedic group. I do not feel it is fair to allow the orthopedic group such a broad ability to participate in the exceptions to the ancillary services. Within our local market the orthopedic group is on the verge of creating a monopoly. Nearly the entire therapy population within our community would attend a satellite of the orthopedic group if these exceptions continue. Even the management contract would end, as well as private practitioners suffering the loss of referrals within the community. Patients typically do whatever their doctor tells them and if the MD indicates the patient should attend therapy "in-house" chances are that patient would not even exercise his ability to choose but rather would go on the recommendation of the MD. Such broadly defined exceptions are certain to impact our ability as practitioners of our art to continue without being under the jurisdiction of a physician group, theoretically defying consumer choice options, free will and free enterprise.

Submitter : **Mr. Jeremy Miller** **Date: 06/23/2004**

Organization : **Miller Health Law Group**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

Comment on Phase II Rules - File Code CMS-1810-IFC- Section VII. Additional Exceptions Related Only to Ownership or Investment Prohibition (Section 1877[d] of the Act; Phase II; Section 411.356)

CMS-1810-IFC-E1-Attach-1.doc

CMS-1810-IFC-E1-Attach-2.doc

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
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Submitter : **Mr. Barry Alexander** **Date: 06/23/2004**

Organization : **Nelson, Mullins, Riley & Scarborough**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

Attached Document Regarding Rule CMS-1810-IFC

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

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Submitter : **Ms. Jane Julian** **Date: 06/28/2004**

Organization : **Carolina Orthopaedic Surgery Associates**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

1. Financial Relationship-Definition

I am a physical therapist who is employeed by a physician group. Our financial relationship bears no effect on the treatment of patients. The patients within our group are all given choice of facilities and most are sent out due to insurance reasons. Often it is their type of insurance that dictates the facility that they can attend for therapy. As within our practice, we find that by working together our patients are treated more effectively and efficiently because we are within the same facility. There are no delays, communication is direct and the patient realizes the benefit. A physical therapist code of ethics and responsible treatment planning prohibits over utilization of services. The regulations and guidelines of CMS provide for this already.

2. In-Office Ancillary Services Exception

As a physical therapist who works directly for a physician group, I would like to comment on the benefits of our relationship. We find that there is greater service and comfort to the patient. They respond more positively to therapy and realize the benefit of a interdisciplinary approach to their care. This is especially important with orthopaedic conditions in which changes can occur daily. By working together in the same facility, there is no delay in treatment. The patient is the ultimate benefactor and we find that with care overall improved is also reduced. I urge you to continue to allow this interdisciplinary relationship to develop and support the physicians who support physical therapy. Physical therapy continues to service as a allied health field and until their educational programs change and MD is added to our name, I feel we need to continue as allied health providers.

Submitter : **Date: 06/28/2004**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 1-10

2. In-Office Ancillary Services Exception

I work in an outpatient physical therapy department in a hospital in middle tennessee. I am a physical therapist. We have an orthopaedic surgeon who works across the street and has his own physical therapist inhouse with him. We only get patients from this orthopaedic surgeon if the patient ask to be sent to us or if they are healthspring or aetna, cigna. This particular physical therapist at times has come to our department and bragged about the amount of patients he will see in one day which would exceed 4-6 an hour. We have in turn had a few patients who have been to this particular therapist at this surgeons office who complained they did not get one on one care and felt like they were in a "factory". I feel this is a detrement to physical therapy and is not in the best interest of the patients. thank you. Sussette Robinson PTOCS

Submitter : **Mr. Lorraine Ryan** **Date: 06/24/2004**

Organization : **Greater New York Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

CMS-1810-IFC Please see the attached comment letter. Hard copies will be hand delivered to CMS. Thank you for this opportunity to comment on Stark Phase II.

CMS-1810-IFC-453-Attach-1.pdf

Greater New York Hospital Association
555 West 57th Street, 15th Floor
New York, N.Y. 10019
Phone: (212) 246-7100
Fax: (212) 262-6350

Kenneth E. Raske, President

June
Twenty-four
2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21233-8013

Re: CMS-1810-IFC – Comments to "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule"

Dear Sirs:

Greater New York Hospital Association (GNYHA) is a trade association representing more than 250 not-for profit hospitals and continuing care facilities, both voluntary and public, in the metropolitan area and throughout New York State, as well as in New Jersey, Connecticut and Rhode Island. The hospital and continuing care members of GNYHA have, for years, suffered from the worst operating margins, ratios and financial indicators of hospitals anywhere in the United States. Yet, with their scarce resources, GNYHA members are nevertheless undertaking significant initiatives to ensure patient safety and improve patient care, while complying with numerous contractual, regulatory, and legal restrictions. GNYHA members often serve as the only source of primary care and related social services for their communities.

GNYHA appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services ("CMS") on the Interim Final Rule with comment period entitled "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)" published by CMS on March 26. 2004 at 69 Federal Register 16,054 *et seq.* ("Phase II") implementing Section 1877 of the Social Security Act ("Stark").

Comments on Phase II of the Stark Law

GNYHA's comments on Phase II fall into the following areas:

- Timing of Compliance with Phase II

- Coordination with the Anti-Kickback Statute
- Enforcement of Stark through the False Claims Act
- Fair Market Value Safe Harbor for Compensation Arrangements
- Physician Recruitment Exception
- Other Exceptions

Timing of Compliance with Phase II

- Phase II Compliance Date. Stark has been on the books for over 10 years, and in the interim, our members have worked hard to structure their financial arrangements to comply with Stark and the Stark regulations promulgated by CMS, many of which have only recently become final. Phase II makes numerous and substantial changes to the existing federal Stark regulations. Many of these changes bring to the Stark regulations greater clarity, practicality, and uniformity. However, other changes made by Phase II call into question arrangements entered into in good faith by GNYHA's members and other health care facilities around the country, prior to Phase II. Given these facts, and that Phase II is an Interim Final Rule with comment period (and that CMS will most likely not be able to respond to the comments it receives on Phase II prior to the July 26, 2004 compliance date), *GNYHA believes it would be appropriate and therefore requests CMS to officially "grandfather" all arrangements that existed prior to July 26, 2004, and were based on a reasonable interpretation of the then existing Stark requirements. Alternatively, GNYHA requests that CMS extend the July 26, 2004, compliance date for any arrangements that existed prior to July 26, 2004, and were rendered non-compliant by Phase II.* While not ideal, extending the compliance date would allow organizations and physicians a more appropriate period of time in which to restructure any arrangements rendered non-compliant by Phase II.

- Exception for Temporary Lapses. In Phase II, CMS added, in Section 411.353(f), an exception for certain arrangements that have satisfied any other exception for at least 180 consecutive days but have fallen out of compliance "for reasons beyond the control of the entity." This exception lasts up to 90 days and covers designated health services ("DHS") furnished during that 90-day period, so long as the DHS entity promptly takes steps to rectify the noncompliance. The exception may not be used more than once every three years with respect to referrals from the same referring physician. While CMS provided several examples of when this exception might apply, including "conversion of publicly-traded companies to private ownership; loss of rural or health professional shortage areas (HPSA) designations; or delays in obtaining fully-signed copies of renewal agreements" (69 Fed. Reg. 16,057), it is not clear in what other circumstances this exception might apply. *GNYHA would appreciate additional guidance from CMS to elucidate the application of this new exception, particularly regarding what CMS believes would appropriately constitute "reasons beyond the control of the entity."*

Coordination with the Anti-Kickback Statute

- Coordination between Anti-Kickback Safe Harbors and Stark. In Phase II, CMS created two new Stark exceptions, for referral services (under Section 411.357(q)) and obstetrical malpractice insurance subsidies (under Section 411.357(r)), tied directly to two existing safe harbors under the federal Anti-Kickback Statute ("AKS"). CMS declined, however, to incorporate any other AKS safe harbors into the Stark regulations, concluding that doing so "would be problematic." In Phase II, CMS also declined requests to create a Stark exception for any arrangement approved in an advisory opinion from the HHS Office of Inspector General ("OIG"). GNYHA is greatly concerned that the continuing lack of coordination between Stark and AKS, and between the agencies that enforce those laws, CMS and OIG, places GNYHA's members in an untenable position with respect to Stark and AKS compliance. The complexity of analysis necessary to ensure compliance with both Stark and the AKS, in addition to the requirements of, among others, similar New York State law and federal tax law, impedes our members' ability to conduct their businesses and diverts their limited resources (intellectual and financial) from more critical matters. *One reasonable way to address this situation would be for HHS to modify the AKS safe harbors to establish a new safe harbor such that an arrangement that meets a Stark exception is by definition within an AKS safe harbor. Alternatively, GNYHA asks that CMS consider how it can more closely align the Stark exceptions with the AKS safe harbors in order to make the Stark compliance burden more reasonable and better achieve CMS's stated goals.*

- Mandatory Compliance with Anti-Kickback Statute: As a condition to meeting the new Phase II regulatory exceptions, as well as the Phase I regulatory exceptions, CMS has included the requirement that the arrangement not violate the AKS. This fundamentally changes the nature of the Stark analysis, by making exceptions that CMS has repeatedly emphasized are intended to be clear, bright-line rules into exceptions subject to a difficult facts-and-circumstances analysis. GNYHA believes this is the worst of both worlds for our member institutions and other DHS entities, as they must comply with the Stark's strict liability structure, with many of the Stark exceptions conditioned upon compliance with the AKS, an intent-based law. This is made even more troublesome by the lack of coordination between CMS and OIG on the advisory opinion process, including CMS' unwillingness to rely on OIG advisory opinions as establishing compliance with Stark. Under these circumstances, and particularly because, as discussed above, CMS continues to refuse to align the Stark exceptions with the AKS safe harbors (except for the two minor safe harbors for referral services and obstetrical malpractice subsidies incorporated into new Phase II exceptions), *GNYHA believes that it is a fundamental mistake for CMS to incorporate AKS compliance into any of the Stark exceptions.*

Enforcement of Stark through the False Claims Act

While GNYHA recognizes that CMS is not solely, or even primarily, responsible for the continuing increase in claims brought against DHS entities under the False Claims Act, GNYHA

is compelled to register with CMS its deep concerns with this development. As CMS is well aware, Stark is a highly complex law that creates innumerable opportunities for violations to occur, especially given its strict liability nature. This is confirmed by the many years that CMS has taken to establish final regulations implementing Stark and the continued requests to CMS for additional exceptions and guidance. GNYHA believes that no one is well served by perpetuating a system in which the harsh remedies of the False Claims Act are available for mere inadvertent technical violations of Stark. *Thus, GNYHA suggests that CMS officially ask Congress to amend the False Claims Act to provide that a Stark violation may not give rise to liability under the False Claims Act unless the violator acts with intent to violate Stark. GNYHA also requests that in the interim, CMS work with the OIG and the U.S. Department of Justice to establish appropriate administrative protocols or other means to ensure that False Claims Act claims are brought (or, in the event of a qui tam action, joined) only when clear intent to violate Stark is believed to exist.*

Fair Market Value Safe Harbor for Compensation Arrangements

GNYHA appreciates CMS' efforts to meet its oft-stated goal of establishing clear guidelines for compliance with the Stark law and regulations, as evidenced by, among other things, the new fair market value safe harbor for hourly payments for physician services established by CMS at 42 C.F.R. Section 411.351 (definition of "fair market value"). Unfortunately, however, the two methodologies used to compute the new fair market value safe harbor (average hourly rate for emergency room physician services in the market, and 50th percentile national compensation level for the same specialty based on four of the six named surveys), will produce hourly rates that render the new safe harbor useless for GNYHA's member hospitals. The higher cost of living and doing business in areas such as the greater New York area necessarily translates into the need for hospitals and other DHS entities to compensate physicians at a higher hourly rate in order to be competitive with other areas of the country where the cost of living is less. *Accordingly, GNYHA requests that CMS modify the new fair market value hourly compensation safe harbor to appropriately take into account such regional disparities in cost of living and doing business.*

Physician Recruitment Exception

As modified by CMS in Phase II, the exception for physician recruitment arrangements presents a number of problems of interpretation and application including the following:

- Definition of "Geographic Area": Phase II defines "geographic area" as the lowest number of contiguous postal ZIP codes from which the hospital or federally-qualified health center ("FQHC") draws 75% of its inpatients. In some circumstances, particularly densely populated urban areas with many contiguous ZIP codes such as exists in the greater New York area, this standard may not yield only one possible outcome. GNYHA asks that CMS clarify that a hospital or FQHC may consider its geographic area on a case-by-case basis, and therefore may vary its geographic area depending on the particular recruitment arrangement being considered, so long as the definition is satisfied.

- Relocation Requirement. Phase II provides that a physician will be deemed to have relocated to a hospital or FQHC's geographic area if the physician has relocated the site of his practice a minimum of 25 miles. *GNYHA requests confirmation from CMS that the relocation requirement is met so long as the physician relocates his practice a minimum of 25 miles, regardless of whether the physician's practice was previously located within or outside the hospital's or FQHC's geographic area.*

- Inapplicability of the Fair Market Value Compensation Exception. In the Phase II preamble, CMS indicated that it did not believe that the exception at Section 411.357(l) for fair market value compensation applies because the relocation of a physician to a hospital's or FQHC's geographic area "is not properly viewed as a benefit to the hospital, except as a source of DHS referrals – a consideration that is antithetical to the premise of the statute." (69 Fed. Reg. 16,096). GNYHA believes that this interpretation by CMS does not appropriately take into account the many benefits that recruiting a physician to a hospital's or FQHC's geographic area offers, not the least of which is furthering the facility's charitable mission by ensuring the delivery of a wide range of quality health care services to the facility's community. This is specifically recognized by the IRS in Revenue Ruling 97-21, which notes that recruitment payments are within a tax-exempt organization's charitable purpose where there is a demonstrable community need for the services offered by the recruited physician. *Accordingly, GNYHA asks CMS to reconsider applicability of the fair market value compensation exception to physician recruitment arrangements.*

- Prohibition on Referral Restrictions. As a condition to permitting a hospital or FQHC to provide recruitment payments to a physician through another physician or physician practice, CMS has imposed the condition (in Section 411.357(e)(1)(vi)) that the physician or practice may not impose additional practice restrictions, such as a non-compete, on the recruited physician. While some states prohibit or limit the ability to restrict a physician's practice through means such as a non-compete, many other states will permit the imposition of (and will enforce) a non-compete on a physician so long as the non-compete is reasonable in scope and duration. GNYHA believes that by imposing this condition, CMS will discourage existing physicians' and physician practices' involvement in hospital-related physician recruitment because those physicians and physician practices will not be able to use non-compete provisions to protect their legitimate business interests, such as their existing relationships with patients and other health care professionals. In effect, the physician recruited by the hospital would be placed at an unfair advantage not only as compared to a physician that the physician or practice might recruit directly (without hospital involvement), but also as related to the existing member(s) of the practice who are subject to such non-compete restrictions. With existing physician practices likely to opt out, GNYHA expects the existence of this condition to hamper the ability of recruited physicians to establish functioning and thriving practices in the areas where GNYHA members are located, as it is considerably more difficult, not to mention more expensive, to start a practice from scratch than it is to join an existing practice. This will consequently diminish the desirability of relocating. *Therefore, GNYHA requests that CMS carefully consider eliminating the "no additional practice restrictions" requirement from the recruitment exception.*

- Pass Through of Recruitment Payments. The physician recruitment exception requires, among other things, that when a hospital provides recruitment assistance to a physician who joins an existing physician practice, the remuneration must be "passed directly through to or remain with the recruited physician." It is not clear from the text of the regulation or the related commentary how this requirement should be implemented. Specifically, it is not clear whether a practice may be reimbursed only for costs directly associated with the recruitment process (e.g., travel, lodging, etc.), or whether a practice also may receive and retain remuneration from a hospital under a recruitment arrangement, so long as the remuneration is paid in recognition of the practice's specific expenses directly attributable to hiring and retaining the recruited physician (e.g., salary, benefits, taxes, professional fees, etc.), during the benefit period of the recruitment arrangement. *GNYHA suggests that CMS revise the physician recruitment exception to clarify that a practice may retain remuneration received from a hospital under a recruitment arrangement, so long as the amount of such remuneration does not exceed the expenses actually incurred by the practice to recruit and employ the recruited physician.*

- Allocation of Overhead of Existing Practice. In the case of an income guarantee to a physician who joins an existing practice, the costs allocated by the practice to the recruited physician may not exceed the "actual additional incremental costs attributable to the recruited physician." 42 C.F.R. § 411.357(e)(4)(iii). Comments made by CMS representatives since the issuance of Phase II suggest that CMS interprets this provision to prohibit an existing practice from allocating to a recruited physician any expenses that existed prior to the recruited physician joining the practice. This would mean that the practice could not allocate to a recruited physician a portion of its existing overhead on, for example, a *pro rata* basis, for purposes of calculating the amount of an income guarantee. GNYHA believes that this restriction will significantly affect the ability of hospitals to coordinate physician recruitment efforts with existing practices. As noted above with respect to practice restrictions, in most instances it is more desirable for the recruited physician and more economically efficient for a hospital, to place a recruited physician with an existing practice than establish a new practice. *For the foregoing reasons, GNYHA requests that CMS revise this section to permit an existing practice, when calculating the recruited physician's income for purposes of an income guarantee, to allocate a portion of its overhead expenses to a newly recruited physician on the basis of a formula applicable to the other physicians in the practice.*

Other Exceptions

- Rental of Office Space and Equipment. The so-called "exclusive use test" is an element of both the rental of office space exception at Section 411.357(a) and the rental of equipment exception at Section 411.357(b). In Phase II, CMS changed these exceptions so that the exclusive use test will be considered met as long as the lessee (or sublessee) does not share the rented space or equipment with the lessor "or any person or entity related to the lessor." In the preamble, CMS noted that "any person or entity related to the lessor" "include[s], but [is] not limited to, group practices, group practice physicians,

or other providers owned or operated by the lessor." (69 Fed. Reg. 16,086). CMS' stated justification for this change ("[t]o preclude referring physicians or group practices from circumventing this rule by setting up separate real estate holding companies or subsidiaries to act as the 'lessor'" (69 Fed. Reg. 16,086)) is reasonable. However, the broad language of the exception, in particular the words "related to," could be read to preclude legitimate subletting of space or equipment by a physician or physician practice lessee to another physician or physician practice that has a relationship with the hospital, whether through medical staff membership, employment or a contract. *GNYHA accordingly requests that CMS modify the rental of office space and rental of equipment exceptions, or provide additional guidance, to make clear that subletting and other legitimate relationships for shared usage of space and equipment between physicians and practices that have relationships with a lessor hospital are permitted and will not jeopardize the availability of these exceptions to the lessor hospital.*

- Charitable Donations by Physicians. GNYHA appreciates that by creating in Phase II an exception for charitable donations by physicians and their immediate family members at Section 411.357(j), CMS has acknowledged the essential role of charitable fundraising in supporting the missions of many hospitals and other health care institutions. Creating a Stark exception to avoid unduly impeding these activities is particularly important in the wake of the limitations on fundraising established by the HIPAA Privacy Regulations. GNYHA is concerned, however, that one of the conditions of the new exception, that "[t]he donation is neither solicited, nor made, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity" (42 C.F.R. § 411.357(j)(2)), introduces uncertainty into application of this exception. In particular, while a hospital or other DHS entity may control the manner in which donations are solicited, it cannot control how someone makes a donation to it. *Thus, GNYHA requests that the exception be conditioned only upon charitable donations from physicians not being solicited in any manner that takes into account the volume or value of referrals or other business generated between the physician and the DHS entity.*

  In addition, CMS helpfully discussed in the Phase II preamble that "broad-based fundraising campaigns not targeted specifically at physicians, such as charity ball tickets or general fundraising campaigns, will qualify under this exception" but cautioned regarding "more selective or targeted fundraising campaigns." However, development officers and staff often contact physicians directly to request their participation in hospital fundraising events, including encouraging their attendance at charity balls and other broad-based fundraising events. *Accordingly, given the critical importance of physicians to the fundraising activities of GNYHA's members, GNYHA would appreciate additional guidance from CMS regarding permissible fundraising appeals to physicians to clarify what steps hospitals and other DHS entities can take to ensure that their fundraising activities will qualify for the new Phase II exception for charitable donations by a physician.*

- Indirect Financial Relationships and the Indirect Compensation Arrangement Exception. GNYHA appreciates CMS' efforts to clarify what constitutes an "indirect financial relationship" and how that relates to the indirect compensation arrangement exception in

Section 411.357(p). GNYHA is concerned, however, with the prong of establishing an "indirect financial relationship" that relates to the entity's "actual knowledge" or acting "in reckless disregard or deliberate ignorance of the fact that the referring physician receives compensation that the volume or value of referrals or other business generated between the physician and the entity" will put many institutions in jeopardy of violating Stark. For example, many academic medical centers collect information regarding potential conflicts of interest of its physician researchers in order to ensure that those conflicts are appropriately screened and resolved in the research review process. Similarly, physician executives and physician members of a board of directors/trustees of a hospital or other institution often submit conflict of interest disclosure forms. Both types of conflict of interest forms may include information about a physician, or an immediate family member, receiving royalties from a medical device manufacturer (which CMS specifically discussed in the preamble as an arrangement that can give rise to "indirect financial relationship"). *GNYHA requests that the routine collection of such information for purposes unrelated to determining physician compensation not be considered to establish the facts necessary to constitute an "indirect financial relationship."*

In addition, availability of the indirect compensation arrangement exception hinges on the compensation received by the referring physician (or immediate family member) being "fair market value for the services and items actually provided." However, in many cases, such as royalties from a medical device manufacturer (the helpful example used by CMS at 69 Fed. Reg. 16,060), the hospital or other DHS entity will have no involvement in or control over the compensation paid to the physician (or immediate family member) by such a third party. *GNYHA believes that it is fundamentally unfair to make the availability of the indirect compensation arrangement exception contingent upon matters over which the DHS entity has no control, and requests that CMS consider amending the indirect compensation arrangement exception to eliminate this unfairness.*

- Retention Payments in Underserved Areas. GNYHA appreciates that CMS, by creating a new exception in Phase II at Section 411.357(t), has acknowledged the challenges to retaining qualified physicians faced by hospitals and FQHCs located in underserved areas, including parts of the greater New York area in which many of GNYHA's members are located. However, to meet this new exception, CMS requires retention payments to fall within strict limits. Specifically, CMS describes the limits in the Phase II preamble as follows:

> The retention payment must be limited to the lower of (i) the difference between the physician's current income from physician and related services and the income the physician would receive from physician and related services in the recruitment offer (over no more than a 24-month period) or (ii) the reasonable costs the hospital or FQHC would otherwise have to expend to recruit a new physician to the geographic area served by the hospital or federally qualified health center in order to join the medical staff of the hospital or federally qualified health center to replace the retained physician.

GNYHA believes that these limitations likely will greatly limit the utility of this new exception to allow hospitals and FQHCs in underserved areas to meet their physician retention challenges and also comply with Stark. In particular, GNYHA is concerned that the "reasonable costs…to replace" limit, if interpreted strictly, would treat physicians as being fungible and thereby allow hospitals and FQHCs to retain only their least experienced, competent and qualified physicians. *Accordingly, GNYHA requests that CMS provide guidance to make clear that hospitals and FQHCs may take into account factors such as the physician's experience, training, competence, and length of service in the area, and patient satisfaction, in determining what constitutes "reasonable costs...to recruit a new physician."*

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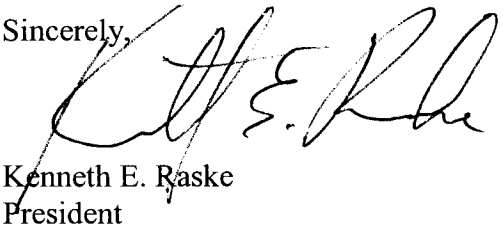
GNYHA appreciates the opportunity to comment on Phase II regulations of the Stark Law. If you have questions or desire additional information or explanation, please feel free to contact Lorraine Ryan at GNYHA at (212) 506-5416 or ryan@gnyha.org. Thank you in advance for your careful review and consideration of our comments and for your efforts to promulgate regulations under Stark that establish clear guidance and bright-line rules.

My best.

Sincerely,



Kenneth E. Raske
President

Submitter : **Mr. Craig Becker** **Date: 06/24/2004**

Organization : **Tennessee Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached pdf file for comments on CMS-1810-IFC

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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