August 29, 2007

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

Re: Changes to Reassignment and Physician Self-referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

Dear Mr. Kuhn:

We are leaders of two of the largest radiology group practices in Connecticut, Jefferson Radiology Associates and Advanced Radiology Consultants. We respectfully submit the following comments in response to CMS' proposed rules for the 2008 Medicare Physicians' Fee Schedule. We are certain that CMS will receive comments from a broad spectrum of interested parties. We will focus here on providing information that is specific to our situation.

CMS has made strong statements in its proposed rules that point to one very important factor in the growth of imaging – the conflict of interest that arises when a physician who orders a test also profits from its performance. Imaging has transformed healthcare and has improved both diagnosis and therapy. Indeed, imaging has been cited by the prestigious New England Journal of Medicine as one of the ten most important developments in medicine in the twentieth century. Thus, it is incumbent upon us to make sure that we preserve the positive aspects of imaging, without undue cost to the system. While this will certainly be a complex process, the first thing to be done is to remove artificial and counterproductive incentives for the use of imaging. Thus, we strongly support CMS' resolve to deal with in-office imaging and the many permutations thereof that, according to CMS, "corrupt(ing) medical decision making."

Thanks to forward thinking legislators and resolute private payers, Connecticut provides what is perhaps a unique perspective on the issue and a model for potential actions that might remedy any future inappropriate growth in imaging. Connecticut has Certificate of Need laws. Unlike many states, Connecticut has not only retained its law, but strengthened it over the years. Most recently, in recognition of the technological advances that have made prior-generation, advanced imaging less costly and available to a broader array of providers through in-office imaging, the legislature removed previous threshold for acquisition and made **all CT, MRI, PET scanners subject to CON requirement**. To this date, only one non-radiologist physician has obtained a CON for advanced imaging, and that was to replace a scanner that was acquired at a cost below the prior threshold.

Also, in 2001, the Connecticut legislature became the first in the country to pass a law that requires ACR accreditation to operate an MRI scanner here. Rhode Island has since become the second state.
The private insurance companies recognized the increased utilization of imaging that was engendered by self-referral. In response, all major private payers have instituted specialty-specific privileging programs that preclude almost all advanced imaging from being reimbursed to facilities that are not owned by radiologists or hospitals. Anthem Blue Cross Blue Shield, HealthNet, Oxford, Cigna, Aetna, and Connecticare have all done so. The first of these was documented in an article in a peer-reviewed journal. (Sample programs and article attached)

The confluence of situations described above has led to relatively lower utilization of imaging among Medicare beneficiaries when compared with Connecticut's neighboring states (see attached annotated map). Connecticut residents have no problems with access to medical imaging. More importantly, there is no adverse effect on the health of Connecticut's Medicare beneficiaries. Notable is the publication by HCFA in the Journal of the American Medical Association in 2000 of the relative overall quality of care in the states, wherein Connecticut, was ranked number 6 in the country for quality of care to Medicare

beneficiaries. This matches up well (especially when one considers the cost of care) in comparison with adjacent states. Perhaps because of the overall paucity of self-referred imaging in Connecticut, the few situations where self-referral has found a foothold can be analyzed more easily and can provide to CMS a stark contrast between the utilization of services with and without the overhanging conflict of interest.

The first situation is that of an IDTF that received a CON to provide cardiac CT/PET. Immediately, the IDTF embarked upon a dual business model: leasing part of the time to cardiology groups who would provide services as if the machine belonged to them; and the rest of the time as an independent provider of the service. We have obtained information from three large private payers in Connecticut showing the following over the 18-month period through June, 2007:

a. 218 cardiac PET examinations were done in the entire state by these 3 payers.
b. the other sites are the two largest hospitals in the state, where the hospitals own and bill for the examinations done on the scanners.
c. 134 of the 218 (63%) were done at the site where the two cardiology practices provide services on leased time. These are the only two cardiology practices who have the ability to bill for PET. These two practices comprise less than 20% of the cardiologists in the stated service area of the IDTF, yet virtually all the examinations in the service area are referred by them, and none was referred anywhere by any of the other cardiologists. Similarly, they comprise a very small percentage of the cardiologists in the state, but perform (63%) of the total studies in Connecticut.
c.100% of all patients done at that address were authorized to be done by the physicians in those two practices as the providers.
d. Zero were done by the IDTF on patients referred by general medical community. This raises serious questions as to the need for this examination if the other cardiologists never order the examination from the IDTF.
e. 128 of the 134 (96%) were referred by physicians with same tax ID or practice address. Thus, only 6/134 might have been in non-self-referred situation. Even those might have been referred at the suggestion of the cardiologists.

Thus, we see an examination where **the only demand comes from self-referring practices. NO other cardiology practices in the area ever order the test**, which is available at an independent facility. Other practices in the building are not really there – "affiliated."

The second situation relates to PET scanning in the hands of a medical oncology group. Here, the oncologists purchased a PET scanner before the CON threshold was eliminated. The oncologists had previously referred their patients to the local hospital, which was leasing a mobile scanner once a week and was planning to upgrade the service to PET/CT, at some additional cost. Prior to the oncologists obtaining their own PET scanner, the hospital in question was performing between 200 and 250 scans per year approximately 20 studies per month with the most during any single month possibly 30. This remained relatively constant over at least 4 years. The oncologist's scanner became operational in July, 2006. Their average monthly volume has been approximately 45 scans per month for a yearly total of approximately 540. The hospital's volume now averages 10 or less per month, just less than half of what they were previously performing. This has put the hospital on uncertain footing as far as the ability to provide ANY PET services in the future, let alone upgrade to PET/CT. The hospital's commitment to the leasing company provides PET scanning one day a week with a minimum guaranteed charge to the hospital of 3 patients per day. Most weeks they are fortunate to make their minimum and, at best, break even providing the service. The hospital is one of the few still providing PET-only scanners (as opposed to the more up-to-date PET/CT). The leasing company would like to phase out its PET-only scanners. Thus, it may not provide PET-only beyond the current calendar year, leaving the hospital with no scanner at all. The leasing company wants a 5 patient minimum to provide PET/CT. This would mean the hospital would definitely lose money to provide the service and cannot be afford to do that. It would now certainly be irresponsible and out of the question for the hospital to consider purchasing a PET/CT unit of its own. Thus, the hospital may be forced to give up the service altogether and send area patients to an out of town facility.

Recently, a group of urologists acquired a CT scanner before the CON law changed. (Incidentally, they obtained a 2-slice scanner, probably the only scanner in the state that is not four or more detectors.) As

reported above, private payers in Connecticut have resisted paying non-radiologists for advanced imaging. Bowing to political pressure, last April one payer relented and gave them privileges. That payer reports an immediate increase of referrals for CT by that practice of 20% - in the first month of the more liberal policy. The payer says it will continue to monitor their utilization.

Historically, insurance companies and the business community have been opposed to CON laws, believing that they restrict competition. Competition, they advocated, would lead to price declines. A significant change in their attitudes was signaled by the recent testimony before the Public Health Committee of the Connecticut legislature by the Connecticut Association of Health Plans and Anthem Blue Cross. The texts of their testimonies are attached. See the highlighted sections which indicate that the in-office imaging is increasing, is becoming onerous, and is not linked to need or quality of care. They make the point that there are more machines in offices of physicians who "drive their patients to these units."

Their testimony reflects their realization of the demand that is CREATED by the opportunity for increased revenues on the parts of the referrers, and that these situations are, in fact, ANTI-competitive. Much as Microsoft controlled the operating systems of computers and made it difficult to use third party software; much as the oil trusts of the nineteenth century controlled both the supply and the demand for their product; so do self-referring physicians control the "demand" for the product that they are "selling." Advocates of in-office imaging have likewise contended that radiologists want to restrict patient choice. Given the unique aspects of the physician-patient relationship and the pressures it brings to bear on the vulnerable patient, it is actually the self-referrers who are restricting the choices of the consumers.

So, what have we reported to you here and what relevance does it have for the proposed rules? We have shown you that you are correct in your assessment of the distortions produced by self-referral of imaging. We have given you some perspective on conditions in our state and among private payers that can limit the opportunities to practice self-referral. **We urge stringent restrictions on all the abuses of the loopholes in the Stark laws that you have recognized and are increasingly being recognized around the country (Illinois, Maryland, Louisiana, Florida, Texas, California, etc).**

There seem to be developing in Washington two distinct approaches to dealing with the cost of imaging. With the DRA, and now with proposals in the House CHAMP bill, Congress has embarked upon a program that would drastically reduce the reimbursement for providing the technical component to levels that may be unworkable for many practices, especially those in rural Connecticut. If this legislation stands, it will cripple an industry and stifle development in a branch of health care that has been a major contributor to the well-being of Americans. As evidenced by the text of its proposed rules, the CMS approach prioritizes the regulation of anti-competitive and abusive practices that artificially increase the cost of imaging. CMS wrote:

At this time, we decline to issue a specific proposal for amending the in-office ancillary services exception. Rather, we are soliciting comments as to whether changes are necessary and, if so, what changes should be made. We are interested in receiving comments on: (1) Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services); (2) whether and, if so, how we should make changes to our definitions of same building and centralized building; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; [[Page 38182]] and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

We applaud CMS for its insight and also prospectively in anticipation of decisive action, and **recommend the following** (in descending order of preference):

1. **That CMS reconsider and issue a specific proposal for amending the in-office ancillary services exception.** As the counterproductive aspects of self-referral have been recognized, measures taken to curb it have been mostly indirect – i.e., dealing with privileging, curtailing the leasing relationships, medical directorships, etc. While CMS did not propose that the exception for in-office imaging be

repealed, we believe what is really needed is, indeed, **the removal of the exception for in-office imaging, thereby obviating the need for the many indirect measures.**

2. Recognizing that the complete removal of the in-office ancillary services exception may not be what CMS wants to do now, we suggest **that CMS remove the exception for certain advanced imaging tests** that were not prevalent in non-radiologist office settings at the time of passage of the Stark laws and are rarely used for immediate evaluation of patients at the times of their initial evaluations. These would include **Computed Tomography, Magnetic Resonance Imaging, and Positron Emission Tomography.** These are not yet overly prevalent in non-radiologists' offices, but have been shown to be the fastest growing procedures in the office setting and the office growth has accounted for the overwhelming preponderance of the growth of imaging. In addition, we are seeing interest by certain specialist groups in purchasing **radiation therapy units for their offices. These should be excluded from any in-office ancillary services exception, as well.**

3. **That non-radiologist physicians not be able to refer patients for imaging services involving the use of the above advanced imaging equipment from which they (or their relatives) might profit in <u>any</u> fashion** - including, but not limited to arrangements involving ownership, as leasors or leasees, or through professional services arrangements, such as medical directorships, etc.

4. **That CMS ban sharing of equipment among different practices, ban markups of the technical and professional components, and ban "under arrangement" relationships.** Likewise, "under arrangements" relationships are being discussed by non-radiologists as ways of profiting from imaging without actually even having the units in their offices. These specialists use their power to bring patients to hospitals and the threat of loss of referrals for imaging as leverage to induce the hospitals to enter into these arrangements.

We thank CMS for the opportunity to present this information and for your consideration thereof.

Respectfully submitted,

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CARECORE NATIONAL
PRIVILEGING BY SPECIALTY
JANUARY 2004

The privileging program is designed to improve quality by limiting coverage of imaging services to those services provided in the most appropriate setting. The list below details the imaging CPT codes that physicians other than radiologists can perform in their office.

Note: The privileging program applies to all settings, including inpatient.
*These procedures require pre-certification.
***Any studies beyond three require pre-certification.

PHYSICIAN TYPE	CPT CODES	DESCRIPTION
Primary Care Physicians: Internal Med., Family Practice	71010-71030 76075,76076	Chest imaging DEXA studies, bone densitometry
Cardiologists	71010-71030 78464*, 78465*, 78469* 78472*, 78473* 78478*	Chest imaging Tomographic SPECT studies Cardiac blood pool imaging Wall motion study
Cardiologists – Pediatric only	76825***, 76826 ***, 76827***, 76828***	Echocardiography, fetal
Chiropractors	72010, 72040, 72069, 72070, 72080, 72100	Spine imaging
Endocrinologists	76075, 76076 76942 76536 (AACE Accredited Endocrinologists only)	DEXA studies, bone densitometry Ultrasonic guidance for needle biopsy Thyroid ultrasound
Gastroenterologists	76975*	Endoscopic ultrasound
General Surgeons: AIUM-accredited	76942	Ultrasonic guidance for needle biopsy
General Surgeons, Vascular Surgeons, Cardio-Vascular Surgeons	75940 75952 75953	Percutaneous placement of IVC filter, radiological supervision & interpretation Endovascular repair of infrarenal abdominal aortic aneurysm Placement of proximal or distal extension prosthesis for endovascular repair
Hand Surgeons	76000 73100-73140	Fluoroscopy Upper extremity imaging

Maternal and Fetal Medicine Neonatal Perinatal Medicine [redacted]	76075, 76076 76083 76092 76801***-76828*** 76830, 76856, 76857 76930, 76941, 76942, 76945, 76946, 76948	DEXA studies, bone densitometry Digitization of radiographic images Screening mammography Ultrasounds-pelvis Ultrasounds-pelvis Ultrasonic guidance Ultrasonic guidance
Ob/Gyns	76075, 76076 76083 76092 76815***, 76816***, 76817***, 76830, 76831, 76856, 76857 76930, 76941, 76945, 76946	DEXA studies, bone densitometry Digitization of radiographic images Screening Mammography Ultrasounds-pelvis Ultrasounds-pelvis Ultrasonic guidance
Ob/Gyns AIUM/ACR Accredited	76801***, 76802***, 76805***, 76810***, 76811***, 76812***, 76818***, 76819***, 76825***, 76826***, 76827***, 76828***	Ultrasounds-pelvis
Oral Surgeons	70100, 70110, 70140, 70150 70300, 70310, 70320 70328, 70330 70350 70355	Mandible and facial bone imaging Teeth imaging TMJ imaging Cephalogram, orthodontic Orthopantogram
Orthopedists	71100-71111 71120-71130 72010-72120,72170, 72190, 72200-72220 73000-73140, 73500-73660 76000, 76003, 76005 76006 76040 76066	Radiologic examination, ribs Radiologic examination, sternum Spine and Pelvis imaging Imaging- Upper and lower extremities Fluoroscopies Radiologic examination, any joint Bone length studies Joint survey
Pain Specialists (physiatrists, anesthesiologists, neurologists, and neurosurgeons)	76000 76005	Fluoroscopy (separate procedure), up to one hour physician time, other than 71023 or 71024 (eg, cardiac fluoroscopy) Fluoroscopic guidance and localization of needle or catheter tip for spine paraspinous diagnostic or therapeutic injection procedures including neurolytic agent destruction
Pediatricians	71010-71030	Chest imaging
Podiatrists	73620, 73630, 73650, 73660	Lower extremity imaging
Pulmonologists	71010-71030	Chest Imaging
Radiation Oncologists	76370	Computerized tomography

		guidance
	76873	Prostate volume study for brachytherapy treatment planning
	76950	Ultrasonic guidance for placement of radiation therapy fields
	76965	Ultrasonic guidance for interstitial radioelement application
Reproductive Endocrinologists [redacted]	76075, 76076	DEXA studies, bone densitometry
	76083	Digitization of radiographic images
	76092	Screening Mammography
	76801***-76828***	Ultrasounds-pelvis
	76830-76857	Ultrasounds-pelvis
	76930, 76941, 76945,76946	Ultrasonic guidance
	76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation
Rheumatologists	72010-72120,72170, 72190,	Spine and pelvis imaging
	72200-72220	Imaging- Upper and lower extremities
	73000-73140, 73500-73660	Fluoroscopies
	76000, 76003	Bone length studies, joint survey
	76040, 76066	DEXA studies, bone densitometry
	76075,76076	
Urologists	76870, 76872	Ultrasounds – echography, genitalia, bladder
	76942	Ultrasonic guidance for needle biopsy

The Effect of Imaging Guidelines on the Number and Quality of Outpatient Radiographic Examinations

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Lynn Gelinas[4]

OBJECTIVE. A significant percentage of outpatient diagnostic radiology is performed by nonradiologists. Studies have shown nonradiologists have higher utilization and cost, as well as quality problems. We sought to determine if, in a managed care environment, a set of guidelines limiting imaging privileges of nonradiologist physicians could decrease imaging costs while ensuring that equipment and personnel providing imaging were of the highest quality.

MATERIALS AND METHODS. We determined the number and type of radiographic imaging studies performed the year after these guidelines were set in place (1997) and compared these findings with those of the year before the guidelines were established (1995) and with preguideline trends. We established quality criteria and, based thereon, inspected imaging offices.

RESULTS. The number of radiographic examinations per 1000 enrollees decreased 20–25% from the previous trend. Nonradiologists' share of the total fell from 39% to 15%. No deficiencies were found in the inspection of five radiologists' offices, whereas significant deficiencies of equipment, equipment maintenance, or documentation of the examinations performed were found in 78% of nonradiologists' offices. None of the quality indicators monitored by the health plan showed significant change.

CONCLUSION. Specific guidelines can effect change in the location and number of radiologic examinations performed, with an improvement in the quality of the studies and a decrease in radiation dose and cost. No decline in quality of care appears to result, despite claims by opponents to such changes that widespread serious quality impairment would occur.

The portion of society's resources devoted to health care has been the subject of significant debate in the United States for decades. In 1965, the United States devoted 5.9% of its gross national product to health expenditures. By 1995, this figure had risen to approximately 14%, and this increase had a significant impact on employers and the government. If current projections hold, it is estimated that expenditures will double to $2.3 trillion (United State dollars) or approximately 17% of the gross national product by 2007 [1]. Methods of curbing this significant increase have been sought, and the results have changed the face of American medicine. The rapid emergence of managed care as a majority health insurer for Americans has been heralded as the reason for some of the recent slowdown in the rise of health care costs. Managed care claims credit for eliminating many of the excesses of the system. However, with the increasing age of our population and their health care needs as well as the continued development of new technology, health care costs now seem to be once again increasing at a rate higher than current inflation. Although managed care has helped the system curtail costs, there have been negative effects related to physician choice, accessibility, and the accountability of health plans. Various techniques to decrease health care costs have been developed. One is to decrease the benefits to which a patient is entitled; another, to decrease the payment for each unit of service. Yet another technique is to institute a utilization management program, with the expectation of eliminating unnecessary services.

Diagnostic radiology services constitute a significant portion of both inpatient and outpatient costs. It has been estimated that radiology services use approximately 8% of the health

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care dollar paid to physicians. Many studies have shown that approximately 50% of nonhospital radiology services are performed in a nonradiologist's offices [2–4] and that nonradiologic physicians who have an X-ray machine in their office perform as many as four to five times as many examinations per patient as physicians in the same specialties seeing patients with the same problems but who refer their patients to radiologists for imaging. [5–7]. Other studies have suggested that many radiologic examinations performed in nonradiologists' offices are of poor diagnostic quality and are interpreted incorrectly [8–11].

Materials and Methods

A large health maintenance organization in the northeastern United States decided to establish an effective radiology utilization program based on several objectives. The organization's goals were to reduce utilization of imaging tests that were noncontributory to patient treatment and that thus were inappropriate and, at the same time, to deliver the most cost-effective, high-quality imaging product. The health maintenance organization wanted to address the problems of volume, cost, and quality and to ensure that the equipment and personnel producing and interpreting a radiographic or imaging study were of the highest quality.

The health plan established a radiology advisory committee that consisted of physicians drawn from various academic and community practices throughout the state. The advisory committee is a multispecialty committee consisting of radiologists, a surgeon, an internist, a primary care physician, an orthopedic surgeon, an obstetrician or a gynecologist, and the medical director of the health plan. These physicians were chosen on the basis of board certification in their field, volume of practice, volume of radiographic examinations performed, and, in some cases, individual physician experience. This committee eventually established the guidelines regarding who could perform imaging studies in their office practice. Imaging studies that could be performed by nonradiologists were carefully delineated on the basis of each physician's specialty and demonstrated expertise.

These expertise- and relevance-based guidelines limited the amount of imaging permitted to be performed by nonradiologists. The guidelines removed all imaging privileges from gastroenterologists, general surgeons, nephrologists, neurosurgeons, oncologists, pediatric surgeons, and physiatrists. Cardiologists were limited to performing chest radiography, echocardiography, and nuclear cardiology, and pulmonologists could perform only chest radiography. The only imaging an obstetrician–gynecologist could perform was obstetric and gynecologic sonography; breast sonography was specifically excluded. If an obstetrician's office obtained United States Food and Drug Administration (FDA) approval for mammography, only the technical component of a screening mammogram would be paid by the health maintenance organization. The images had to be sent to a radiologist for interpretation. Orthopedic surgeons were permitted to perform conventional orthopedic radiography but were excluded from performing and interpreting all CT and MR procedures. Otolaryngologists were permitted to obtain conventional radiographs of the sinuses and nasal bones, but soft-tissue radiographs of the neck and cervical spine were excluded. Podiatrists could perform and bill only for radiography of the foot, and rheumatologists could perform only extremity radiography; they were excluded from performing spine radiography.

Primary care physicians, including family practitioners, internists, and pediatricians, were permitted to obtain only chest, rib, and extremity radiographs and were paid only for the technical component. It was required that these images be interpreted by a radiologist who would then bill for the professional component.

The second aspect of the program was to evaluate and ensure the technical quality of the imaging performed. A technology assessment questionnaire (Fig. 1) was sent to all providers who requested imaging privileges. This questionnaire required details of many aspects of the imaging being practiced, including a description of the imaging equipment present in the office, its year of manufacture, its service records, and a physicist's evaluation of the radiology equipment including its output and radiation dose to a patient. The questionnaire inquired about the availability of quality assurance programs (e.g., whether demographic labeling of a radiograph was performed routinely and whether there was a written radiology report for each imaging examination performed). Another requirement was that only licensed technologists could perform radiography. Patient safety programs—for example, whether a patient was questioned regarding pregnancy status—had to be in place. The health plan required that practices performing mammography have FDA approval. Physicians who wished to perform sonographic examinations had to be accredited by the American Institute of Ultrasound in Medicine, the American College of Radiology, or, in the case of vascular sonography, by the Intersocietal Commission for Accreditation of Vascular Laboratories.

Four hundred fifty-two questionnaires were distributed and 411 completed questionnaires were returned to our office for a return rate of 91%. We then inspected a representative group of radiology offices, and we attempted to inspect approximately 25% (100) of the nonradiology offices at which imaging studies were performed. Because of various scheduling problems we could inspect only 92 of

PROVIDER INFORMATION

Please complete this form for each practice location that provides diagnostic imaging services and one Assessment Checklist for each equipment location.

Please type or print information.

Legal Practice Name: _____

Group Practice Tax ID Number: _____

****Please fill out a separate Application/Checklist for each Imaging Site Location****

Imaging Site

Site Name / D.B.A.: _____
Address: _____ Suite: _____
City, State, Zip code: _____
Phone: _____ Fax: _____

____ Equipment Only ____ Billing and Equipment

Billing Site

Site Name / D.B.A.: _____
Address: _____ Suite: _____
City, State, Zip code: _____
Phone: _____ Fax: _____

____ Billing Only ____ Billing and Equipment ____ Billing Service

Imaging Site Demographics

What is your patient volume for diagnostic imaging per month? _____
What is your maximum patient volume for diagnostic imaging per month? _____
Office Manager: _____
Chief Technologist: _____
Document Prepared by: _____

Fig. 1.—Form shows second page of technology assessment questionnaire. This questionnaire requires provider to respond to questions regarding imaging equipment, personnel, and quality assurance programs in each office. D.B.A. = doing business as.

these 100 offices. The 100 offices selected for inspection were those at which the highest number of imaging studies were performed per month. They were inspected by registered radiology technologists who used a checklist to evaluate each specific facet of the inspection and were required to complete a questionnaire about each office. Evaluation of parameters such as quality of the imaging study, storage and handling of films, patient demographic information on the film (patient name, age, date of examination), and the presence of a report on each imaging study was part of the inspection performed by the technologist (Fig. 2).

Only outpatient radiologic examinations were studied in our research. This article addresses only radiography, essentially the only technique aside from sonography that nonradiologists perform in large volume. CT, MR imaging, sonography, and nuclear medicine studies were specifically excluded. We recognize the importance of these studies on radiology expenditures and their place in the changing patterns of imaging examinations used to work up specific disease entities; they are presently being studied and will be the subject of a separate analysis. Outpatient examinations were included in our study regardless of whether they were performed in a private office, imaging center, multispecialty clinic, or hospital. Data were gathered from billing statistics. Each procedure is identified by a specific *Current Procedural Terminology* code [12] and there had to be an appropriate *International Classification of Diseases indication* [13] for the study. Also, the name of the referring physician as well as that of the physician performing the study and both physicians' specialty were noted. Data were obtained from the HCFA-1500 (Health Care Financing Administration) claim form that was sent to our office for payment of the imaging study.

Our analysis was based on the number of examinations per 1000 enrollees. Because the health plan was growing and the number of enrollees rose during our study years, comparisons of simple counts would not be valid.

The health plan's data for the calendar year before we assumed responsibility for managing radiologic studies (1995) were compared with data for the calendar year after our program had been put into effect (1997). (We assumed responsibility for the health plan in 1996.) This gave us detailed data before our initiation of this program and a complete year's data following, thus avoiding start-up problems. Comparison of the enrollees on the basis of age and sex was undertaken. There was no significant change in the age or sex distribution of the patient population between study years. This was important to study because the number of enrollees rose from 125,000 to 162,000. A change in age or sex distribution of the population could affect radiology utilization. For 1993 and 1994, we had limited access to data that included only the total number of examinations performed and the number of examinations per 1000 enrollees. We used these 1993 and 1994 data to estimate the utilization trends that would have been expected to continue if our program had not been instituted.

RADIOLOGY INSPECTION CHECK LIST

PHYSICIAN NAME: _____ GROUP NAME: _____

ADDRESS: _____ COUNTY: _____

_____

DATE: _____ SURVEYOR: _____

		YES	NO	N/A
1.	Radiology equipment inspected within the past twelve (12) months?			
	A. X-RAY EQUIPMENT:			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
	B. ULTRASOUND EQUIPMENT			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
	C. NUCLEAR IMAGING EQUIPMENT (Dose Calibrator)			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
2.	Program for exposure of women of child-bearing age			
	A. Program/protocol in place to prevent x-ray exposure for women of child-bearing age?			
3.	Patient / Employee Safety			
	A. Office has current OSHA manual?			

Fig. 2.—Form shows page one of three-page inspection document. This document details inspectors' findings regarding equipment service records, patient safety, image quality, and reporting methods. N/A = not applicable, OSHA = Occupational Safety and Health Administration.

Results

Initially, there was considerable unhappiness created by the restriction of physician privileges. Many physician groups insisted that the guidelines would negatively impact their ability to care for patients. After the first several months, it became apparent that these guidelines had not caused significant hardship, and most complaints subsided. All quality-of-care measures charted by the health plan, including those mandated by accreditation from the National Committee for Quality Assurance and those required by the Health Care Financing Administration, were unchanged by the institution of our guidelines. Specifically, there was no significant change in the per enrollee number of hospital days, in emergency department visits, or in quality-of-care complaints by members. In areas such as maternity care management, diabetic care, asthma care management, and all other specific clinical care practices monitored by the health plan, no significant changes occurred.

In 1993, 22,350 radiographic examinations were performed, which is a rate of 226 examinations per 1000 enrollees. In 1994, 30,071 examinations were performed, which is a rate of 257 per 1000. In 1995, of 34,436 radiographic examinations were performed, for a rate of 269 per 1000. In that year, 20,906 examinations, or 163 per 1000, were performed by radiologists and 13,530 (39% of the total), or 105 per 1000, were performed by nonradiologists. In 1997, 38,912 radiographic examinations were performed, for a rate of 253 per 1000. Of the examinations in 1997, 32,970 or 214 per 1000 were performed by radiologists and only 5942 (15%) or 39 per 1000 were performed by nonradiologists. If we directly compare the

1995 data with the 1997 data, a 6% decrease in the number of radiologic examinations per 1000 examinations performed is revealed; a 31% increase in the number of examinations per 1000 enrollees performed by radiologists and a 63% decrease in those performed by nonradiologists are also revealed.

Another comparison reveals that in the years preceding the institution of this plan, radiology services per 1000 enrollees increased approximately 5–10% per year. In 1997, the number of radiographs per 1000 decreased by approximately 20–25% from the number expected if the trend had continued (Fig. 3).

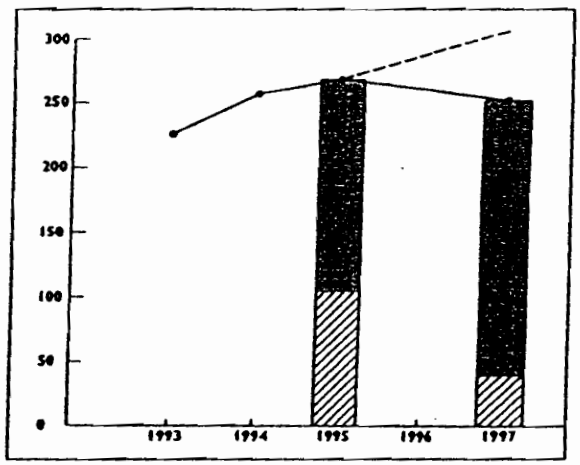

Fig. 3.—Graph shows radiographs per 1000 enrollees. Once plan was instituted, total (*solid line*) decreased 20–25% below previous trend (*dashed line*) and 6% in absolute terms below preplan year. Area with diagonal lines = radiographs obtained by nonradiologists, gray area = radiographs obtained by radiologists.

For each anatomic area, a marked increase in the percentage of imaging examinations performed by radiologists and a marked decrease in that of imaging examinations performed by nonradiologists were also revealed. For example, 96 per 1000 chest radiographs were obtained in 1995, 29% of which were obtained by nonradiologists. In 1997, 104 per 1000 chest radiographs were obtained, with 15% obtained by nonradiologists. These findings indicate a 29% increase in chest radiographs per 1000 obtained by radiologists and a 43% decrease in those obtained by nonradiologists. Even larger changes occurred in examinations of the lumbar spine. In 1995, 10.4 per 1000 examinations were performed, 35% of which were performed by nonradiologists. In 1997, 9.6 per 1000 examinations of the lumbar spine were performed with only 5% performed by nonradiologists. Overall, a decrease in spine examinations of 7% per 1000 was seen; a 35% increase in spine examinations performed by radiologists and an 86% decrease in those performed by nonradiologists occurred. Similarly, of extremity examinations, 11.1 per 1000 wrist examinations were performed in 1995. Of these, 46% were performed by nonradiologists. In 1997, 7.9 per 1000 were performed, only 9% of which were performed by nonradiologists. Overall, a 29% decrease in the number of wrist examinations performed per 1000, with a 20% increase in those performed by a radiologist and an 87% decrease in those performed by nonradiologists (Table 1).

Our technical assessment questionnaire and the follow-up inspection also revealed important findings. Although we examined only five radiology offices, no significant deficiencies were encountered in any of these offices. We then made the assumption that continuing to inspect radiology offices would not be beneficial because they routinely had their equipment inspected, issued a report on each imaging study, and had appropriate patient demographic information on each radiography report and on each image. They also routinely used technologists to perform the radiographic examinations, and all offices had a quality assurance program in place.

Of the 92 nonradiologist offices inspected, 10% had not had their equipment inspected within the previous 12 months. Nine percent of the offices that had deficiencies identified by either a physicist or service personnel had not corrected the deficiencies at the time of the survey. Sixteen percent of the offices did not have the images identified using right-sided or left-sided markers. Sixty-two percent of the offices inspected did not issue a formal radiology report of the imaging procedure performed; a note was made in the chart cryptically stating that a radiograph was either positive or negative, but no formal report was available. This seriously limited audit and quality assurance initiatives.

After tabulation of the deficiencies identified on our inspection, a certified letter was sent to each office requiring that the deficiencies be corrected within 90 days. We required that quality assurance programs be instituted if they were not in place and that all imaging studies have a formal report, either legibly handwritten or typed, and placed in the patient's chart. Of the 92 nonradiologist offices inspected, 72 offices, or 78%, had a significant deficiency identified. If the absence of a report is excluded as a criterion, 32% of the offices had serious deficiencies.

Discussion

There is an extensive literature showing that nonradiologist physicians who have a financial interest in the diagnostic imaging of their patients order more imaging than colleagues in the same specialty who do not have this type of financial interest [3, 5–7, 14–16]. This finding holds regardless of whether the nonradiologist has a financial interest in an outside imaging facility to which he or she refers patients or the financial interest consists of imaging that the nonradiologist performs in his or her own office. The finding also holds regardless of whether data are compared on the basis of the patient's presenting complaint or the data are an aggregate for all patients seen by a physician. Similar findings also hold for other ancillary services, such as physical therapy [17].

Given the ubiquity of this finding and the large differences in imaging frequency typically observed, the usual conclusion has been that financial self-interest is an important cause of the higher imaging utilization of self-referrers. However, because almost all studies are comparisons of two different sets of physicians, rather than comparisons of one set of physicians under two different financial incentives, other explanations are possible. For example, it is possible that physicians whose practice style includes much more imaging (perhaps because they are less inclined to rely on history and physical examination than colleagues) acquire imaging equipment because they naturally use it.

Our study is one of few that directly tests the role of financial incentives. Our plan halted reimbursement to nonradiologists for some forms of imaging but left them entirely free to refer their patients to radiologists if they believed the imaging they had been conducting on their patients was needed.

TABLE 1: Detailed Analysis of Radiographic Procedures: 1995 Compared with 1997

Current Procedural Terminology Codes	Description	1995						1997						Comparison of 1995 and 1997 Values (% per 1000)		
		Total Units	Per 1000	Performed by Radiologists	Per 1000	Performed by All Others	Per 1000	Total Units	Per 1000	Performed by Radiologists	Per 1000	Performed by All Others	Per 1000	Total Units	Performed by Radiologists	Performed by All Others
71010	Chest (one view)	3561	27.8	3209	25.1	352	2.7	4862	31.6	4800	31.2	62	0.4	14	24	–85
71020	Chest (two views)	12,327	96.2	8721	68.1	3606	28.2	16,027	104.1	13,543	88.0	2484	16.1	8	29	–43
73620	Foot (two views)	1712	13.4	74	0.6	1838	12.8	1760	11.4	292	1.9	1468	9.5	–14	228	–25
73630	Foot (complete)	2320	18.1	1128	8.8	1192	9.3	2781	18.1	1924	12.5	857	5.6	0	42	–40
73130	Hand (complete)	1369	10.7	994	7.8	375	2.9	1421	9.2	1285	8.3	136	0.9	–14	8	–70
73610	Ankle (complete)	1877	14.7	1118	8.7	759	5.9	1740	11.3	1641	10.7	99	0.6	–23	22	–89
73600	Ankle (two views)	278	2.2	40	0.3	238	1.9	184	1.2	150	1.0	31	0.2	–45	212	–89
72110	Spine (lumbarsacral)	1326	10.4	867	6.8	459	3.6	1485	9.6	1409	9.2	80	0.5	–7	35	–86
72050	Spine (cervical)	926	7.2	650	5.1	276	2.2	1166	7.6	1087	7.1	79	0.5	5	39	–76
73030	Shoulder	1417	11.1	617	4.8	800	6.2	1145	7.4	1024	6.7	121	0.8	–33	38	–87
73080	Elbow (complete)	471	3.7	294	2.3	177	1.4	571	3.7	538	3.5	33	0.2	1	52	–84
73090	Forearm (two views)	421	3.3	233	1.8	188	1.5	398	2.6	384	2.5	14	0.1	–21	37	–94
73100	Wrist (two views)	591	4.6	87	0.7	504	3.9	206	1.3	179	1.2	27	0.2	–71	71	–96
73110	Wrist (complete)	1417	11.1	767	6.0	650	5.1	1210	7.9	1107	7.2	103	0.7	–29	20	–87
73060	Humerus	188	1.5	104	0.8	84	0.7	203	1.3	198	1.3	5	0.0	–10	58	–95
73510	Hip (complete)	804	6.3	439	3.4	365	2.8	848	5.5	778	5.1	70	0.5	–12	47	–84
72170	Pelvis (anteroposterior only)	665	5.2	396	3.1	269	2.1	850	5.5	804	5.2	46	0.3	6	69	–86
73550	Femur	197	1.5	139	1.1	58	0.5	220	1.4	216	1.4	4	0.0	–7	29	–94
73560	Knee (two views)	1183	9.2	353	2.8	830	6.5	635	4.1	530	3.4	105	0.7	–55	25	–89
73562	Knee (three views)	821	6.4	397	3.1	424	3.3	650	4.2	559	3.6	91	0.6	–34	17	–82
73590	Tibia and fibula	565	4.4	279	2.2	286	2.2	550	3.6	522	3.4	27	0.2	–19	56	–92
Total		34,436	268.9	20,906	163.2	13,530	105.6	38,912	252.7	32,970	214.1	5942	38.6	–6	31	–63

Note.—Codes are from [12].

We found this change produced a decline in imaging of 20–25% from what would have been expected given the previous trend of imaging growth, and an absolute decline of 6%.

Before the institution of our plan, nonradiologists had been performing 39% of outpatient radiographs. The 20–25% decline from the trend that we observed was roughly half this 39% initial share. Thus, our research shows that approximately half the imaging performed by self-referrers disappeared when they lost their financial self-interest in it.

This estimate—that eliminating financial incentives decreases half the imaging self-referrers order—coincides remarkably well with the most relevant data comparing two different groups of physicians. An analysis of Medicare claims data from all nonradiologist physicians in Florida by the United States General Accounting Office reveals that nonradiologists who obtained radiographs of their own patients performed twice as many radiographic examinations per 1000 patient office visits as did physicians who referred their patients to outside offices for radiography [6].

However, results were generally different in the three published studies that, like our research, investigated how physician orders for radiologic studies changed when financial incentives changed. Hemenway et al. [18] reported that when the compensation of primary care physicians at a chain of for-profit ambulatory care clinics was changed from a flat hourly wage to include a bonus related to revenues generated, the number of radiographs per patient visit increased 16% and the number of laboratory tests per visit increased 23%. The authors note that these findings seem like relatively small changes and speculate that the relatively small response may reflect the structure of the bonus system, which provided only a relatively weak financial incentive. Hillman et al. [19] reported that a program somewhat like ours, which generally terminated payment to nonradiologists for the professional component of imaging services but left nonradiologists free to collect payment for the technical component, resulted in a 41% increase in the number of imaging claims payable and a 12% increase in imaging costs in localities in which the insurer instituting the program had a relatively large market share. In contrast, in areas in which the insurer had a small market share, no dramatic changes were seen. It seems possible that if payments from the insurer were a major source of revenues for physicians, physicians noted the new policy and were manipulating the system to maintain their incomes. Kangarloo [20] reported on the effect of a program somewhat like ours that was introduced into the employee health benefit coverage of a large Florida firm that had been experiencing 25% annual increases in total costs for diagnostic imaging. In the first year of the program, the number of radiographs per 1000 covered persons was 419, a 9% decline from the previous year's level. This seems roughly similar to our finding of a 20–25% decrease from the health plan's previous trend, given that there had been a rapid increase in total imaging costs. However, because Kangarloo did not quantify the previous trend in the number of radiographs, only a rough comparison is possible. Obviously, more data than those of the three previous studies plus our study are required to make generalized conclusions about nonradiologists' responses to changes in financial incentives for imaging.

The widely reported finding that self-referrers do more imaging than radiologist referrers casts doubt on the necessity and appropriateness of the large number of radiographs self-referrers obtain. Our finding that many of these radiographs are not obtained, rather than shift to radiologists, when financial incentives change is further evidence of their questionable necessity. To be fair, however, we should note that advocates of in-office self-referral argue that the inconvenience of sending patients outside the office for imaging and then waiting for results causes physicians to omit imaging examinations that would be useful for patient treatment.

However, we could not find any quality-of-care parameters required by accrediting agencies or monitored by the health plan that were altered by our program. There seems to be no measured adverse health effect when self-referral is terminated. The quality parameters monitored may not be particularly sensitive to minor changes in population health, but opponents to programs like ours tend to predict that these programs will produce widespread and severe deterioration in the quality of care. Even somewhat insensitive indicators should detect such changes.

The most dramatic effect of our program was the decline in the number of radiographs obtained by nonradiologists: it fell from 39% of the total before the program was instituted to 15% after it began.

The resulting shift of examinations to a radiologist's office means that more examinations are now performed using modern equipment with low-dose screens, resulting in a reduction in dose per examination and an overall decrease in radiation exposure for the patient. Quality, too, was enhanced; as noted, we found many quality deficiencies in nonradiologists' offices. Although some deficiencies, such as formal reports for each examination, may not have a direct impact on patient care, deficiencies such as failure to have equipment inspected, increased dose per examination, or failure to correct a deficiency that had been identified by a physicist are clinically serious. The lack of adequate labeling of a radiograph could also have serious and tragic consequences.

In addition, we believe our inspection program resulted in improvement in the performance of the imaging that still occurred in a nonradiologist's facility. The program set standards for equipment located in a clinician's office and also ensured that a technologist obtained the radiograph. Quality assurance programs were initiated and deficiencies were corrected. Many offices, faced with increased surveillance and costs, decided to abandon performing radiology examinations. We know that 132 offices have stopped billing the plan for imaging procedures; whether they continue to obtain radiographs and bill other carriers or have ceased imaging is something we do not know.

Like all research, our study has limitations. Data on 1993–1997 trends in the utilization of imaging among health plans not affected by our program would have been useful to show that the trends that were seen in 1993–1995 continued, as we have assumed. The long-term effects of our program can be shown only by data from 1998 and subsequent years, which are not yet available. Quite possibly, utilization may start rising again; historically, the use of health services has grown over time. However, if utilization does start rising, it will start from a level 20–25% below that had we not intervened. Also, effects of our program on other imaging techniques, such as sonography (for which we required accreditation), are presumably important, and there may be spillover effects between radiography and other imaging techniques. As far as we could determine, there was no significant out-of-network utilization of radiology services during the study. Because the health plan is a restrictive health maintenance organization, with a specific panel of providers, there is a small possibility that an occasional patient may have been referred to imaging facilities not associated with the health plan. These studies would not have been paid for by the health maintenance organization, a significant disincentive for this to occur.

In conclusion, our study shows that a program that limits imaging studies to appropriate physicians can decrease cost and improve quality. We reduced the number of radiographic examinations performed by 20–25% from the preceding trend without significantly interfering with the health care of subscribers. Before our study, approximately 40% of radiographs were obtained by nonradiologists; this decreased to 15%, representing a dramatic reduction. One can infer that many of the procedures previously performed in nonradiologists' offices were not necessary. Issues of radiography equipment maintenance, patient safety, and reporting were addressed by inspecting offices that performed imaging. Seventy-eight percent of the nonradiologists' offices had significant deficiencies that we required to be subsequently corrected. Our program decreased cost and radiation burden.

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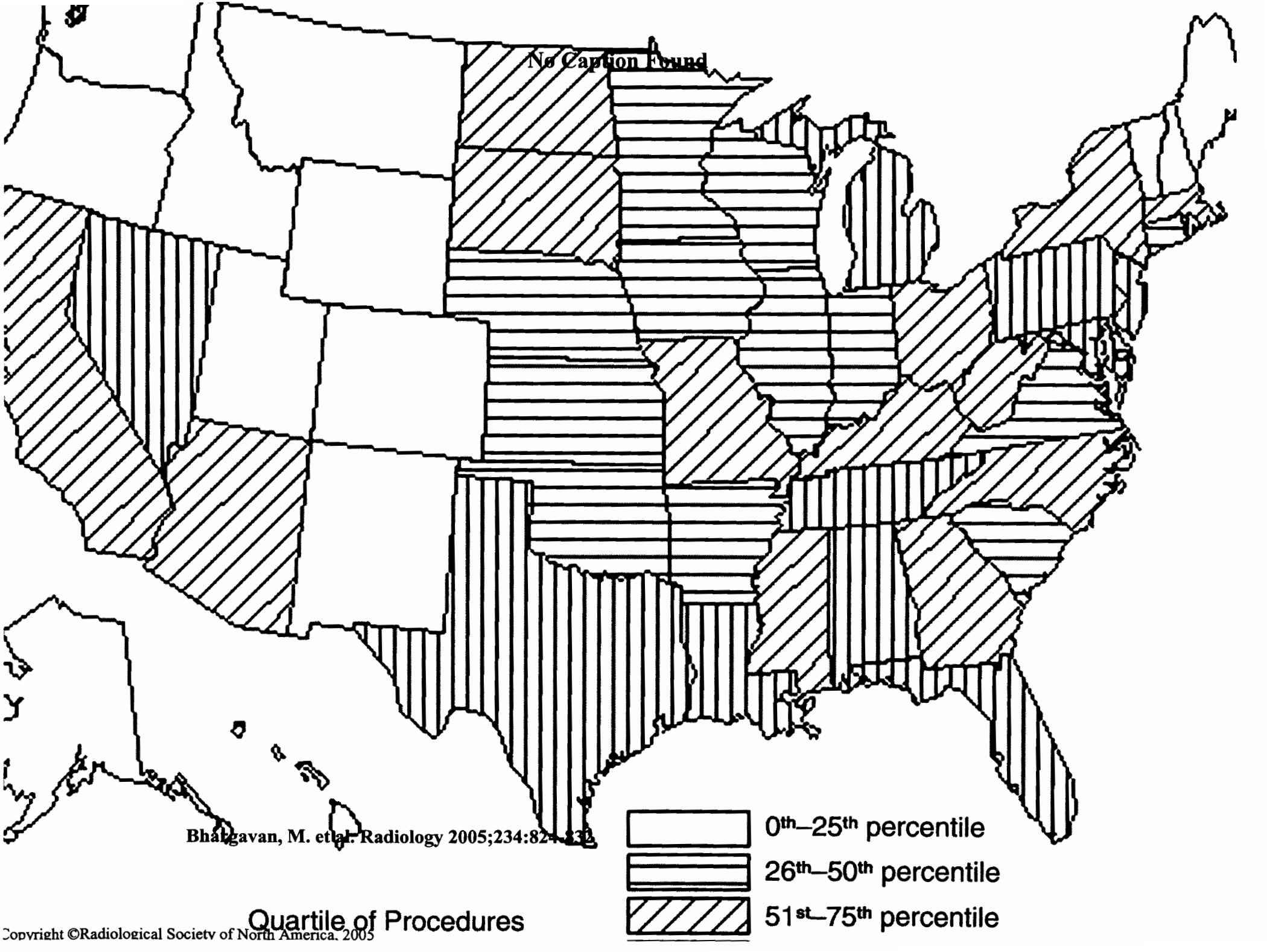

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March 15, 2005

Anthem.

Statement
Of
Anthem Blue Cross and Blue Shield
On
SB1298 An Act Concerning Health Insurance Coverage For Outpatient Imaging Services

Good morning Senator Crisco, Representative O'Connor and members of the Insurance Committee, my name is Christine Cappiello and I am the Director of Government Relations for Anthem Blue Cross and Blue Shield in Connecticut. I am here today to speak against **SB 1298 An Act Concerning Health Insurance Coverage For Outpatient Imaging Services.**

Anthem Blue Cross and Blue Shield oppose **SB 1298** because this legislation is unnecessary and potentially harmful to our members and your constituents. Since 2001, Anthem BCBS has seen a dramatic increase of 15% a year in the utilization around "Advanced Imaging", which are Computerized Tomography (CTScans), MRIs, Positron Emission Tomography (PETScans) and Nuclear Cardiology (Echo Cardiograms). In fact, "Advanced Imaging" costs us 58% of the total costs for imaging services in CT, but is less than 1% of all imaging in CT.

When we saw this trend, we became very alarmed. We were alarmed because we were fearful that this increase meant that our members are being given these imaging services needlessly and excessively. After researching this reason upward spike, we have attributed to specific reasons. The first reason that we discovered attributed to this spike is a result of physicians practicing defensive medicine. In today's world of medical malpractice, physicians are beginning to order unnecessary tests, for instance MRIs when X-rays would be sufficient, because they are concerned that they will be found negligent in the event that their patient files a claim of medial malpractice. Nationally, studies show that on average, that 4.8% of all the members of a health plan have had a one or more CT scans. That is an astounding number.

did not

The second reason is one of supply and demand. General Electric, the largest supplier of MRI machines, expected all of the growth in MRI sales between 2001 and 2005 to occur out side the hospital. We have seen an increase in physicians who did previously have these machines in their office, now having them. Physicians are buying CTscans, PETscans and MRIs machines and driving their patients to these units. It is important to remember in CT, any licensed physician can have any of these machines in their offices and administer the tests, not just radiologists.

That supply and demand has also occurred on the hospital side. In CT, 60% or more of our hospitals have MRIs and 70% to 79% have CT scans. The bottom line is that hospitals need to

have people in those machines to cover the cost of having and maintaining those machines. And it has been our experience that it is not always done with the patient's medical need in mind.

For all these reasons, we believed it was important to put some clinical measures, like prior authorization, in place to fulfill our obligation to the member and the purchaser of health care. We believe it is essential to ensure access to diagnostic imaging when it is clinically indicated. At the same time, consumers need to understand that the newest, most expensive technology is not always necessary and in many cases will not improve the quality or results of their care. Further, we believe that physicians need to reaffirm their commitment to evidence-based medicine and evaluate whether an additional diagnostic test will change their treatment plans before ordering the test. Finally, hospitals and other providers should refrain from engaging in a "medical arms race," where every facility wants to have every technology even if doing so will create substantial excess capacity.

Anthem Blue Cross and Blue Shield also believes it is important that we leverage information on how and where costs and utilization are rising and share it in partnership with providers to ensure access to services while reducing unnecessary utilization.

Prior authorization on these services is an essential tool in ensuring that all these things occur. Therefore, Anthem Blue Cross and Blue Shield ***respectfully oppose*** this legislation and I would be happy to answer any questions that you might have.

I am also attaching a report from the Medicare Payment Advisory Commission's report to Congress which cites the increase new technology, including imaging services.

Quality is Our Bottom Line

The Connecticut Association of Health Plans
Testimony Before The
Insurance and Real Estate Committee
March 15, 2005

Regarding

SB 1298, AAC Health Insurance Coverage for Outpatient Imaging Services

The Connecticut Association of Health Plans strongly urges rejection of SB 1298, because it is, in all honesty, grossly out of touch with the current realities of health care economics. Outpatient imaging is one of the two fastest growing areas of medical expense for many health plans, due in large measure to the enormous investments made by institutions and physician entrepreneurs in imaging equipment. We have excellent data which show that there is a direct correlation between the availability of particular imaging techniques and their utilization – in other words, the high-tech imaging techniques listed in this bill, are consistently ordered when they're available, regardless of whether there is a less expensive imaging option available.

Unfortunately, in imaging, utilization follows the capital investment rather than medical necessity, and prohibiting requirements that members request approval for these services eliminates the only real tool that exists to manage imaging costs.

Please reject SB 1298. It would be very, very costly for members.

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

Dr. Romano,

I am writing this letter in support of your recently proposed Medicare regulations. I am currently employed with a privately owned and operated laser rental company that does not offer ownership to physicians. I am currently in a leadership role as a Regional Manager. I have worked for the last five years exposing and providing training for physicians on new technology and new surgical techniques that will enhance their practices and deliver a higher quality of care to the patients.

As the market for the use of lasers in medicine has grown, there have been businesses established that offer ownership to the end user, in our case the physician, creating what we believe to be an anti-competitive business environment. We welcome friendly competition in our business when decisions that are being made by the customer are based on availability of technology, service levels and marketing efforts. We have experienced that when a business model compensates the end user for increased usage of a service without personally incurring cost for the service, several unhealthy behaviors may happen as a result. The results are unhealthy for our business but more importantly for the patient and the healthcare system. The behaviors that may occur that are of most concern are listed below:

- Over-utilization of services driving increased insurance claims.
- Steerage of business from one location to another or threatening to do so based on increased compensation for the end user. This eliminates the hospital's ability to choose their business partners based on quality of technology, service and competitive pricing.
- Utilization of antiquated or lesser technology to contain cost and keep profitability of the company delivering the services as high as possible. The patient will not be receiving the best possible procedure.

I understand the physician's desire to maximize their earning potential but it should not continue in the form of the physician owned LLC delivering technology services on a per case basis. If additional revenue opportunities are needed to drive the behavior of the physicians to do what is right for the patients and healthcare, it should be done in the format of direct reimbursement for professional services.

Regards,

Patrick Filipovitz
Regional Manager

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August 29, 2007

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

Re: Proposed Revisions to Payment Policies Under the Physicians Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of Clearwater Cardiovascular and Interventional Consultants (CCIC) and our 20 individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the ***"Resource-Based PE RVU's"*** section of the above referenced July 2, 2007 Proposed Rule. We are specifically concerned with the 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact that could result for our practice and our patients if these values are finalized for the 2008 Physicians Fee Schedule.

CCIC is a 20 physician cardiovascular medicine practice located in Clearwater, FL. CCIC operates one outpatient cath lab as an integral part of its practice. The CCIC lab performs approximately 1,400 diagnostic cardiac catheterizations and approximately 150 vascular interventional procedures annually.

CCIC is a member of the Cardiovascular Outpatient Center Alliance (COCA) and as such we have actively been involved in the work that COCA has accomplished this year to collect and submit direct and indirect cost data to the AMA's Practice Expense Review Committee (PERC) of the Relative Value Scale Update Committee (RUC). Unfortunately, this process did not allow all of COCA's data to be considered and resulted in PE RVU recommendations to CMS that severely undervalued the direct and indirect costs associated with providing these procedures to our patients.

(continued)

It is apparent from the July 2, 2007 Proposed Rule that CMS has accepted the RUC recommendations without considering the detailed direct cost information that COCA provided to CMS in May 2007. The PE-RVU values set out in the July 2 Proposed Rule would result in a draconian cut in reimbursement for cardiac catheterizations performed in practice or IDTF locations. For example, if the 2007 conversion factor is applied to the technical component of the primary three CPT codes for a Left Heart Cath (93510TC, 93555TC, and 93556TC) the reimbursement in 2008 would be cut by **32%** and when fully implemented the total reimbursement would be reduced by **49%**. These reductions would undoubtedly result in the closing of the majority of non-facility outpatient cardiac catheterization labs in the country forcing all patients who now benefit from improved access and lower costs into more acute hospital settings.

We request that CMS review the additional cost data provided by COCA and establish PE RVU's for outpatient cardiac catheterization procedures that more reasonably reflect the direct and indirect costs of providing these procedures. If the proposed RVU's are allowed to stand, the outcome will inevitably that will cost the Medicare program more in direct APC payments **and** Medicare patients more in higher deductibles and co-insurance.

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

Sincerely,

Frederic R. Simmons, Jr. CPA
Chief Executive Officer

AND

The Physicians at Clearwater Cardiovascular and Interventional Consultants

Michael D. Williamson, M.D.
Paul L. Phillips, M.D.
Richard Sola, M.D.
Jose L. Gallastegui, M.D.
Douglas J. Spriggs, M.D.
Vanessa J. Lucarella, M.D.
Bernardo Stein, M.D.
Jorge P. Navas, M.D.
Aland R. Fernandez, M.D.
H. Andrew Hazlitt, M.D.
Mark J. Hepp, M.D.
David D. Dieterich, D.O.
Paul E. Kudelko II, D.O.
Kenneth C. Sabatino, M.D.
Federico E. Lenz, M.D.
Jay K. Amin, M.D.
Jason T. Zelenka, M.D.
Paul E. Kudelko, Sr., D.O.
Marilyn Y. Kuo, M.D.
Michael O. Barry, M.D.

CCIC/FRS:jmb

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August 30, 2007

VIA FEDERAL EXPRESS

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

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

Dear Sir or Madam:

For the last 11 years I have been a licensed physical therapist in the state of Tennessee. Over that time I have practiced in a hospital satellite outpatient facility, an outpatient clinic that was part of a large, corporate owned group of rehab clinics, and currently in an outpatient facility within a physicians' practice. I have had additional experience within privately owned rehab facilities. During my career I have had the opportunity to see in great detail both the clinical and business/administrative side of physical therapy and rehab.

I am writing to urge your continued support of physical therapy being offered as an ancillary service within physicians' practices. After being exposed to different practice settings, I am confident the care and attention a patient receives in a rehab setting within a physician practice offers patients the best clinical care as well as most cost effective clinical outcome.

Practicing physical therapy within a physicians' office offers patients the highest quality care simply because therapists and physicians can work together in the same physical setting to offer a true team approach to patient treatment. The points below outline the advantages of the physician setting.

- I have immediate access to my patients' physician to discuss any concerns about that patient's treatment allowing for immediate changes to that patient's plan of care when needed.
- I have immediate access to all physician's notes and radiology reports, etc. allowing me to gain instant access to the information I need to make quick decisions about how to progress a patient.
- I am able to immediately consult the patient's physician with any medical emergent situations that are outside my scope of practice.
- Patients are able to begin physical therapy immediately without going to a separate facility resulting in increased convenience for the patient as well as more cost effective outcomes due to having started therapy quickly.

The advantages that exist with patients receiving therapy in a physician setting collectively lower the number of visits required to reach a quality clinical outcome and likewise lower the costs associated with providing that care. In my experience, there is an average of around 30% fewer visits needed to treat a patient in a physician setting vs. a private practice or corporately owned facility.

I again urge your support of my ability to continue to practice physical therapy within a physician office. I believe it is the most clinically and cost effective model for providing physical therapy and other rehab services and would be a disservice to patients to not allow them the chance to choose this setting for their rehab care.

Sincerely,

David Erber, PT

TAP PHARMACEUTICALS INC.

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Washington DC Regional Office

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Phone: 301.828.3000
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August 30, 2007

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

Re: CMS-1385-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Acting Deputy Administrator Kuhn:

TAP Pharmaceutical Products Inc. ("TAP") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed physician fee schedule rule ("Proposed Rule").[1] TAP is one of the nation's leading pharmaceutical companies and is committed to delivering high quality pharmaceutical products for patients. We provide innovative and effective products in diversified treatment areas, including oncology, gastroenterology and gynecology.

TAP supports CMS's efforts to improve the accuracy of manufacturers' Average Sales Price ("ASP") calculations. We believe, however, that certain provisions in the Proposed Rule require further clarification, in particular issues related to the definition and application of "bundled price concessions." Each of these issues is discussed in detail below.

ASP ISSUES

I. CMS Should Confirm that Bundled Discounts Should Be Reallocated at the NDC-11 Level for Purposes of Average Sales Price ("ASP") Calculations

TAP supports CMS's attempt to promote a consistent method for addressing bundled arrangements in the both the ASP and average manufacturer price ("AMP")/Best Price ("BP") contexts, while also recognizing the need for differences between the two approaches to reflect the differences in the Medicare and Medicaid calculations. One area where TAP believes that the ASP Proposed Rule may differ from the approach adopted in CMS's Medicaid final rule (the "Medicaid Final Rule")[2] is with respect to the national drug code ("NDC") level at which bundled discounts should be allocated. The Medicaid Final Rule makes clear that AMP is to be calculated at the NDC-9 level, but it is TAP's understanding that for purposes of ASP, bundled discounts should be unbundled at the NDC-11 level, because that is the level at which manufacturers are required to calculate ASP. TAP asks that CMS confirm this understanding in its final rule.

II. CMS Should Clarify the Extent to Which Non-lagged Discounts are Part of the Bundled Arrangement.

TAP requests that CMS clarify whether non-contingent discounts that are offered in the same contract that contains a bundled arrangement, whether those non-contingent discounts are offered on the products included in the bundle or on separate products, also are subject to the reallocation requirement in the proposed section 414.804. Such clarity is needed not only to provide additional

[1] 72 Fed. Reg. 38122 (July 12, 2007).
[2] 72 Fed. Reg. 39,142 (July 17, 2007).

requirement in the proposed section 414.804. Such clarity is needed not only to provide additional certainty regarding what discounts are subject to reallocation, but also because such guidance will determine whether such non-contingent discounts, where otherwise considered to be non-lagged, need to be treated as lagged for purposes of the ASP calculation.

TAP commends CMS for recognizing the potential impact of adopting a reallocation methodology for bundled price concessions on the 12-month rolling average ratio that manufacturers are required to use to estimate lagged price concessions.[3] The definition and scope of the bundled arrangement could include:

(i) only drugs subject to contingent discounts and only those discounts offered on those drugs that are contingent,

(ii) any non-contingent discounts also provided on those same drugs, and/or

(iii) any drugs included in the same contract that are not subject to any contingent discounts and that do have non-contingent discounts.

If CMS defines the bundled arrangement to include (ii) and/or (iii), the reallocation methodology could have the effect of converting non-lagged discounts into lagged discounts.

For example, a contract could provide a 15% purchase discount on Drug A as well as an additional 5% rebate on Drug A if the purchaser buys a minimum volume of Drug B. If CMS requires reallocation of the 15% purchase discount as well as the contingent rebate, TAP believes the proposed reallocation methodology could be interpreted to require the inclusion of the purchase discount in the 12-month rolling average ratio for lagged price concessions, because the manufacturer will not be able to calculate the relative sales volume for the two drugs until the end of the performance period for the rebate. The purchase discount would have otherwise been treated as non-lagged and incorporated into the ASP calculation in the reporting quarter. TAP asks that CMS address this issue as it finalizes its proposal and defines the scope of the reallocation methodology.

III. CMS Should Confirm that Manufacturers Are Not Required to Apply the Reallocation Methodology to Quarters Prior to First Quarter 2008

CMS makes clear in the Proposed Rule that if its proposal is adopted, manufacturers would allocate bundled price concessions for purposes of calculating ASP beginning with the reporting period for the first calendar quarter of 2008.[4] CMS does not specify whether manufacturers also should allocate bundled price concessions for those quarters prior to the first quarter of 2008 that are included in the 12-month rolling average used to calculate lagged price concessions. If a manufacturer includes the reporting quarter in the 12-month rolling average, the ratio used to calculate the ASP for the first quarter of 2008 will include eligible lagged price concessions for the second quarter of 2007 through the first quarter of 2008. TAP asks CMS to confirm that manufacturers may choose to apply CMS's new reallocation methodology for all four quarters in the 12-month rolling average, but that they are not required to do so. Allowing manufacturers this choice would provide the flexibility needed to accommodate the variation in manufacturers' system capabilities. For example, some manufacturers may find it operationally less complex to adopt the reallocation methodology all at once for all four quarters, whereas other manufacturers may prefer a quarter-by-quarter implementation based on the quarter being reported. Accordingly, TAP recommends that CMS permit manufacturers to choose whether to reallocate bundled price concessions for quarters prior to the first quarter of 2008.

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[3] 42 C.F.R. § 414.804(a)(3).

[4] 72 Fed. Reg. at 38151.

IV. CMS Should Specify that Manufacturers Are Not Required to Reallocate Discounts That Are Not Subject to a Purchase or Performance Requirement.

TAP urges CMS to clarify that its proposed definition of a bundled arrangement applies only to arrangements involving contingent discounts. In other words, it applies only to those discounts that are offered for meeting a specific purchase requirement of another product. CMS has proposed to define a bundled arrangement as an arrangement in which the price concession is conditioned on the purchase of the same or another drug or some other performance requirement "*or where the resulting discounts or other price concessions are greater than those that would have been available had the bundled drugs or biologicals been purchased separately or outside of the bundled arrangement.*"[5] TAP understands that the determination of whether a discount is considered part of a bundled arrangement is based on the first part of the proposed definition and that the language highlighted above serves as a modifier. However, we are concerned that the regulatory text could be read to create an independent obligation to reallocate discounts even where there are no contingent discounts under the contract or simply because multiple products are covered under the same contract. For example, many line-item contracts provide the customer with purchase discounts on a series of different NDC-9s, without regard to whether the customer purchases any other drug under the contract. In addition, a contract may include a minimum purchase or market share requirement for any purchase under the contract to be eligible for a discount. Such arrangements are not intended to create a bundle but rather, establish conditions for contracting. Reallocation of discounts that are not "conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement" would not reflect the price paid by the purchaser and could have a distorting effect on ASPs and provider reimbursement, which in turn could adversely affect patient access to needed treatments. For these reasons, we ask CMS to specify in the final rule that such non-contingent discounts are not a "bundled arrangement" and are not subject to reallocation under the proposed methodology.

V. CMS Should Delay the Effective Date For Bundling Provisions Beyond January 1, 2008.

Finally, TAP supports CMS's intent to apply the revised ASP calculation on a prospective basis. We believe, however, that it will take manufacturers and CMS considerable time to work through the open issues related to the bundled arrangement provisions of the Proposed Rule so that they can be properly implemented. To that end, TAP would support delaying the effective date of the bundled arrangement provisions to a date after January 1, 2008.

* * * * * * *

TAP appreciates the opportunity to comment on these important issues and we look forward to working with CMS to ensure access to medications to those in need through the implementation of an improved drug price reporting system. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions into the Final Rule. Please do not hesitate to contact me if you have any questions or need additional information.

Respectfully Submitted,

Laura Cline

Laura Cline
National Manager, Government Affairs

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[5] Id. at 38,226 (proposed 42 C.F.R. § 414.802) (emphasis added).

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August 30, 2007

VIA FEDERAL EXPRESS

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

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Dear Sir:

On behalf of University Physician Associates of New Jersey ("UPANJ"), the faculty practice plan of New Jersey Medical School ("NJMS"), Wolff & Samson PC welcomes the opportunity to comment on the *physician self-referral provisions* of the Centers for Medicare & Medicaid Services' ("CMS") proposed rule entitled "*Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008.*" 72 Fed. Reg. 38122 (July 12, 2007).

The purpose of this letter is to comment on the proposed clarification with respect to CMS's standard for percentage compensation arrangements (the "Proposed

Clarification") under the Federal physician self-referral regulations ("Stark" or the "Stark Regulations"). *See* 72 Fed. Reg. at 38184. If finalized without any exception for faculty compensation arrangements within the academic medical center ("AMC") setting, the Proposed Clarification will place an enormous burden on AMCs and, ultimately, their ability to carry out their charitable missions to provide high quality medical education and essential community medical care. The Proposed Clarification, in effect, prohibits faculty compensation formulas that entail any type of initial "pooling" of revenue received on the basis of multiple faculty members' provision of clinical care within a medical school department or institute ("clinical unit"), a common and historical practice among faculty practice plans. It does this by disallowing percentage compensation arrangements where they result in compensation to a physician that is not directly/solely based upon the physician's personally performed services.

As further explained below, the Proposed Clarification would require unwarranted and costly restructuring to AMC faculty compensation methodology, which will severely restrict AMCs' ability – and particularly NJMS's ability, due to the fact that it predominantly serves a very poor population – to (i) distribute faculty clinical and academic assignments in specialties and subspecialties in accordance with community clinical care need and/or student education needs; and (ii) recruit and retain high quality faculty. These effects are severe. We suggest CMS specifically exclude AMCs/faculty practice plan clinical unit "pooling" percentage compensation arrangements from the reach of the Proposed Clarification.

I. Factual Background – NJMS and UPANJ, and AMC Faculty Compensation Arrangements

NJMS Campus – Predominantly Serves Very Poor Population. The NJMS campus is located in Newark, New Jersey and predominantly serves an extremely poor population, which is most in need of healthcare services. NJMS has a continuously eroding payor mix, consisting – up to 70% – of low reimbursement payors, such as Medicaid, Medicaid HMO, charity care, and self-pay. Recent American Association of Medical Colleges ("AAMC") data indicate that the NJMS payor mix is far below the 25th percentile of AAMC members' plans, indeed, it is one of the worst of all schools. *See* AAMC 2007 Faculty Practice Plan Survey. As a result, although NJMS serves the neediest of patients and, thus, fulfills a very crucial community healthcare role, recruiting and retaining high quality faculty is consistently a challenge for NJMS. The reality is that the private sector generally offers a much higher quality payor mix and, thus, a much more competitive salary potential.

UPANJ – Billing and Distribution of Faculty Clinical Practice Funds. UPANJ is the faculty practice plan of NJMS, and as such, it bills for professional medical services

provided by NJMS Faculty and collects and distributes the revenues from such services ("Faculty Clinical Revenues") in accordance with preset percentage-based formulas determined by the clinical faculty of NJMS within its clinical units. These formulas differ from clinical unit to clinical unit and are based upon the specific needs of the individual clinical unit. The portion of the distribution of Faculty Clinical Revenues that an individual Faculty member receives is based upon a formula set by the NJMS clinical unit in which such individual is a member, and is compensation for his or her performance of clinical services, as specified by his or her faculty employment agreement with NJMS.

Faculty Compensation Clinical Unit Formulas – the Partial Pooling Distribution Formula. NJMS is one of many AMCs that compensates faculty for clinical services via clinical unit, percentage-based formulas. While most NJMS Faculty members will only receive compensation based upon a percentage of Faculty clinical revenues solely attributable to services such Faculty members personally perform (i.e., a compensation based solely on personal productivity), certain NJMS clinical unit formulas are based, in part (i.e., only a certain percentage of Faculty compensation in such a scenario is based), upon a collective pooling of Faculty Clinical Revenues received from clinical services performed by the entire group of Faculty members of the particular clinical unit (the "Partial Pooling Distribution Formula").

Purpose of NJMS Partial Pooling Distribution Formula. The NJMS clinical units that utilize a Partial Pooling Distribution Formula operate in a manner similar to single-specialty group practices, where each physician member partially shares the risks and rewards of the practice. As such, the Partial Pooling Distribution Formula is a product of the history, culture, and particular circumstances of a given clinical unit. The Partial Pooling Distribution Formulas are generally used when there is a particular sub-specialty or procedure performed within a clinical unit that is more remunerative than others within the unit, or where there are certain procedures or specializations of comparatively low remunerative value that are needed to be performed within the clinical unit for academic or community care purposes. The Partial Pooling Distribution Formula enables the clinical unit to distribute academic and clinical faculty assignments within such unit based solely upon the academic/student or community clinical need, and not on any faculty member's preference to perform more lucrative procedures or to specialize in a certain area for purposes of increased compensation. The Partial Pooling Distribution Formula greatly supports NJMS in fulfilling its mission of providing high quality health instruction and community health care via an efficient and appropriate distribution of faculty clinical assignments.

The flexibility of the Partial Pooling Distribution Formula is an important tool and significantly assists NJMS to recruit and retain high quality faculty to carry out its mission. In reality, maintaining faculty appeasement and fostering an incentive to

practicing physicians to join the AMC setting and remain employed in an AMC setting, beyond a charitable or community health-care motivation, is extremely important and presents a continuous challenge for AMCs. This is particularly the case for NJMS, where, due to NJMS's exceedingly low quality payor mix, the private sector tends to be much more attractive to a practicing physician, regardless of the most noble of charitable or educational intentions or aspirations.

II. Regulatory Background – AMC Exception

CMS had initially rejected the creation of a Stark exception specific to faculty practice plans. However, CMS revisited its position and, in the Phase II regulations, instituted an exception specific to academic medical centers (the "AMC Exception"). 66 Fed. Reg. 856, 915-16 (Jan. 4, 2001). CMS's rationale behind this exception was as follows:

> Academic medical settings often involve multiple affiliated entities that jointly deliver health care services to patients (for example, a faculty practice plan, medical school, teaching hospital, outpatient clinics). There are frequent referrals and monetary transfers between these various entities, and these relationships raise the possibility of indirect remuneration for referrals. The exceptions under section 1877 of the Act do not easily apply...*[W]e believe the fundamental need of faculty practice plans is for a separate compensation exception for payments to faculty of academic medical centers that takes into account the unique circumstances of a faculty practice*, including the symbiotic relationship among faculty, medical centers, and teaching institutions, and the educational and research roles of faculty in these settings.

66 Fed. Reg. at 916 (emphasis added).

III. History of the Proposed Clarification – the "Set In Advance" Standard, and Percentage Compensation Arrangements

The AMC Exception requires, in part, that faculty compensation be "set in advance." 42 C.F.R. § 411.355(e)(1)(ii). As is evident in the Stark II, Phase I preamble, CMS did not initially consider percentage compensation arrangements, such as those commonly used in AMC settings, to be "set in advance." *See* 66 Fed. Reg. 856, 877-78 (Jan. 4, 2001). CMS subsequently decided to consider percentage compensation arrangements as "set in advance" provided certain requirements are met. 42 C.F.R. § 411.354(d)(1).

IV. The Proposed Clarification

CMS has proposed to clarify that percentage compensation arrangements "(1) [m]ay be used only for paying for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided)." 72 Fed. Reg. at 38184. Although CMS is largely concerned with the inappropriate use of percentage compensation arrangements in the context of space and equipment leases and endorses the Proposed Clarification for this primary reason, the Proposed Clarification clearly applies to all types of percentage compensation arrangements, including the typical clinical unit formulas used to compensate AMC faculty for their clinical services.

V. The Harsh and Burdensome Effect of the Proposed Clarification

The Proposed Clarification Causes Historical and Highly Beneficial Faculty Compensation Methods to Fail to Meet the Stark AMC Exception.

The Proposed Clarification would appear to cause historical AMC faculty compensation methods such as the NJMS Partial Pooling Distribution Formula to fail to meet the AMC Exception "set in advance" standard. This is because the NJMS Partial Pooling Distribution Formula may result in compensation to a Faculty physician that is not solely attributable to such Faculty physician's personally performed services, but is, in part, attributable to services performed by fellow Faculty physician members within the same clinical unit. This is a most devastating effect. As set forth above, CMS created the AMC Exception because AMCs/faculty practice plans do not fit easily, or at all, in other Stark exceptions. Faculty practice plans generally do not meet the Stark definition of "group practice", and UPANJ in particular, in fact, does not. Therefore, meeting the AMC Exception is crucial for many AMCs, including NJMS.

Comparison to Physician Compensation Permitted in Group Practice Definition – Faculty Practice Plans Should Have, at the Very Least, Equal Latitude in their Compensation Methodology.

The Stark group practice definition states that physicians in the group may be paid a share of overall profits. 42 C.F.R. § 411.352(i). This is a form of "pooling" compensation directly comparable to the NJMS Partial Pooling Distribution Formula: just like the NJMS Partial Pooling Distribution Formula, the sharing of "overall profits" among group practice physicians would result in compensation to each group practice physician member that includes, in part, remuneration that is not solely attributable to such physician's personally performed services. The group practice definition takes this

a step further and allows even greater flexibility by defining the term "overall profits" to include entire profits from a component of the group practice that consists of at least five physicians. *Id.* at 411.352(i)(2). This, in effect, means that group practice physicians can compartmentalize their practices and share in the productivity of a relatively small portion or the overall practice. Such a "pooling" form of compensation is acceptable under Stark, provided the compensation is distributed in a manner that does not *directly* relate to the volume or value of referrals of the physician being compensated. *Id.* The group practice definition provides a few distribution methods of such pooling compensation that are *deemed* not to take into account the volume or value of referrals, including the per capita method of distribution. *Id.* As CMS has stated, the rational for these "deemed indirect" standards is that they result in compensation in which there is "no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's DHS referrals (regardless of whether the services are personally performed)." 66 Fed. Reg. 856, 908 (Jan. 4, 2001).

In spite of the flexibility of the compensation methodology afforded by the Stark Regulations to *any* physician entity that meets the "group practice" definition, faculty practice plans such as UPANJ – which does not meet the "group practice" definition, yet is a non-profit 501(c)(3) tax-exempt organization, and exists solely to support the charitable and educational missions of NJMS – are effectively stripped of the much needed flexibility to compensate faculty physicians in a manner similar to that permitted for group practices under the Stark Regulations. In light of the great community healthcare and educational needs that medical schools and faculty practice plans fulfill – and in particular, UPANJ due to the poor population it serves – this is an illogical and unfair result that is incongruent with CMS's intent in establishing the AMC Exception.

Faculty practice plan clinical units should be afforded, at the very least, flexibility in their compensation structures that is commensurate to that afforded in a "group practice" setting. As stated above, the NJMS Partial Pooling Distribution Formula serves a very important purpose that is directly supportive of NJMS's charitable and educational missions. Stripping AMCs such as NJMS of the availability of such compensation formulas would require massive and costly changes to existing historical compensation methods and will have deleterious effects on an AMC's ability to (i) efficiently and appropriately distribute faculty clinical assignments in accordance with direct academic/student and community clinical care needs and (ii) recruit and retain high quality physicians to serve the AMC's mission and meet an underserved community's needs, by severely limiting the AMC's flexibility to provide faculty physicians with competitive/commensurate compensation. These effects are particularly severe in the case of NJMS, due to the poor population it predominantly serves. Flexibility in compensation methodology is crucial for NJMS.

VI. Suggestion to Alleviate the Devastating Effects of the Proposed Clarification

We are mindful and appreciative of CMS's primary concern in instituting the Proposed Clarification, which is to control the application of percentage compensation arrangements in the context of equipment and office space rentals. However, we strongly urge CMS not to overlook the unintended and devastating impact that the Proposed Clarification would have on AMCs and faculty practice plans.

CMS can address its concern regarding percentage compensation arrangements in the space/equipment rental and other contexts, and still afford AMCs the flexibility they require in their compensation structures. We propose that CMS specifically exclude from the reach of the Proposed Clarification AMC compensation formulas that include a pooling of revenue derived from the combined clinical services of a group of AMC faculty physicians, such as the NJMS Partial Pooling Distribution Formula.

For instance, such an exception can be made for percentage compensation arrangements used by a medical school clinical unit (which could be defined as a single-specialty department or institute of the medical school) to compensate faculty physicians within such unit where (i) each faculty physician in the medical school clinical unit meets the referring physician requirements of the AMC Exception (at 42 C.F.R. § 411.355(e)(1)(i)); (ii) such clinical unit is comprised of 5 or more faculty physicians; and (iii) the compensation distribution methodology is such that the compensation to a faculty physician does not relate directly to such physician's volume or value of referrals (e.g., the compensation distribution method satisfies Section (i)(2) of the group practice definition at 42 C.F.R. § 411.352).

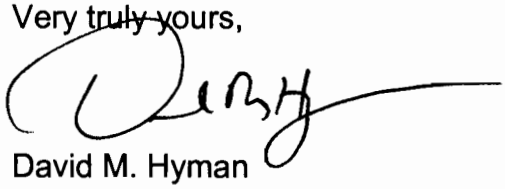
This type of revision to the Proposed Clarification would allow medical schools the flexibility to compensate their faculty physicians commensurate with private group practice physicians, while still presenting a low risk of fraud and abuse by (i) requiring the members of the clinical unit to be bona fide AMC faculty members; and (ii) ensuring that any faculty physician compensation resulting from the percentage compensation arrangement is not directly based upon the faculty physician's volume or value of referrals (by, for example, basing the exception on CMS's articulated standards for compensation methodology located in the group practice definition). In addition, since a medical school clinical unit is largely comprised of faculty physicians engaged in the same specialty, this type of revision to the Proposed Clarification would not encourage cross-specialty referrals (i.e., referrals across different medical school clinical units).

In light of (i) the "unique circumstances of faculty practice," which CMS has itself acknowledged (*see* 66 Fed. Reg. at 916); (ii) the existence of AMCs such as NJMS that have serious difficulty in attracting physicians from the private practice sector due to the

fact that it predominantly serves a very poor population; and (iii) the crucial educational and charitable missions AMCs such as NJMS and UPANJ serve, this is a most fair and just result. We are hopeful that CMS will agree and will amend the Proposed Clarification accordingly.

Thank you very much for your consideration. Please contact me should you require any additional information or if we can be of any further assistance.

Very truly yours,



David M. Hyman

DMH/ed
Enc.

Comments on Proposed Rule C 1385 for Physician Fee Schedule

I would like to comment on the Physician Self Referral Information section. In particular, I am concerned about the proposal to limit the ability of a physician group to purchase equipment and then hire a specialist to provide the professional services. In urban areas where multiple imaging or physical therapy centers are available, it may not be necessary for physicians to provide services, but CMS must also consider the rural areas where resources are less available.

When a physician group recognizes the need for services in their location, there are only two options to develop the services. The group can persuade a hospital to purchase the needed equipment or the group can do it. Either way, the specialist who knows how to provide the services must be hired. It should make no difference to CMS whether the hiring entity is a hospital or a group practice. In fact, as the physicians in a group have more expertise on the quality of the care provided that any administrator of a hospital could possibly have, the physician group is more likely to insist on better quality. Similarly, a physician working with peers, or as a member of the group is more willing to voice concerns about quality of care than an employee of a hospital.

The concern of CMS that over-utilization will occur should be equal for hospital owned facilities or physician owned facilities, as both have the same incentive for Return on Investment of the equipment. Proof of medical necessity should be required in both instances.

Therefore, CMS should recognize that the owning entity being a hospital does not eliminate the possibility of overuse and is not necessarily superior or more ethical than physician ownership. The rules for both situations should be the same.

In response to your decision to prohibit per click leases for equipment, I would request that you leave the rules as they are. Many arrangements have been made and are functioning well for the hospitals, the physicians and the patients. When the equipment is used for medically appropriate reasons, and the volume of use is impossible to predict in advance this is a good way to encourage doctors and hospitals to share equipment rather than having each purchase equipment separately. This keeps costs lower, and allows the site of service to vary according to patient need. For example, our radiation oncologists can lease the High Dose Rate machine to the hospital when a patient needs the more intensive inpatient setting, and then transport the machine back to the office when a patient can be treated in the outpatient arena. If we could not do this, both the hospital and the practice would have to purchase the same machine, thus increasing the cost per patient for treatments, ie practice expense.

As more functions can be provided in the physician office setting, it is time for CMS tro recognize that the expenses to recruit trained personnel are the same in the hospital setting as in the office setting. The cost of the machinery, maintenance software and other overhead items is identical. Therefore the practice expense calculation should be

they did not fit the stage requirement for the colon cancer patient reporting, it was unclear how to properly report.

On Physician Scarcity Areas
The 5% bonus for physicians practicing in physician scarcity areas has been deleted, but the undersupply of physicians has not been addressed. Please reconsider this decision.

Respectfully submitted,
Barbara McAneny MD
Former PPAC member

614

Coastal Gastroenterology
525 Jack Martin Blvd
Brick, NJ 08724

August 17, 2007

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

Re: Proposed Full-Time Physician Employee Requirement

To Whom It May Concern:

On behalf of my gastroenterology physician practice, I am writing to express our opposition to CMS's proposed requirement that our pathologist must be our full-time employee in order for us to bill the Medicare program for the professional services he renders. Currently, we have an independent contractor relationship with a pathology practice that provides us with a part-time pathologist and vacation, sick and continuing medical education relief, as needed. We will no longer be able to provide professional pathology services to our patients if the proposed full-time employee requirement is adopted. In other words, we do not have a sufficient number of specimens for a pathologist to work for us [40] hours per week. CMS's adoption of this requirement would unfairly prohibit us from providing our Medicare and other patients with the best professional care possible.

We believe that the best approach to caring for our Medicare and other patients is to be multi-specialty: gastroenterology and pathology. While this type of multi-specialty practice is different than the traditional multi-specialty practices (e.g. internal medicine and cardiology), adding a part-time independent contractor pathologist to our gastroenterology practice has significantly improved the overall quality of the professional services we provide to our patients. For example, our part-time independent contractor pathologist specializes in gastroenterology. His expertise makes us more confident in the accuracy of the diagnosis which enables us to make better treatment decisions. Candidly, the "one size fits all" pathologists we had to rely on at the national lab companies made uneasy at times as we reviewed their pathology reports.

We also would like to make you aware that timely communication has improved by having a part-time independent contractor pathologist working with us side by side in our offices. Follow-up questions about a diagnosis no longer involve the tremendous effort to track down a specific pathologist at a large national lab located in another part of the country Our part-time independent contractor pathologist is practicing in our offices which means we can easily discuss his findings and even review a slide together using our microscope. From our vantage point, the ability to have personal contact on a day to day basis with our part-time independent contractor pathologist has also shortened the turnaround time associated with diagnosing and treating our patients. For these quality of care reasons, we urge CMS not to adopt the full-time employee regulation.

It is also important to note that the addition of a part-time independent contractor pathologist to our gastroenterology practice has not led to an increase in the number of tests we order for our patients. If CMS has preliminarily concluded that Medicare would spend more money if physicians independently contracted with part-time pathologists because more lab tests would be ordered, this conclusion is simply not true in our case. We strongly urge CMS

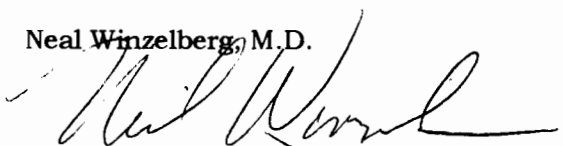
to distinguish our anatomic pathology services and the tests we order from clinical pathology services. Our patient procedures are invasive and require us to take tissue from patients. We do not perform these procedures nor do we take tissue from our patients lightly. If CMS has preliminarily concluded that a gastroenterology practice would subject a patient to additional invasive procedures and physicians would take extra tissue in order to generate additional Medicare reimbursement, CMS has really drawn the wrong conclusion. There is a world of a difference between the anatomic pathology we do and the clinical pathology that CMS has been rightly concerned about over the years.

Our gastroenterology practice would no longer be able to provide professional pathology services to our patients if CMS adopts the full-time employee requirement. We have four gastroenterologists and the number of specimens we take from our patients is no where close to the number needed to support a full-time pathologist employee. Frankly, we need to independently contract with the local pathology practice. This independent contactor relationship ensures us that we will have the pathologist coverage we need at all times. Even if we could support a full-time pathologist employee, it would be impossible for us to provide vacation, sick and continuing medical education coverage without having an independent contractor relationship with the local pathology practice. Our independent contractor relationship with the local pathology practice not only improves the quality of care but provides for continuity of the pathology care we provide to our Medicare patients.

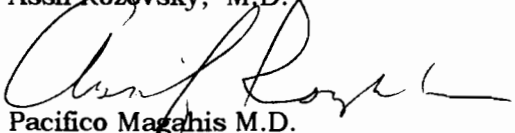
In our view, the adoption of the full-time employee requirement by CMS stops us from practicing medicine the way we believe is best for our patients. Because we have a significant Medicare patient population, a CMS decision that prohibits the Medicare program from reimbursing us because we only need a part-time pathologist which we obtain through an independent contractor relationship with the local pathology practice is, no matter how ones slices it, interfering with the practice of medicine. Because of the improved turnaround time and better quality of care our Medicare patients receive, we urge CMS to continue to permit the Medicare program to reimburse professional pathology services that are provided through part-time, independent contractor relationships.

Very Truly Yours,

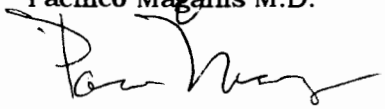
Neal Winzelberg, M.D.



Assif Rozovsky, M.D.



Pacifico Magahis M.D.



Kenny Chiu, M.D.

615

GE Healthcare

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Via Federal Express

August 30, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS- 1385-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

GE Healthcare is a unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research, drug discovery and biopharmaceuticals. Worldwide, GE Healthcare employs more than 42,000 people committed to service healthcare professionals and their patients in more than 100 countries.

We appreciate the opportunity to submit comments on the proposed Revisions to Medicare Payment Policies Under the Physician Fee Schedule for Calendar Year 2008, published in the July 12, 2007 Federal Register (Vol. 72, No. 133).

ASP Issues

Bundled Arrangements

We agree with CMS that the alternate approach (contingent discounts) suggested by MedPAC for handling bundled price concessions would introduce greater computational complexity and could not be implemented by manufacturers in a timely fashion.

There are circumstances, however, under which CMS' proposed treatment of allocating the total value of all price concessions proportionately across each drug will result in payments to Independent Diagnostic Testing Facilities (IDTFs) that do not approximate costs for the drugs. For example, when a high market volume product at low price is bundled with a smaller market volume product at medium price and incremental discounts are provided on all products in the bundle, pricing can become extremely skewed using the proposed treatment.

In these situations it is highly likely that some providers will be over compensated for the high market volume product, while other providers will be under compensated for the smaller market volume product.

The following examples will examine potential outcomes if CMS' proposed treatment is implemented:

- We have approximated the Allocated ASP for two product categories that are very commonly bundled in GE Healthcare contracts (Table 1). Please note that these ASPs were calculated at the brand level for illustration purposes only, and not using the 11 digit NDC level that CMS requires.

  - CT Contrast Material - (LOCM, HCPCS Codes Q9945, Q9946, Q9947, Q9948, Q9949, and Q9950) – High Volume, Low Price

  - MRI Contrast Material – (Inj, gadolinium-based MR, per ml, HCPCS Code Q9952) – Medium Volume, Medium Price

- Many IDTFs only have MRI capability or CT capability, but not both. Some IDTFs will provide both imaging modalities. We have applied the proposed treatment of bundling to each of the three configurations (Examples 1-3).

TABLE 1

	Units	Sales at List Price	% of Sales	Actual Discount	Allocated Discount	Current ASP	Allocated ASP	% Change
CT Contrast Material	224,690	263,741,130	77.84%	203,423,022	188,367,062	268.45	335.46	24.96%
MRI Contrast Material	78,872	75,066,422	22.16%	38,557,374	53,613,334	462.89	272.00	-41.24%
TOTALS	**303,562**	**338,807,553**	**100.00%**	**241,980,396**	**241,980,396**			

EXAMPLE 1 (CT only)

	Units	Sales at List Price	Current ASP	Allocated ASP	Current Payment	Allocated Payment	Percent Change
CT Contrast Material	1,000	1,173,800	268.45	335.46	268,450	335,458	24.96%
MRI Contrast Material	0	0	462.89	272.00	-	-	

EXAMPLE 2 (MRI only)

	Units	Sales at List Price	Current ASP	Allocated ASP	Current Payment	Allocated Payment	Percent Change
CT Contrast Material		0	268.45	335.46	-	-	
MRI Contrast Material	1,000	951,751	462.89	272.00	462,890	272,000	-41.24%

EXAMPLE 3 (Both CT and MRI)

	Units	Sales at List Price	Current ASP	Allocated ASP	Current Payment	Allocated Payment	Percent Change
CT Contrast Material	1,000	1,173,800	268.45	335.46	268,450	335,458	24.96%
MRI Contrast Material	351	334,065	462.89	272.00	162,475	95,472	-41.24%
Total					430,925	430,930	0.00%

These examples show that the implementation of CMS' proposal will result in a perverse incentive for CT procedures using contrast media. The MRI-only IDTF would have a perverse incentive to avoid using contrast media, even when medically advantageous. Example 3 shows that an IDTF providing both MRI and CT in roughly the same mix as the total market will be reimbursed at appropriate levels.

Given the large number of single modality providers and the variable mix of procedures for multi-modality providers, CMS should continue to use the current ASP methodology for medical imaging drugs.

Thank you for the opportunity to comment on this important rule. Should you have any questions, please contact me at 609-514-6701 or at jane.majcher@ge.com.

Sincerely,

Jane Majcher

Jane Majcher
Director, Reimbursement Strategy

616

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August 30, 2007

VIA FEDERAL EXPRESS

Mr. Kerry Weems
CMS Administrator Designate
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P: PHYSICIAN SELF-REFERRAL PROVISIONS

Dear Mr. Weems:

We have been asked to submit these comments on behalf of a specialty medical device company (the "Company") that is affected by the proposed changes to the Physician Self-Referral Provisions in the above referenced proposed rule ("Proposed Rule"). Our comments focus primarily on the "Services Furnished 'Under Arrangements'" portion of the Proposed Rule. In brief, we request that CMS either (1) withdraw the proposed amendment to the definition of designated health services (DHS) "entity", or (2) clarify that the "entity that has performed the DHS" or that "caused a claim to be presented" includes only an entity that performs all required components of the service.

Background

The Company manufactures equipment and associated devices that are FDA approved and covered by Medicare for treatment of certain conditions. Given the cost of the equipment (well over $200,000), as well as the fact that only physicians who are specially trained are able to use the technology, few hospitals outside the academic setting have the case volume to justify purchasing the equipment. Until this year, fewer than ten hospitals purchased the equipment outright, thus limiting the treatment options available to patients and their physicians.

A number of physicians who are trained to perform the procedures using the Company's technology, particularly "early adopters" of the technology, wished to make the treatment available to their patients. These physicians have invested in mobile equipment businesses ("Businesses") that purchase the equipment, purchase the necessary vehicles to mobilize the

equipment, and employ a specially trained technician. The Businesses then provide the equipment, related disposables and the technician to hospitals on a per case basis. This permits the hospital to provide the types of procedures that utilize the equipment without investing in the equipment, and permits the physicians to make these procedures available to their patients.[1]

It is important to note that the equipment and technician services at issue here are not items formerly provided by hospitals that have been spun off for purposes of permitting physician investment. Also, the physician owners of the Businesses are not passive referral sources who are receiving revenues from patient referrals for services which ordinarily would not result in income to the physicians. Rather, the physician investors in all cases we are aware of are surgical specialists who personally perform the procedures. In order to perform the procedure, the physicians must be willing to spend the time necessary to be trained on new technology. The only way to bring the benefit of that training to the community is to make the necessary equipment available as well.

Proposed Rule: Services Furnished "Under Arrangements"

Definition of "Entity"

Under the current physician self-referral rules, the DHS entity is the entity that bills Medicare for services. The Proposed Rule states "we propose to revise our definition of entity at § 411.351 so that a DHS entity includes both the person or entity that **performs** the DHS, as well as the person or entity that submits claims **or causes claims to be submitted** to Medicare for the DHS." *(Emphasis added.)*

The **definition of a DHS "entity" needs to be explicitly defined to EXCLUDE providers that provide only a portion of the DHS**. Here, the provision of equipment and customized devices for a medical procedure and/or the services of a technician to monitor the equipment should not be defined as "performing the DHS." In such cases, the hospital continues to provide pre-operative care, surgical facilities, pharmacy supplies, nursing care, post-operative and recovery room care and other associated inpatient care services. Indeed, the service is not covered and cannot be performed in a physician office or otherwise using only the components furnished by the Businesses. Yet, without further clarification, the Proposed Rule could sweep these types of arrangements into the definition of "entity". Although we think that providing only some of the components of DHS should not be considered to be "performing" DHS or "causing a claim to be submitted," the proposed rule has created a level of uncertainty for the Company, the Businesses, physicians and hospitals. Taken to its extreme, the amended definition of "entity" could be viewed as making any equipment lessor or entity that performs services for a DHS entity – even a provider of linens or food services - into a DHS entity itself. Obviously, it is not intended that an entity becomes a DHS entity simply by virtue of providing items or services to a DHS entity.

[1] There are a number of legal structures of the Businesses. In general, a number of individual physicians and/or physician groups invest. In some cases, a commercial mobile service provider also invests in the Business.

Yet, particularly in the hospital context, since all inpatient and outpatient hospital services are DHS, arguably all services performed for a hospital could raise this concern.

If companies that provide only a portion of DHS are considered to be DHS entities, then there will be no applicable investment exception for physicians who are willing to make the investment of time and capital necessary to make new technology such as that provided by the Company available in their communities. Eliminating the possibility that physicians who are trained to use new technology could invest in that technology would likely reduce the number of mobile service businesses available to hospitals. This would translate to increased costs to hospitals to purchase equipment and to hire and train technicians, who must have very unique skills and training. The equipment cost to a hospital to acquire specialized equipment would be greater than simply renting or paying a "per procedure" fee when cases are scheduled. Also, mobile companies are able to provide services to a number of hospitals and thereby generate volume to maintain technician proficiency. Finally, Medicare patient access may be placed in jeopardy as many hospitals that currently contract on a per procedure basis would elect not to purchase the capital equipment and hire and train technicians for a low volume procedure.

The indirect compensation exception that currently applies to arrangements between physician-owned service businesses such as the Businesses and DHS entities such as hospitals already ensures that these types of arrangements are not abusive. The indirect compensation exception strikes an appropriate balance between permitting physician investment in entities that do business with hospitals and ensuring that physician-owned businesses are not overpaid by hospitals and other DHS entities to which they refer. Hospitals that do business with mobile service providers that furnish the Company's equipment routinely require disclosure of physician ownership prior to entering into a contract with the mobile service provider, and, consistent with the indirect compensation exception, document the fair market value of the services.

Consequently, we urge CMS to take one of the following approaches:

(1) **Withdraw the proposed amendment to the definition of "entity".**

(2) **Adopt the amendment, but limit its scope to true "under arrangements" structures.** This could be accomplished by clarifying the following:

> *The "entity that has performed the DHS" includes only entities that perform* ***all*** *required components of the DHS.* Restricting the rule in this way would address concerns about freestanding suppliers entering into "under arrangements" transactions to game the Medicare payment system, as well as avoid the confusion and uncertainty of a rule that could potentially prohibit long-standing, simple equipment/staff leasing arrangements. Note that if those equipment/staff leasing arrangements involve physicians or physician-owned businesses, the physician self-referral law would continue to apply to the relationship, just like other direct and indirect relationships between physicians and DHS entities.

Eliminate the language of the amendment that deems the entity that "causes claims to be submitted" to be a DHS entity. To the extent that this provision is intended to be coextensive with the amendment deeming the entity that "has performed the DHS" to be a DHS entity, it is superfluous. To the extent that this clause applies to other entities, it is not clear how it would apply. For example, if it refers to any entity that charges a DHS entity for an item or service that, in turn, is included on the DHS entity's bill or cost report, it raises the same concerns as the noted above, *i.e.*, it would appear to make virtually any vendor to a DHS entity into a DHS entity itself.

MedPac Proposal

The preamble to the Proposed Rule also notes that MedPac had recommended expanding the types of relationships that constitute physician ownership of a DHS entity, so that a physician would be deemed to own a DHS entity if the physician has an ownership interest in an entity that derives a "substantial" proportion of its revenue from a provider of DHS. Although this approach has not been adopted in the Proposed Rule, the Proposed Rule solicits comments on implementation of the MedPac approach, either in combination with or instead of the proposed approach, and also solicits comments on how to define the word "substantial" for purposes of the MedPac approach. If physician ownership in a company that receives a "substantial" proportion of its revenue from a provider of DHS is deemed to be an ownership interest for physician self-referral law purposes, physician ownership of any such company that provides only a portion of DHS would be prohibited. Many mobile service providers do business primarily with hospitals, so almost any definition of "substantial" likely would preclude physician investment in such businesses. For the reasons stated above, physician investment can help to bring new technology to communities, and is already adequately limited by the currently applicable physician self-referral law rules, including the indirect compensation exception. It is not necessary to sweep away all physician investment in order to address specific identified abuses that can be addressed in a more focused manner.

Thank you for the opportunity to submit these comments.

Very truly yours,

Joan Polacheck

JP/bjs

CHI99 4870632-1.061813.0010

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August 30, 2007

VIA FEDERAL EXPRESS

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1835-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS-1385-P Physician Self-Referral Provisions

Dear Sir/Madam:

Please allow this letter to serve as comments to the above referenced Proposed Rule published by the Centers for Medicare and Medicaid Services ("CMS") on July 12, 2007 in the *Federal Register*. This Proposed Rule is intended to address CMS' expressed concerns regarding potentially abusive arrangements between health care providers.

After reviewing such Proposed Rule, we have certain comments for your consideration as outlined below. We believe such comments are consistent with protecting against Medicare Program ("Program") and patient abuse while serving to except legitimate relationships which have a longstanding basis and which have formed the basis of long term strategic planning. We also believe that, on balance, smaller hospital operations as well as rural hospitals are at greater risk as a result of these proposals.

Consequently, please find below our comments.[1]

1. Unit-of-Service (Per-Click) Payments in Space and Equipment Leases. The Proposed Rule would add language to the space and equipment lease exceptions that would prohibit unit-of-service or "per-click" rental charges to a physician-lessor for services rendered by an entity-lessee to patient referred by such physician. CMS has stated that it believes such arrangements are "inherently susceptible to abuse" because the physician-lessor has an incentive to profit from referring a higher volume of patients to the entity-lessee.[2] We believe the Proposed Rule is directly contrary to Congress' stated legislative intent and reverses CMS prior analysis in the Phase I rulemaking. It also ignores the challenges that smaller hospitals have with access to capital.

[1] References to page numbers within the Proposed Rule are taken from the Federal Register published July 12, 2007 (Vol. 72, No. 133).
[2] Page 38,183.

In an August 4, 1993 House Conference Agreement, Congress expressed its intent related to charges for space and equipment leases.

> The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or unit of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.[3]

In the commentary to the Phase I rulemaking, CMS acknowledged this intent and provided that in reviewing the legislative history with respect to the exception for space and equipment leases, it concluded that "Congress intended that time-based or unit-of-service based payments be protected, so long as the payment is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals."[4] CMS further stated that "per use" rental payments would be protected, even for services performed on patients referred by the physician-lessor, provided the "per use" rental payment was fair market value and did not vary over the lease term.[5] CMS would not require a separate payment arrangement for the use of equipment on patients referred by the physician-lessor.[6]

Many providers have relied in good faith on the position of Congress, as interpreted by CMS, in structuring commercially reasonable, fair market value lease arrangements with "per click" rental charges that are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Speaking for providers that we assist in evaluating these options, their intent has not been to circumvent the law or to cause increased costs to the federal health care programs. Rather, these "per click" arrangements provide a cost-effective means for a hospital, physician group, and/or other health care providers to share the business risk in bringing cutting-edge treatment modalities and higher quality into the community in which they serve. The Proposed Rule, which would force the hospital to bear all of the business risk, would effectively eliminate the provision of certain part-time or mobile health care services, including mobile lithotripsy services, thereby limiting access to health care in smaller communities where there is not sufficient volume to support the full-time provision of such modalities.

In light of the above-noted legislative history, the Proposed Rule is directly contrary to the published intent of Congress. Further, CMS' own commentary to the Phase I rulemaking acknowledges that these exceptions were intended by Congress to permit "per click" payments, regardless of whether such payments were for services performed on patients referred by a physician-lessor.

In sum, we believe that a modification of CMS' proposed clarification of the use of percentage-based compensation arrangements in lease agreements will effectively address the

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[3] H.R. Rep. No. 103-213, at 814.
[4] 66 Fed. Reg. 856, 876 (Jan. 4, 2001).
[5] *Id.*
[6] *Id.*

risk of abuse from lease arrangements, without contravening the expressed intent of Congress. The modification we recommend could be a prohibition on a percentage of DHS revenues but allow other percentage formulas, such as those for personally performed services and those based on actual costs (e.g., actual costs plus some fair market value percentage mark-up). An outright prohibition on arrangements involving percentage calculations could disrupt many other types of innocuous relationships in the health care field.

2. Services Furnished "Under Arrangements". The Proposed Rule would also change the definition of "entity" under the Stark law regulations to include both the entity that submits to the claim to Medicare for designated health services ("DHS") and the entity that performs the DHS (i.e., the under arrangements service provider). CMS notes its concern with the risk of overutilization for services provided under arrangements, particularly those services which are separately paid under Medicare.[7] CMS is also concerned that the services furnished under arrangements are furnished in a less medically-intensive setting than the hospital but billed at a higher hospital outpatient rate.[8]

We believe the definition in the Proposed Rule is contrary to the historical intent of Congress and CMS' longstanding policies. Legislative history indicates that Congress intended that certain services be provided "under arrangements" to a hospital.[9] Further, CMS' own policies permit hospitals to furnish certain services through a service agreement with independent providers.

Further, both Congress and CMS have historically considered such arrangements to create a compensation arrangement, as opposed to an ownership interest. Congress created a compensation exception for under arrangement services at Subsection (e)(7)(A) of the Act.[10] Further, the Stark law regulations provided that an "'under arrangements' contract between a hospital and an entity owned by one or more physicians (or group of physicians) providing DHS 'under arrangements' to the hospital" shall not be considered an ownership or investment interest.[11]

The Proposed Rule, by prohibiting referrals by a physician to an entity that performs the DHS, would effectively make the "under arrangements" relationship an ownership interest in the hospital, contradicting long-settled law on this matter. If such arrangements continue to be viewed as problematic, perhaps CMS could first undertake more aggressive enforcement efforts to ensure compliance with the standards of the relevant Stark law exception, for example, whether the arrangement is fair market value. It could also survey quality data and ascertain whether these relationships, as we feel, serve to enhance quality.

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[7] Page 38,186.
[8] *Id.*
[9] H.R. Rep. No. 103-213, at 815.
[10] As an aside, this exception also references "compensation per unity of service", further indicating Congress' intent on this method of compensation.
[11] 41 C.F.R. § 411.354(a)(3)(iv).

Along this line, the Proposed Rule is also very problematic for small and rural hospitals and other providers insomuch as it ignores several very common and non-abusive effects of "under arrangements services." CMS purports that "there appears to be no legitimate reason for these arranged services other than to allow referring physicians the opportunity to make money on referrals for separately payable services."[12] CMS fails to acknowledge that many of these arrangements are the most cost effective manner for hospitals to provide certain DHS. Access to capital at reasonable costs in today's marketplace is not easy for hospitals. Further, most of these arrangements are clinically driven by physician-directed protocols. Involving physicians in the management of the care provided helps to align incentives related to quality and patient safety rather than to cause such incentives to diverge as CMS suggests. Some arrangements are not merely just an extension of the physicians' practice but also a means for the hospital to provide comprehensive, cost effective, high quality, diagnostic and therapeutic services.

As a further aside, we believe the Proposed Rule also creates unnecessary ambiguity. The term "performs" is left undefined by the Proposed Rule. Therefore, it is unclear whether an entity that performs a component of the DHS "performs" the DHS. Under the Proposed Rule, we believe that an entity that provides management services does not "perform" the DHS for purposes of this proposed definition.

On a final and related note, we also believe that the MedPac proposal is also contrary to the basic tenets of a hospital being able to provide services under arrangements as described above. Again, in sum we propose that CMS address the issue with respect to fair market value and percentage compensation methodologies and reconsider this proposed change.

* * *

Thank you for your consideration of these comments. We look forward to your responses to these comments when the Final Rule is issued.

Sincerely,

HALL, RENDER, KILLIAN, HEATH & LYMAN, P.C.

Gregg M. Wallander

Erin D. Abraham, Esq.

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[12] Page 38,186.

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August 29, 2007

Centers for Medicare & Medicaid Services
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RE: File Code CMS – 1385-P

To Whom It May Concern:

As Medicare participating providers, we appreciate the opportunity to voice our comments concerning a possible change by CMS of its interpretation of the In-Office Ancillary Exemption. We like you, are concerned about the integrity of the Medicare program both fiscally and ethically. From our experience we feel a "closer" or "tighter" interpretation of the in-office ancillary exemption will not accomplish the desired results.

Our experience having physical therapy as part of our practice has shown:

1. Improved communication between the patient, therapist and physician. If a question or problem arises it can be addressed immediately with all parties being present if necessary, thus enhancing outcomes and quality.

2. To be more cost effective by reducing the number of visits and/or modalities versus independently owned therapy facilities.

3. To be convenient for the patient in terms of location and scheduling appointments. Many times patients are able to initiate treatment the same day they are seen by their physician. This is valuable to patients from outlying areas that would have to make an additional trip for treatment.

4. To be able to develop, implement and revise, if necessary, specific protocols for treatment of specific problems. Since only our patients are treated by our therapy department, this insures that standards are met and maintained, resulting in improved outcome.

5. To enhance continuity of care.

The ORTHOPAEDIC CLINIC

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Many argue the In-Office Ancillary Exemption has led to over-utilization resulting in higher healthcare costs. Our experience has shown improved patient care and decreased utilization resulting in lower cost.

We appreciate the opportunity to share our thoughts concerning this very important matter.

Sincerely,

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August 30, 2007

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

FILE CODE: CMS-1385-P

To Whom It May Concern:

By way of background, DMS Imaging, Inc. (DMSI) provides mobile imaging services in many parts of the United States. DMSI provides these services as an IDTF. Virtually all of our IDTF services are provided to patients at critical access hospitals and small rural clinics. We are proud of our service to patients who would otherwise have to travel or perhaps even delay care if mobile imaging services were not available.

The following are our comments and recommendations regarding CMS-1385-P.

"IDTF ISSUES"

Physician Supervision:
The proposed rule in which a physician providing general supervision could oversee only three IDTF mobile units will significantly impact the consistency and quality of care delivered by mobile IDTFs. Requiring multiple physicians will result in different approaches to patient care and make coordinating care between physicians difficult, particularly for those organizations that have multiple mobile IDTFs.

In addition, rural or frontier areas served by mobile IDTFs do not have a large pool of physicians qualified to serve as supervising physicians. For example, one site could be serviced by five separate mobile units, (i.e., Ultrasound, MRI, CT, DEXA, and Nuclear Medicine). If one physician can supervise only 3 mobile units, this small community would need 2 to 3 supervising physicians. Given the existing shortage of physicians in rural areas, it is apparent that services will be limited because of lack of physicians to cover as a supervising physician.

In summary, it is not logistically, financially, or operationally feasible for any company to employ or utilize the services of numerous physicians as supervising physicians. Mobile companies already have established corporate committees, policies and procedures that govern the operations for all mobile units and IDTFs. It would appear

procedures that govern the operations for all mobile units and IDTFs. It would appear that this requirement will add additional expenses and administrative overhead to an existing system that is compliant with the Joint Commission Standards for patient safety and quality, as well as the requirements of the Nuclear Regulatory Commission and other accrediting agencies. This approach will drastically change the way a mobile IDTF operates without improving the quality of care. Moreover, it raises serious doubts as to the financial viability of offering mobile IDTF services to communities who either cannot afford to offer the services in their community or cannot attract the personnel necessary to deliver the services on their own.

We recommend CMS consider utilizing a single medical director for an organization's general supervision requirement in lieu of individual supervising physicians per mobile IDTF. This would be a similar approach to that which is taken in other areas within the health care industry where a single medical director oversees the clinical and quality areas for a health care organization which may have multiple locations. CMS' goal of ensuring high quality service and compliance with the performance standards can be accomplished through a single medical director for general supervision. In those instances where more supervision is required it is already being provided in those situations where direct supervision is required. All mobile IDTFs already employ or contract with physicians to provide direct supervision as required by CMS guidelines.

Definition of Mobile IDTF:
It would be beneficial to define what is considered a mobile IDTF. We have received conflicting information regarding the definition from various Medicare Carriers. For example, one carrier has defined that a separate mobile IDTF be required for each piece of equipment while another has defined a mobile IDTF at the organizational level which may have multiple practice locations and multiple pieces of equipment all encompassed in one Mobile IDTF. Please clarify the CMS position on what is a Mobile IDTF.

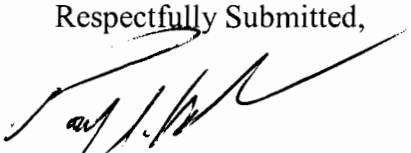
Sharing of Space for Mobile IDTF:
We do not agree that the standard prohibiting sharing of space should be applied to mobile IDTFs. Mobile units for example do not have bathrooms or waiting areas for patients because of space limitations. Additionally, there are many types of mobile IDTFs, which by their very nature require space at the facility to conduct the test (for example, ultrasound and mammography). Therefore, patients need to register and wait in a location that is apart from the mobile unit, which is generally the facility where the services are provided. In summary, the proposed standard is impractical for a mobile IDTF to comply with and should not be extended to mobile IDTFs.

"PHYSICIAN SELF REFERRAL PROVISIONS"

Contract Employees:
Given the challenges of recruiting and retaining qualified staff in rural areas that meet the CMS guidelines, it is sometimes necessary to contract with an agency to provide

temporary staffing services until a permanent employee can be hired. This is consistent with the staffing practices in healthcare facilities across the country. Contracted personnel are trained and governed in accordance with all of the policies and procedures an employee would be subject to. Without the ability to use contract personnel, an organization may need to limit or discontinue services to beneficiaries. In summary, the proposed standard is impractical for a mobile IDTF to comply with and should not be extended to mobile IDTFs.

Respectfully Submitted,



Paul Wilson
Chief Executive Officer
DMS Health Group

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Sutter Health
With You. For Life.

Office of the General Counsel
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August 29, 2007

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

Re: CMS-1385-P;
INDEPENDENT DIAGNOSTIC TESTING FACILITY ISSUES;
Comments to Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule

Dear Mr. McClellan:

These comments are submitted on behalf of Sutter Health, a charitable nonprofit health system that operates in California and Hawaii. Affiliates of Sutter Health operate imaging centers that are certified under the Medicare program as independent diagnostic testing facilities ("IDTFs"). These comments concern IDTF issues only.

Self-Insurance Issues

The proposed rule provides that IDTFs must have a "comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a non-relative owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter."[1]

a. Apparent Prohibition on Self-Insurance. Despite commentary in the preamble to the proposed rules to the contrary, the language of the regulation provides that the insurance be purchased from a "non-relative owned company." It appears to be contradictory to provide in the preamble that this does not preclude self-insurance. If self-insurance is permitted, the requirement that the insurance be purchased from a "non-relative owned company" should be removed, or replaced with a provision that permits an alternate method of meeting the requirement by maintaining insurance through a relative-owned company that has been approved

[1] See Proposed Rule 42 C.F.R. 410.33 at 72 Fed. Reg. 38222 (July 12, 2007).

by a state department of insurance or comparable state agency or that can be validated by a placing broker.

Proposed Change: Eliminate the requirement that IDTF insurance be purchased from a "non-relative owned company" so long as the IDTF can provide evidence of the legitimacy of its self-insurance program from specified third parties.

b. Verification Requirements—Self-Insurance.

Commentary to the proposed rule provides that:

> "[t]he proposed revision will not preclude the use of self-insurance to demonstrate compliance with the comprehensive liability insurance policy as long as CMS or our designated contractor can verify the policy and its coverage provision with an independent underwriter."[2]

Self-insurance programs do not make use of underwriters—self-insurance programs insure healthcare providers in the insured companies that are covered irrespective of the degree of risk. There is no commercial underwriter per se that is involved that would be available to legitimize the self-insurance.

CMS' goal in finding a means to verify the legitimacy of self-insurance programs is understandable, however, and its needs can be met in an alternate way. It is customary for legitimate insurance captives to use a placing broker to validate the insurance programs. Auditors and financial institutions needing to have information on the insurance captive customarily accept the placing broker's opinion as to the reasonableness and appropriateness of the insurance program for known exposures and claims. Legitimizing a self-insurance program in this way would serve CMS' purpose by validating the insurance through an independent third party.

In addition, CMS could accept proof of the approval of the insurance captives from state agencies in the business of regulating this industry as a means of demonstrating the legitimacy of the program. Sutter Health's relative-owned insurance company currently provides general liability and professional liability to Sutter Health-affiliated IDTFs. This relative-owned insurance company has obtained a certificate of authority as a captive insurance company from the State of Hawaii, Commissioner of Insurance, after approval of an application that contained evidence of the amount and liquidity of its assets relative to the risks assumed; the adequacy of the expertise, experience and character of the person or persons who will manage it; the overall

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[2] See 72 Fed. Reg. 38169.

soundness of its plan of operation; and the adequacy of the loss prevention programs of the Sutter insurance captive and its affiliated entities.[3] In addition, the Hawaii captive insurance rules require the Sutter captive to file annual financial reports and be subject to an examination no less often than every three years by the Insurance Division of the Hawaii Department of Commerce and Consumer Affairs.[4] Sutter Health, in its capacity as an employer, has similarly obtained from the State of California a certificate of consent to self-insure its workers' compensation liabilities after an application demonstrating its financial strength and competence.[5]

Precluding insurance from being provided by a captive insurance company has increased the cost of caring for Medicare beneficiaries by requiring self-insured entities to purchase duplicative ADDITIONAL insurance (for claims that are sufficiently provided for already) for its IDTFs. There is no compelling reason that the risk management resources available to IDTFs should be limited to policies purchased from commercial insurance companies. Requiring IDTFs to purchase additional insurance from commercial insurers has unnecessarily increased the cost of providing diagnostic imaging services to Medicare beneficiaries, while benefiting only the commercial insurance industry. If self-insurance is to be permitted, it is important that CMS' rules permit self-insured IDTF's to have a feasible means of showing the validity of the IDTF's insurance.

Proposed changes: Permit insurance provided by a relative-owned company to be legitimized by:

(1) an opinion by a placing broker as to the reasonableness and appropriateness of the captive insurance for the risks of the IDTF; and

(2) proof of the program's approval as an insurance captive by a state regulatory agency after review of the captive's financial solvency and ability to pay claims or a certificate of consent to self-insure from a state regulatory agency so long as the insurance department has reviewed the company's financial solvency and ability to pay claims.

Remove the proposed requirement that an independent underwriter validate the captive insurance program.

Commingling of Space, Equipment and Staff.

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3 See 431 Hawaii Rev. Stat. 19-102.
4 See 431 Hawaii Rev. Stat. 19-107, 19-108.
5 See 8 Cal. Code of Regs. 15203.

The proposed rule provides that an IDTF may not "share space, equipment, or staff or sublease its operations to another individual or organization."[6] Commentary to the proposed rule provides that it would be inappropriate to commingle waiting rooms and receptionists. While we sympathize with the need to ensure that enrollment and billing requirements are filled, and also that clinical space and staff are not commingled (e.g., when technical and supervising staff are disclosed on the 855 form, they should be dedicated to the IDTF during the times that the IDTF is open), there can be no legitimate reason why non-clinical space and staff may not be shared such as waiting rooms, receptionists and schedulers. Sharing such personnel and waiting rooms are common in the healthcare industry, and ceasing such practices can only increase the cost of providing healthcare services without legitimate benefit. This requirement should be dispensed with.

Thank you in advance for your consideration. If you have any questions concerning any of these comments, please do not hesitate to contact me.

Most respectfully submitted,

Gary Loveridge
Sr. Vice President
& General Counsel

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[6] See proposed 42 C.F.R. 410.33(g)(15).

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August 30, 2007

VIA OVERNIGHT DELIVERY

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

Re: **CMS-1385-P**
Physician Self-Referral Provisions
In-Office Ancillary Services Exception

Dear Sir/Madam:

We represent individual physicians, physician group practices, physical therapists, facilities, freestanding ambulatory surgery centers, institutions and a number of associations and networks comprised of physicians and physician-related entities and joint ventures. We submit these comments on their behalf in response to **File Code CMS-1385-P**, *Medicare Program; Proposed Regulations to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008* published in 72 Federal Register 38122 on July 12, 2007 ("Regulations").

In particular, this comment addresses the proposed changes to the **Physician Self-Referral Provisions: In-Office Ancillary Services Exception**. According to the regulatory preamble, CMS, and certain comments to the Phase I and Phase II physician self-referral rules, indicate that the In-Office Ancillary Services Exception is susceptible to abuse. CMS also states that it has received "hundreds of letters from physical therapists and occupational therapists stating [that] the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices." Unfortunately, however, CMS fails to cite any of the arguments raised in those letters or to elaborate on its "concerns."[1]

[1] **We specifically request that CMS elaborate its concerns in this area and acknowledge that the numbers of letters received on a subject are not always indicative of the gravity of the issue or the need for correction.**

Instead, CMS has requested comments on "whether certain services should not qualify for the exception." As an example, CMS specifically mentions "any therapy services that are **not** provided on an "incident to" basis and services that are **not** needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment."

Previously, the **Phase II Regulatory Preamble** included specific inquires from physical therapists and a professional association representing physical and occupational therapists. In response to their inquiries, CMS responded that the Stark rules are not the "appropriate vehicle" for the changes proposed by the therapists and the professional association. 69 Federal Register at 16071 - 16072. We agree and submit now, more than three years later, that the Stark Law and its regulations are still **not** the "appropriate vehicle" for the changes sought by these groups. This is essentially a "turf battle" being waged by private practice physical therapists against POPTS at the state and now, federal, level, which is being pursued with an anti-competitive purpose against physician-owned physical therapy services.

If the In-Office Ancillary Services Exception is limited to only those physical therapy services that are provided as "incident to," CMS will be using the Stark Law in a manner for which it was never intended - that is - (1) to change the physician supervision requirements for therapy services provided in private physician offices[2]; and (2) to restrict access to therapy services. The Stark Law is intended to restrict physician referrals to entities with which the physician has a financial relationship that does not meet an applicable statutory or regulatory exception. The Stark Law does not, and should not, alter Medicare billing, claims submission or physician supervision policies and requirements, but must work within those stringent policies to effectuate its purpose.

The concerns raised by CMS regarding "non-incident to" therapy services provided in physician offices is unwarranted. Many physicians, especially those specializing in orthopaedics, occupational medicine, and physical medicine and rehabilitation services, are keenly aware of the continuity of care and successful medical outcomes resulting from an interdisciplinary team approach to surgery, therapy, rehabilitation, and recovery. Physician office practices have engaged or employed therapists to provide therapy services within the physician office environment for many years. Such practices, referred as a POPTS, must, and do, comply with very strict federal laws and regulations, which prevent any improper relationships, overutilization of services or performance of unnecessary services.

POPTS provides continuous oversight and overall physician supervision, which reduces cost to the Medicare Program.[3] It is far superior to situations where the physician only receives periodic, delayed reports of the patient's progress. POPTS focus on a team approach for the delivery of health care services within a physician group practice that is more convenient for the patient, who is always free to choose his or her therapy provider, and is consistent with current Medicare billing rules and the In-Office Ancillary Services Exception.

Indeed, this effort reflects an ongoing attempt by physical therapists in private practice and national and state physical therapy associations to eliminate competition from physician-employed physical therapists and Physician-Owned PT Services ("POPTS").

[2] The In-Office Ancillary Services Exception follows the Medicare physician supervision requirements. Consequently, whatever level of physician supervision is required for Medicare billing purposes is the same level of physician supervision required when those services are provided (and protected) under the In-Office Ancillary Services Exception.

[3] The continuous physician oversight and supervision reduces cost to the Medicare Program because the treating physician is continually aware of the patient's improvement and can modify the therapy regimen as necessary at each visit.

Current Medicare billing rules require a physician order before physical therapy services may be provided to Medicare beneficiaries. Medicare billing rules also permit a physician to provide physical therapy services or to hire a PT to provide therapy services in-office to the physician practice patients, provided all of the applicable billing rules are met, and the individual providing the physical therapy services is appropriately qualified and meets specific Medicare requirements. Nothing in the Stark statute or regulations prohibits physicians from providing therapy services as a core component of a physician's practice so long as such services are "not essentially a separate business enterprise.[4]" 69 Federal Register 16074. Attempts to modify the In-Office Ancillary Services Exception to prevent physician office physical therapy services is an unwarranted intrusion into physician practices and significantly impairs a physician's right to practice medicine.

Often times, ancillary services are ordered by a physician at one visit, but provided to the patient on a subsequent visit to the physician's office. The separate patient encounter may not require a direct encounter with the physician, and may not be required for Medicare billing purposes. These types of visits occur routinely in physician offices and may involve all types of ancillary services, not just physical and occupational therapy services. We strongly urge CMS **not** to implement changes to the In-Office Ancillary Services Exception that would restrict access to physical therapy services provided in physician offices when those services are provided by qualified therapists and when those services are not provided as "incident to" services.

We encourage CMS to share its "concerns" with the POPTS community for specific feedback before any decision regarding changes to the exception are implemented that would result in restricted patient access to Physician-Owned Physical Therapy Services.

Sincerely,

Lenora W. Pate
FOR THE FIRM

Cynthia Ransburg-Brown
FOR THE FIRM

LWP/CRB/cm

[4] **Most physician group practices, which offer therapy services as an ancillary service to their patients, generally do not accept PT referrals from physicians who are not a part of the physician office practice. Consequently, a "separate business enterprise" is rarely an issue.**

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JP901023:tj August 30, 2007

BY FEDERAL EXPRESS

Centers for Medicare and Medicaid Services
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7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: File Code CMS 1385 (PHYSICIAN SELF-REFERRAL ISSUES)

Dear Sir or Madam:

We are writing to you on behalf of one of our health system clients described below that wishes to remain anonymous. On July 2, 2007, as part of its proposed 2008 Medicare Physician Fee Schedule, the Centers for Medicare and Medicaid Services ("CMS"), proposed substantial changes in the regulations promulgated pursuant to 42 U.S.C. § 1395nn (the "Stark Law"). As explained below, while targeting legitimate concerns for the Medicare program, these proposed regulations carry adverse consequences for hospitals and physicians seeking to avoid the unnecessary and inefficient duplication of high cost ancillary services (e.g., magnetic resonance imaging ("MRI") or 64-slice computed tomography ("CT") services) and to gain the benefit of economies of scale, which would allow the hospital and physicians to price their ancillary services at a lower cost to patients and payors. These proposed regulations may also have the unintended consequence of reducing the quality of patient care that hospitals can provide to their patients.

To address this concern, CMS should either (i) continue to permit ventures that are owned either wholly or in part by referring physicians to provide services to hospital patients under arrangements and therefore not adopt the proposed changes to the definition of "entity", (ii) prohibit physicians from owning or operating such ancillary services so that only a hospital would be permitted to provide such services, or (iii) come up with some other exception that will allow hospitals and physicians to provide services to their respective patients on a cost-sharing basis. Unless one of these actions is taken, many hospitals will be forced to choose between acquiring, on its own, expensive medical technologies like MRI and CT services, knowing that it will suffer significant losses from the provision of such services to its patients because it does not have sufficient demand to operate such services at a profit (because a physician-owned service draws substantial business away from the hospital service), or not providing such services to its patients resulting in a substantially diminished quality of patient care.

Factual Background. CMS issued the proposed regulations at the same time that a health system, which is recognized as an organization described in Internal Revenue Code § 501(c)(3) (the "Health System"), sought our advice in connection with establishing a new hospital facility in a community that is not considered a rural area under the Stark Law. The economics of establishing the new hospital in the community are marginal given a level demand for outpatient services, but the Health System sees the new hospital as a means to further its charitable health care mission. The ability of such a hospital to survive financially after it opens will be greatly diminished if it must acquire high cost, high quality medical technologies on its own if it desires to offer such services to its patients.

In this particular case, a multi-specialty physician practice has already established a large presence in the community, including diagnostic laboratory and radiology services. The physician practice, however, lacks the resources or ability to provide inpatient hospital and most outpatient hospital services to the community. A key factor in the Health System's decision of whether to establish the hospital is the extent to which it can leverage the community's existing medical resources, including those of the physician practice, to reduce its capital costs and operating expenses.

For example, the physician practice owns and operates an MRI and a CT. Although the physician practice currently provides MRI/CT services to its patients, the practice is not fully utilizing the MRI or CT and has the capacity to provide such services to patients of the proposed hospital. Prior to the issuance of the proposed regulations, the Health System and the physician practice discussed the possibility of structuring a relationship that would allow the new hospital facility to utilize the physician practice's MRI and CT.

The Health System had proposed that the physician practice establish a full-service office at the new hospital facility, which would include the physician practice's MRI and CT capabilities. The Health System and physician practice would structure the lease to comply with the Stark Law exception for office space rentals. *See* 42 C.F.R. § 411.357(a). The Health System could then access the MRI and CT for the hospital's inpatient and emergency room patients on a "per click" basis in accordance with the existing Stark Law compensation rules. *See* 42 C.F.R. §§ 411.354(d)(2) and (3) and 42 C.F.R. §§ 411.357(l) and (p). The hospital would then bill for these diagnostic imaging services "under arrangements" as part of its APC ambulatory or DRG inpatient charges, as applicable. The physician practice, in turn, would continue to provide its patients with MRI and CT services pursuant to the Stark Law exception for in-office ancillary services. *See* 42 C.F.R. § 411.355(b). It should be noted that, as a result of this proposed arrangement, referrals of such services from the physician practice to the new hospital or other providers affiliated with the Health System would not likely increase, in part, because the physician group already owns and provides MRI/CT services and will likely continue refer any potential "outpatients" to the group's MRI/CT. Likewise, with respect to inpatients of the new hospital, the Medicare program will not suffer any increased costs from the

ordering of MRI/CT services by members of the physician group because those services will be considered part of a diagnosis-related group that is paid under the prospective payment system.

Impact of Proposed Regulations. The proposed regulations eliminate the ability of the Health System to utilize the physician practice's MRI and CT on a "per click" and "under arrangements" basis for hospital patients.

First, the proposed regulations largely reverse CMS's present interpretation of the "volume or value" standard as it applies to "per-click" arrangements. In Phase II, CMS allowed per-click compensation if the per-click fee was fair market value for the services or items actually provided and did not vary during the course of the agreement based on DHS or other referrals. *See*, e.g., 69 Fed. Reg. 16054, at 16069 (March 26, 2004); *see also* 42 C.F.R. §§ 411.354(d)(2) and (3). CMS now finds such arrangements to be "inherently susceptible to abuse" because "the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee." 72 Fed. Reg. 38122, at 38183 (July 12, 2007). To address this valid concern, CMS proposes to disallow all "per-click" compensation in lease arrangements if the per-click charge reflects "services provided to patients referred by the lessor to the lessee." *See* Prop. Reg. 42 C.F.R. §§ 411.357(a)(5) and (b)(4). CMS notes that "[s]uch arrangements could take the form of a physician leasing equipment that he or she owns to a hospital, and receiving a per-use (per-click) fee each time a patient is referred by the physician-owner to the hospital for the use of the equipment." 72 Fed. Reg. at 38182.

Second, the proposed regulations prevent the Health System from obtaining MRI and CT services from the physician practice "under arrangements" by revising the definition of an "entity" for Stark Law purposes. The proposed regulations revert to a prior CMS proposal that the term "entity" would include persons or entities that perform, but do not bill for, DHS. CMS first announced this interpretation in the 1998 proposed Stark Law regulations. At that time, CMS stated:

> We also believe that a physician can have an incentive to overutilize services if he or she has a financial relationship with the entity that directly furnishes designated health services, even if this is not the entity ultimately billing for the services. In these situations, the physician can potentially recognize a profit from each referral based on the fact that the designated health services will, in essence, be sold to the entity that bills.

63 Fed. Reg. 1659, at p. 1707 (Jan. 9, 1998). Phase II took a less onerous approach, interpreting an "entity" as including only the person or entity that bills Medicare for the DHS, and not the person or entity that performs the DHS (where the person or entity performing the DHS is not the person or entity billing for it). *See*, e.g., 42 C.F.R. § 411.351; *see also* 72 Fed. Reg. at 38186.

CMS believes that the "risk of overutilization" that it identified in 1998 now requires it to modify the definition of the term "entity" to include individuals or organizations that perform (but do not bill for) DHS. *See* Prop. Reg. 42 C.F.R. § 411.351 In commentary to the proposed regulation, CMS specifically addresses imaging joint ventures. CMS states:

> We have received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly. There appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. Many of the services furnished by the joint venture were previously furnished directly by the hospitals and, in most cases, could continue to be furnished directly by the hospitals.

72 Fed. Reg. at 38186. This change effectively eliminates the Health System's ability to purchase MRI and CT services "under arrangements" from the physician practice. Under this proposed regulation, the physician practice would be considered an "entity" that is performing DHS (inpatient and outpatient hospital services) that are referred by physicians in the physician practice for which no Stark Law exception exists because the community is not "rural" for Stark Law purposes. Not only does this modification prohibit the Health System's proposed structure for imaging services at the new hospital facility, but it will likely decrease the scope and, perhaps, quality of all "under arrangements" services in non-rural areas with limited demand for high cost, high quality services.

Finally, the proposed regulations leave the Health System with few options for providing MRI and CT services to inpatients and outpatients of the new hospital facility. For example, the Health System could purchase the MRI and CT owned by the physician practice (if it were willing to sell the equipment to the new hospital, which is unlikely) to use on the hospital's inpatients and outpatients. However, the Health System could not recoup a portion of these capital costs by leasing the MRI and CT back to the physician practice for use by the practice on its own patients when the same is not being used by the hospital (the likely condition for the sale of the equipment to the hospital). It is our understanding that it is CMS's view that joint use of the imaging equipment, space and personnel would violate the public awareness requirement of the provider-based regulations. *See* 42 C.F.R. § 413.65(d)(4). Likewise, even if the Health System were to forego billing for the imaging services as provider-based, the Health System could not bill for the services that it provided to hospital inpatients and outpatients as an independent diagnostic testing facility ("IDTF") and then, during down times, lease the MRI and CT to the physician practice to recover a portion of its capital costs. The proposed regulations would also prohibit an IDTF from sharing its equipment, space and personnel with the physician group. *See* Prop. Reg. 42 C.F.R. § 410.33(g)(15).

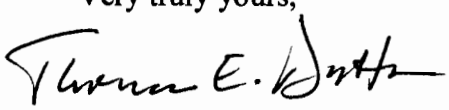
If the proposed regulations are adopted as drafted, the cumulative effect of the resulting regulatory matrix will force the Health System to choose between duplicating the physician practice's capital costs and staffing expenses by acquiring its own MRI and CT and operating the service at a substantial operating loss or not offering needed high cost, high quality ancillary services. It should also be noted that, as neither the physician practice nor the hospital will be able to gain the economies of scale that would otherwise result, both the physician practice and the hospital will need to price these services at a higher cost to patients than would otherwise be necessary.

CMS Should Provide Continue to Permit the Performance of Under Arrangement Services by Physician Groups. The proposed regulations target legitimate areas of concern for CMS, but the implementation of these proposed changes will likely eliminate many legitimate under arrangement service arrangements, particularly in areas that do not have sufficient demand to support multiple, competing high cost, high quality services. Therefore, CMS should either (i) continue to permit ventures that are owned either wholly or in part by referring physicians to provide services to hospital patients under arrangements and therefore not adopt the proposed changes to the definition of "entity", (ii) prohibit physicians from owning or operating such ancillary services so that only a hospital would be permitted to provide such services (thereby ensuring sufficient demand for the hospital service), or (iii) come up with some other exception that will allow hospitals and physicians to provide services to their respective patients on a cost-sharing basis.

Unless one of these actions is taken, many hospitals will be forced to choose between acquiring, on its own, expensive medical technologies like MRI and CT services, knowing that it will suffer significant losses from the provision of such services to its patients (and at a higher than necessary cost to patients) because it does not have sufficient demand to operate such services at a profit (because a physician-owned service draws substantial business away from the hospital service), and not providing such services to its patients resulting in a substantially diminished quality of patient care.

Please do not hesitate to give me a call if you would like to discuss the foregoing issues. Thank you for you attention to this issue.

Very truly yours,



Thomas E. Dutton

624-1

MIDWEST PAIN CONSULTANTS, P.C.

Jeffrey P. Meyer, MD, FIPP

Board Certified American Board of Anesthesiology
Added Qualifications Pain Management
Interventional Treatment for Chronic Pain

August 30, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. **CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.**

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

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress

never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

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Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Jeffrey P. Meyer, MD, FIPP
Midwest Pain Consultants, P.C.
238 N. Midwest Blvd., Suite 201
Midwest City, OK 73110
405-733-5900

625-1

CSA
Cardiovascular Services of America

August 27, 2007

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

Re: Proposed Revisions to Payment Policies Under the Physicians Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of **Cardiovascular Services of America**, *the* Outpatient Cath Lab Company and our 20 partnered but independently practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the ***"Resource-Based PE RVU's"*** section of the above referenced July 2, 2007 Proposed Rule. We are specifically concerned with the 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact that could result for our practice and our patients if these values are finalized for the 2008 Physicians Fee Schedule.

Cardiovascular Services of America , based in Nashville, TN., is a founding member of the Cardiovascular Outpatient Center Alliance (COCA) and as such we have actively been involved in the work that COCA has accomplished this year to collect and submit direct and indirect cost data to the AMA's Practice Expense Review Committee (PERC) of the Relative Value Scale Update Committee (RUC). Unfortunately, this process did not allow all of COCA's data to be considered and resulted in PE RVU recommendations to CMS that severely undervalued the direct and indirect costs associated with providing these procedures to our patients.

It is apparent from the July 2, 2007 Proposed Rule that CMS has accepted the RUC recommendations without considering the detailed direct cost information that COCA provided to CMS in May 2007. The PE-RVU values set out in the July 2 Proposed Rule would result in a draconian cut in reimbursement for cardiac catheterizations performed in practice or IDTF locations. For example, if the 2007 conversion factor is applied to the technical component of the primary three CPT codes for a Left Heart Cath (93510TC,

93555TC, and 93556TC) the reimbursement in 2008 would be cut by **32%** and when fully implemented the total reimbursement would be reduced by **49%**. These reductions would undoubtedly result in the closing of the majority of non-facility outpatient cardiac catheterization labs in the country forcing all patients who now benefit from improved access and lower costs into more acute hospital settings.

We request that CMS review the additional cost data provided by COCA and establish PE RVU's for outpatient cardiac catheterization procedures that more reasonably reflect the direct and indirect costs of providing these procedures. If the proposed RVU's are allowed to stand, the outcome will inevitably that will cost the Medicare program more in direct APC payments **and** Medicare patients more in higher deductibles and co-insurance.

Cardiovascular Services of America was founded on the premise of providing cost-effective care in the most convenient environment for our patients. We have accomplished these goals by keeping costs lower than hospitals while giving our patients and physicians an easily accessible and friendly outpatient setting. **If these cuts are implemented, our company, and perhaps this entire segment of the outpatient delivery system, will be driven out of business.**

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

Sincerely,

Mark Donati

Mark Donati
Chief Operating Officer
Cardiovascular Services of America
320 Seven Springs Way
Nashville, TN 37027

Anu Chirala M.D., F.A.C.C
Board Certified in Cardiovascular Diseases
& Nuclear Cardiology

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626-1

August 23rd, 2007

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

Re: CMS-1285-P: CY 2008 Physician Fee Schedule Proposed Rule
Practice Expense -- Equipment Usage Percentage

Dear Ms. Bassano:

Thank you for considering this comment on the 2008 Physician Fee Schedule Proposed Rule. I am a Board Certified Cardiologist (and Nuclear Cardiology), and I am writing to discuss payment for Microvolt T-wave Alternans (MTWA) diagnostic test. MTWA is an important tool to determine a patient's risk of sudden cardiac death. I am concerned that Medicare payment for physicians for MTWA is based on an incorrect utilization assumption that results in a significantly lower payment. CMS should consider the actual utilization of MTWA when calculating the practice expense for MTWA.

In patients at high risk for sudden cardiac death, Medicare has expanded coverage of implantable cardioverter defibrillators (ICDs) as a preventive measure. MTWA is extremely valuable in identifying which patients will benefit most from an ICD. Published data indicates that patients with negative MTWA tests will typically receive no significant reduction in cardiac arrest-related deaths, allowing us to identify patients who are more likely to benefit from an ICD.

MTWA testing is a non-invasive procedure that takes about [60] minutes. Unfortunately, the Medicare Practice Expense formula significantly decreases physician payment for MTWA. Reimbursement for MTWA is calculated using an "equipment usage assumption" of 50 percent. The assumption that the MTWA equipment is used 50 percent of the time is inaccurate and results in an inappropriately low payment. In my practice, MTWA is typically used only for the specific high-risk patients who will benefit greatly from its analysis. On average, we use MTWA several times per week, but significantly less than 50 percent of the time.

In order for Medicare to pay appropriately for this valuable technology, and to ensure that physicians continue to use it for their patients when appropriate, CMS should use the actual usage rate when available. I would be happy to provide documentation to demonstrate our actual utilization rate. Please do not hesitate to contact me for this information or if I can answer any other questions about MTWA.

Sincerely,

Anu Chirala MD, FACC

Patricia A. Ness

DATE: August 21, 2007

TO: Centers for Medicare & Medicaid Services

FROM: Patricia Ness

SUBJECT: Comments to File Code CMS-1385-P
"PHYSICIAN SELF-REFERRAL PROVISIONS"

I am responding to your solicitation of comments on this subject. For the following reasons, I am writing to ask CMS not to adopt the requirement that a pathologist be employed full-time by a physician practice in order to bill the Medicare program for professional pathology services.

Background Comments

I have worked in the laboratory industry for several commercial laboratories. I have a very keen sense of the need for quality laboratory work and high levels of service to patients and physicians alike. I was a supervisor of client services for one of the large commercial laboratories for several years. I had a recent experience with my mother that should shed some light on the issue of using part time pathologists vs. full time. The specific items are:

- My mother had a colonoscopy at age 82 last July in the Chicago suburbs as a hospital outpatient:
    - The procedure was performed on a Monday in the AM. Her GI physician told her it looked like cancer to him but he needed to have the biopsy report before a final diagnosis could be rendered.
    - On that Friday my mother had not been given the results of her pathology result. Imagine an 82 year old widow being told by her GI doctor she may have cancer and not knowing for certain for 5 days. She was told the results usually take a week from the hospital.
    - My husband, who is a national authority in pathology services, had to call the GI doctor and threaten legal action if my mother did not have her results in the following 15 minutes.
    - Sure enough, my mother's GI doctor called her with the results. She was diagnosed with colon cancer. We got a 2nd opinion from a world renowned GI pathologist as we did not trust this delayed report.
    - She was operated on the next week and the mass was removed.
- The idea that pathologists need to be full time employees does not mean that Medicare patients, like my mother, get the best level of pathology service. Our

5035 Cartagena Drive, Toledo, OH 43623 419.841.7355 pkness@BEX.net

above example is very typical of the majority hospital-based pathologists regard to service for Medicare patients. A week to ten days is considered normal and adequate for pathology results by organized pathology. As you can see from my personal example it is not good medical practice.

- We could have taken my mother to a Cleveland based endoscopy center for her procedure (2.5 hour drive).
- They have an in-office pathology laboratory on site with a part time pathologist as a staff member.
- Her tissue biopsy would have been processed the same day in the center and read by the GI group's part time pathologist that afternoon.
- My mother would have been notified of her results the following day.
- Medicare would have been billed by the GI practice for the laboratory work and paid by the OH Medicare fee schedule.
- Which example, part time pathologist vs. full time pathologist, provided better medical care for a Medicare beneficiary?
- Which level of service and care would you prefer for your mother, father, or other Medicare aged family member?
- I feel my mother did not get the best medical care from a full time hospital based pathologist. She would have been better served by a part time pathologist working directly in the endoscopy center where her procedure was performed.

I appreciate the opportunity to contribute my comments to CMS' understanding of many issues facing pathology and laboratories in our changing healthcare environment. In summary, I respectfully request that CMS not adopt the "full time employee" requirement in order for a physician practice to bill and collect from the Medicare program for the professional services rendered by its pathologist.

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

Dear Sirs:

I am a practicing urologist in St. Louis, MO. I have been in clinical practice for nearly 20 years. During this time I have been providing quality lithotripsy and other services to Medicare patients through joint ventures. I am concerned that the proposed changes by CMS will adversely affect patient care.

The proposals that are most worrisome are: Under Arrangements, Per Click Fee, Percentage Fee Arrangements, Stand in the Shoes, and Burden of Proof.

First, Under Arrangements, CMS would not permit hospitals to bill for services provided by physicians in a "under arrangements" with the hospital. I feel this is an abuse of the Stark laws and would encourage that it only be applied to services that are know to be abusive. No one has shown that relationships with urologists and hospitals have been shown to be abusive. The service delivered is performed by the urologist and not another entity. It allows state of the art procedures and technology to be available to hospitals and towns where normally they would not be able to afford them. By joint venturing, the hospitals can extend these services such as lithotripsy and imrt to under serviced areas.

Even with the cost of technology coming down, hospitals are unwilling or unable to purchase these technologies that improve patient care and outcomes. Laser turp is a good example. The laser is a significant cost saver, because patients typically do not need to be admitted postoperatively, in contrast to the standard turp. The outcomes have been proven to be excellent and are similar to traditional turp. Without a physician partnership, this technology would not be available to patients.

As physicians we want the best technology to be available to our patients. In many instances, individual hospitals do not have enough volume to support a laser. However, by physician partnerships, this technology can be shared by many hospitals at an affordable rate. The cost of the equipment is spread among the doctors and the hospitals.

I feel that lithotripsy, laser turp, imrt are good examples of win/win relationships with patients and their doctors.

Under the Per Click Fee Ban, doctors would be unable to bill for per click fees. This fee structure was accepted in order to keep the hospitals from having to take unnecessary risks in providing new services such as with lower volumes.

Occasionally patients' services will need services that are less frequently performed and it is difficult to calculate this in a compensation arrangement.

Percentage Fee prohibition will restrict the way doctors can provide services. By using a percentage fee arrangement, physicians can balance the differences in payor mix and shoulder some of the risk that hospitals can take, while at the same time provide fair reimbursement for the physician.

The next proposed change that I take exception to is the Stand in the Shoes. This proposal would stipulate that a referral to a ASC owned by a hospital would be the same as a referral to a DHS facility. This is an overextension of the Stark laws because the procedures performed at the ASC's are rarely designated as health services under Stark.

This would likely result in physicians withdrawing from ASC's.

Finally the Burden of Proof is a proposal that would put the onus on health care providers to prove their innocence. This is unfairly puts the physician on the defensive since we are the ones providing the services to the patients. This process would put us in the position of having to prove the negative, that we had not knowledge of any unfair arrangement. Furthermore, it is very difficult and controversial how to value services provided. Fair marked value is often a moving target as patient volumes fluctuate.

I ask that CMS do the following:

Please accept the burden of proof that the law has placed on the one creating the rules, and not put on the health care providers.

Accept that urological joint ventures that provide therapeutic procedures are not DHS services, just because of where the services are delivered.

Drop any prohibition of per click or percentage fees as related to these same therapeutic joint ventures in order to preserve the access ands cost savings that the shared service model has created.

Clarify that the stand in the shoes provision to except hospital ownership or control in an ASC to clarify that legitimate joint ventures are not forced to abandon all ASCs with any hospital participation.

Thank you for listening to my concerns.

Sincerely,

J. Perry Lovinggood, M.D.

629-1

Urology Specialists
OF THE CAROLINAS, PLLC

G. Albert Dasher, MD
Roberto F. Ferraro, MD
Timothy A. Gajewski, MD
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Samuel J. Peretsman, MD, FACS
Thomas H. Phillips, MD
Harrison K. Rhee, MD
William C. Rice, MD, FACS
G. Kenneth Scholl, Jr., MD
Kevin C. Shandera, MD
Ralph N. Vick, MD
Daniel L. Watson, MD, FACS
Bradley K. Weisner, MD
Xavier A. Harrison, PA-C
A. Holly Thomas, PA-C
L. Jason Byrd, FNP-C

August 30, 2007

VIA FEDERAL EXPRESS

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

Re: CMS-1385-P; Comments on Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule

Dear Acting Deputy Administrator Kuhn:

I am a urologist who practices in the State of North Carolina as a member of Urology Specialists of the Carolinas, PLLC. With thirteen physicians and five physician extenders we provide general Urology care to the five county metropolitan area of Charlotte. We also provide specialized care in advanced laparoscopy, robotics, incontinence and infertility, which is unique to our practice. I specialize in treating patients with kidney stone disease and enlarged prostates as well as many other disease states of the urinary tract. The physicians of Urology Specialists are dedicated to furnishing the highest quality of medical and surgical urologic care in the State of North Carolina with a full range of services provided in a convenient, comfortable, supportive and patient-friendly setting.

As a North Carolina urologist, I thank you for the opportunity to comment on the Proposed Rule, published by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. See 72 Fed. Reg. 38122 (July 12, 2007). Although I commend CMS on its continuing efforts to develop clear and comprehensive regulations that implement the Stark Law, I write to express my concerns about the changes contained in the Proposed Rule and the nature of the Preamble discussion with respect to the in-office ancillary services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against program or patient abuse. In fact, any narrowing of the Exception, or the

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Urology Specialists
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communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

Because our pathologist is part of our practice, he has access to the patient's complete medical record, previous biopsies and clinical history, something that cannot easily be done, if at all, if a member of our practice is forced to rely on community or large commercial labs. Finally, our pathologist clearly is exercising his prerogative to affiliate with Urology Specialists in an arrangement of his choosing, something that might be prohibited by changes to the purchased diagnostic tests rule or a narrowing of the Exception.

With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in North Carolina and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. The rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. As a result, we have incorporated CT technology into our practice to provide more effective and cost efficient diagnosis and treatment to our patients. It is important to note that no matter where a North Carolina patient goes for his or her CT scan, the actual images will be taken by trained technicians who are licensed by the North Carolina Board of Physicians using the appropriate imaging technology, and a radiologist will read and interpret the images. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

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Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Urology Specialists practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,

Timothy A. Gajewski MD

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SureScripts®
The prescription for better healthcare®

August 30, 2007

VIA OVERNIGHT MAIL & ELECTRONIC FILING

Mr. Kerry Weems
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Attention: CMS-1385-P

Re: CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008 - Proposed Elimination of Exemption for Computer-Generated Facsimiles

Dear Mr. Weems:

Thank you for the opportunity to comment on the proposed rule (the "Proposed Rule") relating to Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008. Our comments, however, will be limited to the portions of the Proposed Rule related to the *Proposed Elimination of Exemption for Computer-Generated Facsimiles*.

BACKGROUND

By way of introduction, SureScripts, LLC was founded in August of 2001 by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), which together represent the interests of the 55,000 chain and independent pharmacies throughout the United States. SureScripts is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders and organizations to improve the safety, efficiency, and quality of healthcare by improving the overall prescribing process. At the core of this improvement effort is the Pharmacy Health Information Exchange™, a healthcare infrastructure that establishes electronic communications between pharmacists,

prescribers, and payers, and which enables the two-way electronic exchange of prescription and prescription related information.

SureScripts does not develop, sell, or endorse specific electronic prescribing software. Instead, SureScripts works with software companies that supply electronic health record (EHR) and electronic prescribing applications to physician practices and pharmacy technology vendors to connect their solutions to the Pharmacy Health Information Exchange, operated by SureScripts. Technology vendors cannot connect to the Pharmacy Health Information Exchange until they complete a comprehensive certification process. As part of its certification process, SureScripts establishes ground rules that safeguard the fairness of the prescribing process, including rules that, among other things, ensure patient choice of pharmacy and physician choice of therapy.

On a technical level, the certification process specifies the standard technical format for transmitting prescription information and tests each vendor's electronic connections to the network. The standards are based on the NCPDP SCRIPT Standards as mandated by the Medicare Modernization Act of 2003.

The certification rules also ensure that prescribing decisions are based on best medical practices, not on financial considerations or the interests of one particular entity. For instance, by prohibiting commercial messaging to physicians at the point of prescribing, SureScripts is helping to safeguard the fairness of the prescribing process and to prevent improper messaging activities.

Today, more than 95 percent of all pharmacies in the United States are certified on the Pharmacy Health Information Exchange. In addition, today most major, and many small to medium size, EHR and e-prescribing vendors in the United States are certified on the Pharmacy Health Information Exchange. This means that approximately 150,000 prescribers are using a software or application that has been certified on the Pharmacy Health Information Exchange for the exchange of prescriptions and prescription related information pursuant to the NCPDP SCRIPT Standards. As explained in greater detail below, however, not all of these prescribers are using their software or application to send prescriptions electronically using the NCPDP SCRIPT Standard (as defined in the MMA Final Rule) – many continue to use the software application to send computer generated faxes.

You can find more information about SureScripts at www.surescripts.com.

SureScripts Comment to "PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES"

We support the desire of CMS to eliminate the exemption currently contained in Section 423.160(a)(3)(i) of the Final Rule (70 FR 67571) promulgated under the Medicare Modernization Act - Medicare Program; E-Prescribing and the Prescription Drug Program – that exemption provides that entities transmitting prescriptions or prescription related information by means of computer generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard in transmitting such prescriptions or prescription-related information.

For all the reasons postulated by CMS at the time, we supported the exemption for computer-generated faxes when the MMA Final Rule was first promulgated in 2005. It has been our experience, however, that many in the industry point to Section 423.160(a)(3)(i) as support for them continuing to fax prescription information, and as a result they do not take steps to implement true electronic prescribing pursuant to the NCPDP SCRIPT Standards adopted by CMS. This loophole in the Final Rule has resulted in, and continues to result in, an adverse impact and slowdown in the adoption of electronic prescribing pursuant to CMS standards. We agree with CMS that the time has now come to address this loophole in the Final Rule that has slowed the adoption of e-prescribing; however, rather than eliminate the exemption in its entirety, we believe that the exemption should be narrowed in a manner that will produce significant and demonstrable results, but without unduly disrupting workflows related to the prescribing process and without becoming an undue economic burden for the industry.

In the Proposed Rule, CMS distinguishes between computer generated faxes, on the one hand, where the prescriber's/dispenser's software has the ability to generate NCPDP SCRIPT transactions, but the feature is not activated because the prescriber has not activated the feature on the software, as compared to, on the other hand, where the prescriber's/dispenser's software (such as word processing program) is used to create and send a fax that results in a paper prescription or response at the receiving end, but does not have true e-prescribing (electronic data interchange using the NCPDP SCRIPT standard) capabilities. *See Proposed Rule at pages 397-398.*

We believe that the exemption should be narrowed to eliminate the exemption for those prescribers/dispensers that fall with in the first category; namely those prescribers/dispensers who have software or an application that has the ability to generate NCPDP SCRIPT transactions, but the feature is not installed/activated because the prescriber/dispenser has not activated the feature on the software application or the prescriber/dispenser has not upgraded to the version of the software application that has true e-prescribing capabilities. We believe there are over 100,000 prescribers and 15,000 pharmacies who fall within this category. Those prescribers/dispensers can convert to

true electronic prescribing without significantly changing their workflow and without significant expense. With respect to workflow, their application works with minor modifications, whether the prescription related information is sent via computer generated fax or NCPDP SCRIPT e-prescribing – the prescriber/dispenser hits the send button, and the new prescription order is sent. How the application sends the prescription message happens in the "background" of the application, out of sight and out of view of the prescriber/dispenser. In fact many of those prescribers/dispensers do not even know or realize that the prescription message is being sent by computer generated fax when they hit the send button. If they were to activate the true e-prescribing feature or upgrade to the version of their software application that has true e-prescribing capabilities, their workflow would remain substantially the same. With respect to cost, we understand that the required upgrade is usually included in the costs associated with annual software maintenance that the prescriber/dispenser is already paying, so there should not be any, or if there is, only minimal, incremental cost to the prescriber/dispenser to turn on the e-prescribing feature or upgrade to the version of their software that has true e-prescribing capabilities. We believe that if the exemption for computer generated faxes were eliminated just for these prescribers/dispensers, the number of NCPDP SCRIPT transactions would increase significantly in a short period of time, thus creating the "tipping point" that CMS is seeking for the adoption and utilization of electronic prescribing.

We believe, however, that to eliminate the computer generated fax exemption for those prescribers/dispensers who fall within the second category; namely those prescribers/dispensers who use software (such as word processing program) to create and send a fax that results in a paper prescription or response at the receiving end, but does not have true e-prescribing (electronic data interchange using the NCPDP SCRIPT standard) capabilities, would create an undue burden on those prescriber/dispensers, and we are concerned that they would revert to issuing paper prescriptions – thus, eliminating the exemption for those prescribers/dispenser might have the unintended and paradoxical effect of discouraging true electronic prescribing. Accordingly, we recommend that the computer generated fax exemption continue to apply for those prescribers/dispensers until such time as CMS creates initiatives to further the adoption of electronic prescribing.

We also believe that, for those prescribers/dispensers who fall within the first category today or on the date that the Proposed Rule is promulgated in final form (the "Final Rule Date"), the suggested deadline (see below for discuss of the implementation date) provides ample time for those prescribers/dispensers to activate, or upgrade to, the version of their software application that has the ability to generate NCPDP SCRIPT transactions. There will be prescribers/dispensers, however, who fall within the second category on the Final Rule Date, but who would find themselves in the first category **after** the Final Rule Date because their software application becomes certified to generate

NCPDP SCRIPT transactions after the Final Rule Date. Those prescribers/dispensers should not be allowed to continue to rely on the computer generated fax exemption, but they would need sufficient time to install, activate, or upgrade to the version of their software application that has the ability to generate NCPDP SCRIPT transactions. We believe that twelve (12) months after their software application becomes certified to generate NCPDP SCRIPT transactions would be sufficient time to stop generating computer generated faxes and convert to true e-prescribing.

In addition, we believe that there are other specific circumstances in which computer generated faxes should still be permitted, as follows:

First, the regulations promulgated and enforced by the Drug Enforcement Agency prohibit the electronic transmission of prescriptions for controlled substances. This prohibition, in and of itself, is a tremendous barrier to the adoption of electronic prescribing by prescribers, and we certainly encourage the DEA to amend its regulations to permit prescribers to send prescriptions for controlled substances by electronic means. We believe that where a law or regulation prevents the transmission of an electronic prescription using the NCPDP SCRIPT Standard, prescribers/dispensers need the ability to use the most efficient alternative to deliver the message, including by computer generated fax. Accordingly, the exemption should apply in any circumstance in which a law or regulation would prohibit the delivery of prescription-related information using the NCPDP SCRIPT standard.

Second, there are times when there are communications failures impacting electronic prescribing, due to power outages, other temporary system failures, down time due to maintenance operations, or otherwise. These temporary outages could occur with respect to the prescriber EHR or e-prescribing system, the pharmacy management system, or networks and exchanges. We believe that these circumstances are relatively rare, and hopefully will become even more rare as the industry and technology develops; however prescribers and dispensers need the ability to deliver prescription information in the most secure and efficient means possible when these temporary outages occur, and computer generated faxing may be the best alternative during temporary communications failures. Accordingly, we suggest that the computer generated fax exemption be available for prescribers/dispensers during such temporary communication failures.

Finally, we believe in the core principle that patients should have free choice to use the prescriber and the pharmacy of their preference. Accordingly, if a patient chooses to use a prescriber that has the capability to electronically prescribe using the NCPDP SCRIPT Standard but chooses a pharmacy that does not have such capability, or vice versa, that prescriber/dispenser should have the right and ability to send the prescription message by the means that is most efficient and best for the circumstances, including by a computer generated fax. Accordingly, the NCPDP SCRIPT enabled sending entity should be able

to send a computer generated fax if the receiving entity is not capable of receiving an NCPDP SCRIPT message, and the sender believes that a computer generated fax is the best and most efficient way to send the prescription message. Of course, if both the sender and the receiver are both capable of communicating with the NCPDP SCRIPT standard, then they should do so (unless another exemption applies).

We have taken the liberty to draft language that we believe captures the intent of the changes suggested above, and we encourage CMS to revise the fax exemption so as not to eliminate the exemption in its entirety, but rather to eliminate the exemption for those prescribers/dispensers who today have, or who in the future purchase or license, software that is capable of sending prescriptions messages through true electronic means in compliance with the NCPDP Script standards. Our proposed language is as follows:

Effective as of April 1, 2009, notwithstanding the requirement herein for prescribers and dispensers who electronically transmit prescription and prescription related information for covered drugs prescribed for Medicare Part D eligible beneficiaries to comply with the Foundation Standards for the communication of prescription or certain prescription related information by and between prescribers and dispensers for the transactions listed at Section 423.160(b)(1)(i) through (xii), the transmission of such prescription or prescription related information by means of computer generated facsimiles shall be permitted in the following circumstances:

1. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) does not own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the Foundation Standards, whether on the version that the prescriber/dispenser is currently using or another version of such software.*

    a. *This exemption shall not apply to prescribers/dispensers sending a transaction listed at Section 423.160(b)(1)(i) through (xii) who own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the Foundation Standards, but who has not upgraded to the version that is compliant with the Foundation Standards and/or has not activated that functionality.*

    b. *In addition, in the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) owns, licenses, or otherwise uses software that does not have or did not*

have the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated] to send and receive transactions compliant with the Foundation Standards, but such software becomes capable to send and receive transactions compliant with the Foundation Standards at any time after [insert date rule promulgated], then this exemption shall not apply with respect to such software twelve months after such software becomes capable to send and receive transactions compliant with the Foundation Standards.

2. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) is sending the transaction to a dispenser/prescriber who does not own, license, or otherwise use software that has the capability to receive transactions compliant with the Foundation Standards.*

3. *In the event any applicable law or regulation would prohibit the electronic transmission of the prescription and prescription related information using the Foundation Standards.*

4. *In the event there is a temporary communications failure, whether technological or otherwise, that would prohibit the electronic transmission of the transactions listed at Section 423.160(b)(1)(i) through (xii) using the Foundation Standards. Such temporary communications failures include, by way of example and not limitation, power outages, connectivity failures, or temporary outages of the either the prescriber's or dispenser's computer or management systems.*

Finally, we note that the receiver of a prescription message via a computer-generated fax likely will not have the ability to know whether or not the sender had the ability to send the message via NCPDP SCRIPT, but failed to do so in violation of the regulation. We propose that the rule state that receiver of a computer-generated fax should not be penalized for receiving such a fax, and the receiver should be free to act upon the message for the benefit of the patient and patient care.

Finally, with respect to the implementation date of the rule, we would suggest an effective date of April 1, 2009, rather than January 1, 2009. This date would coincide with the expected promulgation of additional standards under the MMA, and we believe that using coinciding dates for the elimination of the fax exemption will reduce confusion in the marketplace. However, if the promulgation of additional standards under the MMA were to be delayed past April 1, 2009, we would not support further delay of the

elimination of the fax exemption, and would suggest that the fax exemption be eliminated no later than April 1, 2009.

Of all parts of healthcare, the automation of the prescribing process is the most advanced and has made the most progress in the readiness to exchange information in electronic formats. We applaud CMS for its efforts to promote electronic prescribing pursuant to the NCPDP SCRIPT standard and for taking steps to eliminate barriers to adoption of the appropriate technology. If we may be of any additional assistance, please do not hesitate to contact Paul Uhrig, General Counsel and EVP, Corporate Development, of SureScripts at 703.921.2179 or paul.uhrig@surescripts.com.

Sincerely,

Paul L. Uhrig
General Counsel, EVP – Corporate Development

ENCLOSURE 1

PROPOSED OBSTETRICAL SHORTAGE AREA

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

Obstetrical Shortage Area

A. *Criteria for Obstetrician Shortage Area.*

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

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

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

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

B. *Methodology*

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

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

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

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

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

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

ENCLOSURE 2

COMPENSATION ARRANGEMENT EXCEPTION

42 C.F.R. § 411.354 (e)

(e) Compensation Arrangement Exception

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

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

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

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

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

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August 28, 2007

VIA FIRST CLASS MAIL

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

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

To The Addressee:

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

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

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

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

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

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

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

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

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

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

Best regards,

Barry F. Rosen

Christopher P. Dean

Enclosures

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CYTYC

Via Electronic Submission
August 24, 2007

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

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies for Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (CMS-1385-P)

Dear Mr. Kuhn:
Cytyc Corporation appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare Physician Fee Schedule proposed rule for fiscal year 2008, published in the Federal Register on July 12, 2007 (CMS-1385-P, Federal Register, Vol. 72, No. 133).

Cytyc Corporation, a medical device company, provides therapeutic and screening technologies for multiple areas of health and is particularly focused in women's health. In the area of therapeutics, Cytyc manufactures the MammoSite Radiation Therapy System (RTS) the most widely used method of breast brachytherapy to treat breast cancer. Additionally, Cytyc manufactures the ThinPrep Pap Test, the most widely used cervical cancer screening test. As an industry leader in women's health, Cytyc is focused on ensuring that issues impacting women's health and certain cancer therapies and diagnostics are given appropriate consideration in the formation of federal health care and reimbursement policy.

2008 Update of the Conversion Factor and the Sustainable Growth Rate
The proposed rule indicates that payment rates for physicians' services will be reduced by 9.9% for 2008. Such a drastic reduction will impact continued provider participation in the Medicare program. At a time where the number of Medicare beneficiaries is growing substantially, access to providers and services is crucial. We acknowledge annual review of the conversion factor according to the sustainable growth rate (SGR) formula is required by law. Nonetheless, CMS must recognize that the reductions under the SGR system forecasted for 2008 and subsequent years will limit provider participation. Cytyc does not support the proposed 9.9% reduction and recommends that CMS replace the Sustainable Growth Rate in 2008 with an alternate annual update system that more accurately reflect actual increases in physician practice costs.

Clinical Laboratory Issues
Cytyc offers diagnostic testing for cervical cancer with the ThinPrep test which has been shown to increase the detection of pre-cancerous cells, and Cellient™ Automated Cell Block System which can aid the pathologist with more diagnostically useful cell blocks. Payment for many of the diagnostic tests for cervical cancer is made under the clinical laboratory fee schedule.

CMS proposes a new reconsideration process relating to the basis for and the amount of payment for any new clinical laboratory test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008. We commend CMS for proposing a reconsideration process for use in future new lab test payment determinations. The reconsideration process as describe would allow the necessary dialogue to ensure adequate pricing is set for new tests. Cytyc urges CMS to establish payment amounts at the national limitation amount (NLA) of the new tests on the Clinical Laboratory Fee Schedule to which the new tests are cross-walked. The NLA should replace carrier-specific amounts below the NLA for new tests. Carrier specific low rates would inhibit patient access.

Resource-Based Practice Expense Issues
First, with regards to the treatment of breast cancer, we wish to express our concerns about CMS's proposed changes in RVUs and the potential impact of significant reductions in practice expense values on access to cancer care. Under the new practice expense methodology, two (2) breast brachytherapy and two (2) HDR brachytherapy codes are slated to be significantly reduced over the four-year transition period. CPT codes 77781 and 77782 are the primary procedures reported for ovarian, breast and cervical cancer treatments. The proposed reductions in reimbursement may influence treatment decisions.

Breast brachytherapy, or partial breast irradiation, is a viable treatment option for many women receiving a lumpectomy. The most common brachytherapy method utilizes a balloon catheter and High Dose Radiation (HDR). CPT codes 19296 and 19297 are used for the placement of the balloon catheter in conjunction with HDR brachytherapy codes 77781 & 77782. Decreasing the length of a course of radiation therapy improves the quality of life for these women. Currently 20% of women with breast cancer are foregoing radiation therapy. Partial breast irradiation provides an opportunity for some women to receive radiation who may otherwise not be able to endure 7 weeks of whole beam radiation. By implementing the proposed payment changes, this rate may continue to increase.

Second, Cytyc supports the recommendations submitted by the Coalition of Advanced Brachytherapy in this area.

Third, Cytyc supports the CMS decision not to revise the 50% equipment usage assumption until adequate data has been collected on equipment costs.

Quality Indicators
Cytyc wishes to acknowledge CMS efforts to implement the PQRI and to thank CMS staff for providing a clear description of the process included in the Proposed Rule. Cytyc would request CMS include providers, device manufacturers and patient groups in the continued development of PQRI. Additionally, Cytyc would request CMS include an indicator for radiation therapy following breast conservation surgery as included in the inpatient quality indicators.

Data from multiple large randomized trials have demonstrated the addition of radiation after breast conserving surgery in patients with invasive breast cancer lowers the risk of local recurrence. Therefore, we commend CMS for including PQRI Measure #74 'Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery' under the PWRI program in 2007 and for proposing to continue it in 2008. We also commend CMS for proposing to include a screening mammography quality measure in 2008 from the AQA starter-set measures. As a manufacturer that provides technology for women faced with breast cancer, we believe including these quality indicators will help to ensure all Medicare beneficiaries with breast cancer are evaluated and offered the most appropriate technology. We request that CMS allow manufacturers of advanced therapies involved in the treatment of breast cancer to be involved in the development of the quality measures.

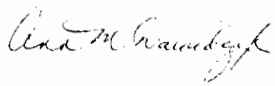
Recommendations
Cytyc respectfully requests that CMS consider an implement the following recommendations:

- ◊ Make final the proposed new reconsideration process relating to the basis for and the amount of payment for any new clinical diagnostic laboratory test
- ◊ Base payment for new tests included in the Clinical Laboratory Fee Schedule on the National Limitation Amount, replacing local carrier rates to avoid disparity in rates which may have an impact on patient access.
- ◊ Reconsider reductions in the proposed practice expense relative value units (RVUs) specific to 19296, 19297, 77781 and 77782. These proposed reduction combined with the forecasted reductions in the annual update factor will have an adverse impact on Medicare beneficiaries' access to proven treatment advanced technologies for the treatment of breast cancer.
- ◊ Work with the Congress, physicians and manufacturers on an alternate annual update system to replace the SGR system.

Cytyc supports the specific recommendations included in the ADVAMED and CAB comment letters.

Cytyc appreciates the opportunity to provide comments during this proposed rule period. Should you have any questions or need additional information, please do not hesitate to contact me at 508-263-8961 or via email at ann.dawidczyk@cytyc.com.

Sincerely,



Ann Marie Dawidczyk
Senior Manager, Managed Care

cc: Margaret Eckenroad, Sr. Director Women's Health & Professional Relations

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UROLOGY ASSOCIATES OF FREDERICKSBURG
A Division of Mid-Atlantic Health Alliance, Inc.

Peter O. Carey, M.D., F.A.C.S.
Daniel M. Hoffman, M.D., F.A.C.S.
Elmore J. Becker, M.D.
Scott M. Sell, M.D.

Gregory R. Szlyk, M.D.
Matthew D. DuMont, M.D.
C. Ralph Beamon, M.D. (Retired)
F. Brad Gray, M.D. (Retired)

August 27, 2007

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

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

Ladies and Gentlemen:

I am a general Urologist practicing in Fredericksburg, Virginia as part of a private practice group of six Urologists. As the only group in the greater Fredericksburg area, we provide all of the urological care for over 350,000 people. We provide virtually all aspects of urological care and refer few if any patients to the university hospitals in the state.

As are all of my five other partners, I am an owner in two joint ventures which provide therapeutic services to our patients. One partnership provides lithotripsy services (for the treatment of kidney and ureteral stones) and the other provides cryotherapy services (for the treatment of prostate and kidney cancer). We are in the process of forming a partnership so that we can utilize a high-powered laser for the treatment of benign prostatic hyperplasia.

Our patients have benefited significantly from these services. Lithotripsy has become the gold standard for treating many stones. Cryotherapy offers a minimally invasive means of curing both prostate and kidney cancer. Likewise, laser treatment offers a much less morbid means of treating the symptoms and side effects of benign prostatic hyperplasia.

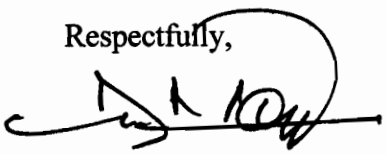
Our single hospital in Fredericksburg does not have enough volume to justify the expense of purchasing the lithotripsy, cryotherapy and prostate laser technologies. Since our partnership consists of many physicians in our region (and costs are spread out more), we can currently offer these services. Were we not able to offer these services, our patients, who tend to be *sick* and *elderly*, would not be able to benefit from the tremendous advantages these treatments offer. Most would *not* be able to travel to the larger hospitals in our region due to their frail conditions and would consequently be denied appropriate medical care.

As a simple Urologist, I have had some difficulty in trying to understand the nuances of the Stark rules and regulations. I do understand that CMS may want to ban services under arrangements where there is physician ownership because of questionable diagnostic imaging arrangements. Overuse or improper referrals for our therapeutic services (lithotripsy, cryotherapy for the treatment of cancer, laser treatment of prostate disease) have **not** been identified. Simply put: one cannot perform lithotripsy if the patient does not have a stone; one cannot perform cryotherapy if the patient does not have cancer; one cannot perform a laser vaporization of the prostate if the patient does not suffer from benign prostatic hyperplasia.

I could offer daily examples of patients who would suffer more than they already do were these services not available in Fredericksburg: a ninety-two year old woman who underwent the successful treatment of a large kidney stone last Friday and was able to recover in her own home the very same day; a sixty-six year old retired Pentagon employee who returned home last Thursday after a two day hospital stay for cryotherapy of his kidney cancer (he would have been faced with a significantly more morbid procedure, a partial nephrectomy and its attendant week long stay in the hospital); an eighty eight year old man who went home the next day (Tuesday) without his catheter after laser vaporization of his prostate for urinary retention (he would have been faced with the standard transurethral resection of the prostate which is much more morbid and typically requires a four day hospital stay). And that is just last week. And I am just one of six Urologists here.

As you try to stop abusive arrangements, please do not jeopardize the care that our patients currently enjoy.

Respectfully,



Matthew D. DuMont, MD
Chairman, Division of Urology, Mary Washington Hospital

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Aug. 28, 2007

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P

Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: CMS-1385-P Proposed Revisions to payment policies under the physician fee schedule and other Part B payment policies for CY 2008

Dear Mr. Weems:

I urge CMS reevaluate the cuts in reimbursement for DXA screening. DXA (77080) should not be considered an imaging service within the meaning of the section 5012 (b) of the Deficit Reduction Act of 2005 because the diagnosis and treatment of osteoporosis is based on a score and not an image.

The utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease or a preventive health service should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the utilization rate for DXA to 12%.

According to "Bone Health and Osteoporosis: A Report of the Surgeon General (2004)," screening and assessment for osteoporosis are already underutilized for the at risk population. Access to DXA screening is essential to the osteoporosis population in the state and there is already a reduction in the number of facilities that provide DXA screening because of reduced reimbursement rates. This decrease in providers limit access to and quality of care. In the longer term this will only increase the fracture rates in New Jersey adding more financial burden both to the state and to its the residents.

Sincerely,

Virginia Mc Govern

DIVISION OF UROLOGY
Michael J. Naslund, M.D.
Richard B. Alexander, M.D.
Toby C. Chai, M.D.
Michael W. Phelan, M.D.
Andrew C. Kramer, M.D.
James Borin, M.D.

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DEPARTMENT OF SURGERY

UNIVERSITY OF MARYLAND
SCHOOL OF MEDICINE

August 29, 2007

Mr. Herb Kuhn
Acting Deputy Administrator, CMS
Department of Health and Human Services
ATTN: CMS-1385-P Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Kuhn:

I am a practicing urologist and chief of urology at the University of Maryland School of Medicine. I wanted to submit my comments to you on the revisions that CMS has proposed for payment policies for ambulatory services beginning in 2008. I believe the number for this policy is CMS-1385-P.

It is important for the practice of urology that urologists have access to radiological imaging equipment. A great example of this benefit has been seen over the last 20 years where ultrasound of the prostate, used by urologists, has greatly enhanced our ability to detect, stage and, treat prostate cancer. More recently CT scanning has been used by urologists to evaluate patients for the possibility of stones in the urinary tract or cancers, and obstruction of the kidneys.

I'm aware that there is literature published showing that the cost of imaging has increased at significant rates over the past 5 to 6 years. Many have suggested this increase is due to physicians over-utilizing imaging for their own financial gain. Over-utilization is an issue throughout medicine and it is an issue in imaging as well. From the urology perspective however, over utilization is unlikely to be the main reason that imaging in urology is increased.

The reason imaging has increased is that improved technologies with imaging equipment will now allow us to diagnose diseases and problems accurately which in past years required either surgical exploration or other, less expensive and less accurate imaging tests which often did not give the correct or complete diagnosis. In the past, patients underwent surgery that in retrospect, was not helpful because of incorrect imaging. The improvements in imaging, particularly CT and MRI, have led to an increased utilization of imaging but a significantly decreased incidence of inappropriate or unnecessary surgery because of better diagnostic abilities.

22 South Greene Street, Room S8D18 • Baltimore, Maryland 21201-1595

410 328 5544 • 800 492 5538 x5544 *toll free* • 410 328 0595 *fax* • 410 328 9600 *tdd*

Another issue I know you are concerned about with imaging is quality. The American Academy of Radiology continues to say that imaging done in a urologist office is less likely to be of high quality than that done in a radiologist's office. The point they often fail to make is that a CT scan done in a urologist office is read by radiologist in exactly the same way that it would be had it been done in a radiologist office. Radiologists do not do CT scans or MRI's, they have technicians, just like another specialty would, who do the scans and then the radiologists read them. With internet technology, scans can be sent to expert radiologists in different parts of the country for a reading that is often better than what local radiologists could perform. For example, the department of radiology at Cornell University reads films from all over the world on the internet. They have radiologists who sub-specialize in certain areas and read only films in those areas. This type of arrangement leads to a higher level of care than when CT scans are done locally by local radiologists.

The other issue in the proposed revisions is whether pathologists should be allowed to work individually with urologists and other specialties. My sub-specialty in urology is prostate cancer and, even in an academic institution such as ours, some of our pathologists are much better at reading prostate cancer biopsy slides than others. As a result, we direct our prostate biopsies to one or two of our pathologists for their expertise. Other urology groups in private practice have adopted the same policy recognizing that some pathologists are just better than others at reading prostate cancer and making the appropriate diagnosis. To eliminate the ability of urologists to choose which pathologist they work with will lower the quality of care to patients. Pathologists based in hospitals obviously have an economic interest to prevent this from occurring but the bottom line is patient care is better in instances where urologists, or other specialties as applicable, can choose the pathologist that they want to work with.

I appreciate your consideration of these comments. As you can see, I do not think that this proposed change in the rules should be passed. I think it will be detrimental to patient care and it will interfere with the ability of urologists and other physicians to provide top quality patient care. If there are any further questions, please contact me at 410-328-0800.

Sincerely,

Michael J. Naslund, M.D.
Chief, Division of Urology
University of Maryland School of Medicine

MJN:blg

Beth Israel Deaconess Medical Center

A teaching hospital of Harvard Medical School

Osteoporosis Prevention and Treatment Center
Bone Density Testing
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Boston, MA 02215
Phone: 617-667-9344
Fax: 617-667-7060

Harold N. Rosen, MD
Director

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

RE: CMS-1385-P Proposed Revisions to payment policies under the physician fee schedule and other Part B payment policies for CY 2008

Comments:

The Physician Work RVU-CPT 77080 (DXA)
The Direct Practice Expense RVU for 77080 (DXA)
Indirect Practice Expense for DXA and VFA
Deficit Reduction Act

Dear Mr. Weems:
I appreciate the opportunity to offer general comments on the proposed rule regarding changes to the Medicare physician fee schedule CMS-1385-P.

As a provider of DXA and/or VFA services, I request CMS to reevaluate the following:

a. The Physician Work RVU for 77080 (DXA) should be increased from 0.2 to 0.5, consistent with the most comprehensive survey data available;

b. The Direct Practice Expense RVU for 77080 (DXA) should reflect the following adjustments:
   - the equipment type for DXA should be changed from pencil beam to fan beam with a corresponding increase in equipment cost from $41,000 to $85,000;
   - the utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease or a preventive health service should be calculated in a different manner than other utilization

rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the utilization rate for DXA to 12%.

c. The inputs used to derive Indirect Practice Expense for DXA and VFA should be made available to the general public, and

d. DXA (77080) should not be considered an imaging service within the meaning of the section 5012 (b) of the Deficit Reduction Act of 2005 because the diagnosis and treatment of osteoporosis is based on a score and not an image.

Sincerely,

Harold Rosen, MD
Director – Osteoporosis Prevention and Treatment Center
Beth Israel Deaconess Medical Center

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ION
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August 27, 2007

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

Re: CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B payment Policies for CY 2008

Dear Acting Deputy Administrator Kuhn:

International Oncology Network (ION), a registered name of International Physician Networks, LLC, is pleased to submit the following comments regarding "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B payment Policies for CY 2008" published in the July 12, 2007 *Federal Register.* ION recognizes the difficult task CMS faces in addressing a myriad of payment policies in the proposed rule and we commend the agency for its effort. However, ION does have a few specific concerns regarding proposed policy changes included in the rule that potentially impact its physician members. As detailed below, we urge CMS to consider these concerns before it makes any final determinations.

Overview of International Oncology Network

ION, a wholly owned subsidiary of AmerisourceBergen Corporation, is the leading physician specialty group purchasing organization with membership of over 10,000 community-based medical specialists. ION members range from solo practitioners to some of the country's largest and most renowned private practices -- all committed to improving the quality of patient care in their own communities. ION's physician membership is comprised of medical specialists who perform a significant volume of drug administration services, including oncologists/ hematologists; urologists, rheumatologists; and gastroenterologists.

ION serves as a Group Purchasing Organization (GPO) for its members in an effort to ensure that they receive the pharmaceutical products necessary for high-quality patient care at the lowest possible costs. It believes that these group purchasing arrangements

are critical in ensuring that medical specialists operate their practices at optimum efficiency, and that patients continue to have access to the highest quality of care in community settings. In addition to negotiating and administering group purchasing arrangements, ION provides a variety of related practice management and clinical educational services to its members in an effort to enhance the efficiency of their practices and the quality of care received by their patients. These services include facilitating participation in clinical trials, developing timely clinical and scientific education programs, and providing information related to various practice management support services. By bringing clinical research, educational symposia, information systems, and other innovative services to the local oncology community, ION provides tools to physicians that can help maintain a level of expertise so needed in the rapidly changing medical environment.

ION provides a variety of services on behalf of its vendors in return for administrative fees that are paid pursuant to the applicable safe harbor regulations governing health care group purchasing arrangements. Although the exact nature of the work ION performs varies for each vendor, generally, ION provides the following services to pharmaceutical companies in exchange for its GPO administrative fees:

- Negotiating and administering the purchasing agreement on behalf of its physician members;
- Informing its members of the vendors' services and programs related to particular products;
- Distributing educational material to its members on behalf of the vendors;
- Assisting the vendors with data collection efforts related to its members' utilization of products and services;
- Providing vendors with logistical and administrative support related to conducting Advisory Boards, and providing other assistance related to gathering feedback from its members related to vendors' products and services; and
- Publishing both clinical and marketing materials in ION publications on a regular basis.

ION, and other physician-based GPOs, serve a valuable and beneficial role in ensuring quality healthcare by providing significant assistance and services to community-based practitioners, and the vendors who provide them necessary products and services.

Bundled Price Concessions/ASP Issues

In the proposed rule, CMS asserts that it is appropriate to implement a specified method for treating bundled price concession in the calculation of average sales price (ASP). Specifically, CMS is proposing that the manufacturer must allocate the total value of all price concessions proportionally according to the dollar value of the units of each drug sold under a bundled arrangement.

ION urges CMS to ensure that the methodology adopted by CMS to calculate bundled price concessions allows for an accurate representation of the price paid by physicians . We recognize CMS' desire to implement a consistent methodology across manufacturers' ASP calculations. However, it is also important that CMS not adopt any one specific methodology that may be inflexible and prevent beneficial arrangements. If CMS decides to adopt a specific methodology that manufacturers must use for the treatment of bundled price concessions, CMS should ensure that the methodology will accurately reflect the prices paid by physicians, and most importantly, ensure beneficiary access to innovative drugs.

TRHCA—Section 110: Anemia Quality Indicators

The Tax Relief and Health Care Act of 2006 (TRHCA) requires that, effective January 1, 2008, physicians requesting payment for anti-anemia drugs furnished to treat anemia resulting from the treatment of cancer must report the beneficiary's hemoglobin or hematocrit level. As CMS examines implementation of this requirement, ION urges the agency to minimize any additional burdens this new reporting requirement will impose on physician practices. Physicians face unprecedented regulatory requirements and burdens as a result of substantial Medicare changes in recent years. CMS should ensure that the process for reporting hemoglobin or hematocrit levels is integrated as much as possible into the standard claims submission process that physicians follow when treating patients. We urge CMS to consider delaying this requirement until the administrative burden is understood and can be better addressed in the future as we progress toward electronic health records.

Drug Compendia

CMS is proposing to implement a new process to add new compendia to the statutorily recognized list or remove current compendia from the list. Under the new process, CMS would annually post a notice on the CMS Web site offering an opportunity to request changes in the list of recognized compendia. The request would need to demonstrate how the specific compendium complies or does not comply with the desirable characteristics identified by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC).

ION commends CMS for proposing an open process for determining changes to the compendia list. This process will present stakeholders an opportunity to provide important feedback on particular compendia, which CMS can then incorporate into assessing any potential changes to the compendia list. ION also encourages CMS to swiftly clarify and identify acceptable compendia, including a determination by CMS whether DrugPoints is a "successor" publication or a "substitute" publication to USP-DI.

CAP Issues

The proposed rule details changes to the Competitive Acquisition Program (CAP) that will enhance the attractiveness of the program to physicians as well as vendors. ION is

encouraged to see CMS re-examining ways to enhance the CAP program. As a member of the Specialty Biotech Distributors Association (SBDA), ION echoes the position set forth by the SBDA in its recently submitted comments regarding the 2008 Fee Schedule, pertaining specifically to changes targeted toward physicians relating to proposed new exigent circumstances under which physicians may terminate CAP participation, as well as new rules that would permit physicians to transport drugs among office locations.

Specifically, CMS is proposing to establish an additional exigent circumstance to permit physicians to opt out of CAP outside of the annual election process. Under this proposal, CMS would establish a process through which physicians could request to end their CAP physician election agreement if they are able to prove that continuing their participation would place a significant burden on them. ION believes such a change will encourage greater physician participation in CAP because physicians will have additional options to terminate their participation if it becomes burdensome.

CMS is also contemplating a positive modification to the current rules governing transport of CAP drugs. Currently, a significant drawback in terms of physician participation in CAP is the restriction on a physician's ability to transport CAP drugs to office locations beyond the site of delivery. In the proposed rule, CMS indicates that it is considering narrowing this restriction where permitted under State law and other applicable laws and regulations. ION supports easing the parameters of the transportation restriction, while also being mindful of the importance of ensuring that the integrity of the product is not compromised.

ION encourages CMS to make the aforementioned changes as well as other proposed changes detailed in the rule that will increase the likely success of CAP. However, we suggest that the agency refrain from making these changes during the performance of the current CAP contract. Bidders and other parties relied on the language in the enabling statute and implementing rules in assessing the viability to participate in CAP under its current structure. ION believes it would be inequitable for CMS to adopt substantial revisions to the program midstream that would harm those who relied on the original language and governing rules. Therefore, CMS should only implement the proposed changes if other interested entities are provided an opportunity to participate in CAP under the same rules.

Physician Fee Schedule Update

CMS projects a negative update of -9.9 percent for 2008 due to the application of the Sustainable Growth Rate (SGR) formula. Oncologists, along with all physicians, continue to face unprecedented financial and administrative pressure. This negative update is compounded by additional payment reductions confronting oncologists, such as payment reductions for certain imaging services. ION urges CMS to pursue all policy changes that would provide relief from the flawed physician payment update formula. One such step that CMS could adopt is to apply the $1.35 billion Physician Assistance

and Quality Initiatives Fund to the CY 2008 conversion factor update. The fund will help lower the cost of Congressional action needed to reduce the projected 9.9 percent cut.

Conclusion

ION appreciates the opportunity to comment on these important issues. We hope that CMS addresses our concerns and incorporates changes as warranted. ION looks forward to working with CMS on these and other critical issues to ensure that oncologists throughout the country can provide the most effective and efficient care to their patients. If you should have any questions regarding these comments, please contact Aaron Krupp, JD at (202) 775-1329.

Sincerely,

Mike Martin
President, ION

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NOVARTIS

Barbara Washington
Vice President Health Policy

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Aug. 31, 2007

Herb Kuhn, M.D., Ph.D., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on the Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 (CMS-1385-P)

Dear Acting Administrator Kuhn,

Novartis Pharmaceuticals Corporation appreciates this opportunity to comment on the Center for Medicare and Medicaid Services' (CMS) proposed physician fee schedule rule: **Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 (the "Proposed Rule)**[1]. Novartis is a leading global pharmaceutical manufacturer that is dedicated to the discovery, development and marketing of innovative products to cure diseases, to ease suffering, and to enhance the quality of life. Novartis manufacturers both traditional pharmaceuticals and physician administered drugs and biologics, many of which are utilized under the Medicare Part B benefit. In addition to our traditional pharmaceutical business, Novartis Vaccines and Diagnostics, created in 2006 following the acquisition of Chiron Corporation, offers products that prevent over 20 viral and bacterial diseases and is currently pursuing clinical research for over ten different pipeline products. Novartis Vaccines maintains the world's fifth largest vaccine business and is the world's second largest manufacturer of flu vaccines, as well as important meningococcal, pediatric, adult and travel vaccine franchises.

ASP Issues

Novartis appreciates the guidance that CMS has provided in the Proposed Rule regarding the treatment of bundled price concessions for purposes of the average sales price (ASP) calculation. We write, however, to highlight areas where we believe there is continued uncertainty and where manufacturers would benefit from additional clarification in the Final Rule. Because ASP is used for reimbursement, Novartis believes it is critical that manufacturers and providers have certainty regarding any changes to ASP policy to avoid creating potential barriers to patient care.

Novartis appreciates that CMS has provided specific guidance in the Proposed Rule regarding the definition and treatment of bundled price concessions and believes that this guidance will

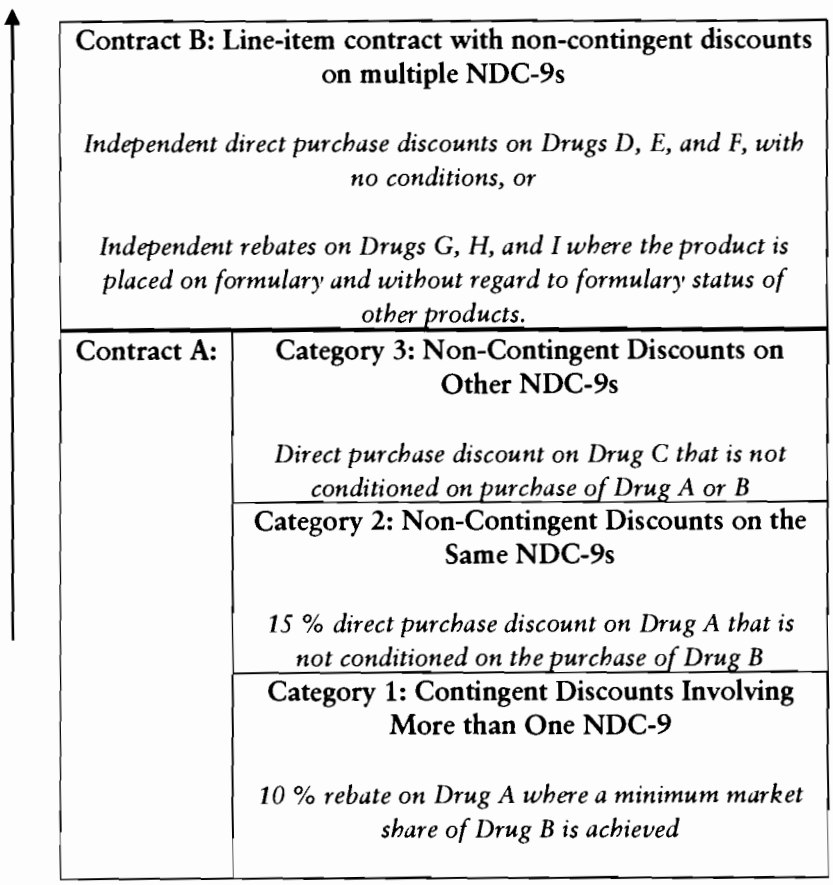
[1] 72 Fed. Reg. 38,122, July 12, 2007

help to ensure accurate and consistent ASP calculations across manufacturers. Nonetheless, Novartis has identified several areas of ongoing concern, as discussed in more detail below.

A. CMS Should Specify that the Reallocation Requirement Is Limited to Contingent Discounts Involving More than One NDC-9.

As CMS notes in the preamble to the Proposed Rule, there is the potential for great variation in the structure of bundled arrangements and the characteristics of the drugs included in such arrangements.[2] Because of the variability in commercial contracts, and the complexity involved in defining a bundled arrangement, Novartis believes that manufacturers will need more detailed guidance from CMS regarding the scope of the proposed definition of a bundled arrangement and the reallocation methodology. As illustrated by Figure 1, a single purchase agreement may include multiple categories of discounts. Novartis urges CMS to make clear that only those discounts that trigger the definition of a "bundled arrangement"—i.e., the Category 1 discounts that are contingent on the purchase of more than one NDC-9—are subject to reallocation. Specific guidance from CMS on this issue will promote the consistent application of the methodology across manufacturers and ultimately enhance the accuracy of ASP reporting.

Figure 1: Contracting Arrangements



[2] *Id.* at 38,151.

The Proposed Rule directs that "the total value of *all price concessions* on all drugs sold under a bundled arrangement must be allocated proportionately according to the dollar value of the units of each drug sold under the bundled arrangement."[3] Novartis is concerned that this language could be read to mean that all discounts associated with drugs included in the bundled arrangement, both contingent and non-contingent, must be reallocated. In the example illustrated by Figure 1, this would mean that both the 10% rebate in Category 1 and the 15% purchase discount in Category 2 must be reallocated. Novartis believes it would be inappropriate to require reallocation of the non-contingent Category 2 discount because that discount is not linked to the purchase of any other product and therefore is not part of the "bundled arrangement." Similarly, a contract that includes a "bundled arrangement" involving certain NDC-9s may also include discounts on other, distinct NDC-9s that are not conditioned on a purchase or performance requirement (see Category 3 of Figure 1). Novartis urges CMS also to make clear in its final rule that because such non-contingent discounts on different NDC-9s do not meet the definition of a "bundled arrangement", they also are not subject to reallocation.

B. CMS Should Confirm that Arrangements that do not Involve Contingent Price Concessions Are Not a Bundled Arrangement.

Certain line-item purchase agreements offer the customer discounts on a series of distinct drugs where the discounts are not contingent on formulary placement, the purchase of any other drug under the contract, or any other purchase or performance requirement. Novartis believes that the discounts under such line-item contracts, depicted as Contract B in Figure 1, do not meet the proposed definition of a "bundled arrangement," because they are not "conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement."[4] Such agreements also may be structured to include a formulary placement requirement for each individual drug, but still without any linkage to any other product, i.e. get a 5% rebate on a product if the product is included on the formulary. Novartis believes that the discounts on these drugs also do not create a "bundled arrangement" because they are not related to or contingent on the purchase or formulary placement of any other drug under the contract.

Novartis raises this issue because it is concerned that the proposed regulation text could be read to require reallocation even where a contingent discount does not exist, as is the case in the two scenarios discussed in the prior paragraph. The Proposed Rule defines a bundled arrangement as an arrangement under which a discount is conditioned upon the purchase of the same drug or biological, other drugs or biologicals, or some other performance requirement "*or where the resulting discounts or other price concessions are greater than those that would have been available had the bundled drugs or biologicals been purchased separately or outside of the bundled arrangement.*"[5] Novartis interprets this language to require the reallocation of discounts only where contingent discounts are present because it modifies and relates back to the beginning of the definition, which requires the presence of a purchase or performance condition. Requiring the reallocation of discounts where there are no purchase or performance requirements or any other linkage between the products other than being sold under the same contract would be a distortion of market transactions and would jeopardize the accuracy of ASP payment rates. For these reasons, Novartis asks CMS to confirm its interpretation and include it in the Final Rule.

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3 72 Fed. Reg. at 38,226 (proposed 42 C.F.R. § 414.804)(a)(2)(iii) (emphasis added).

4 Id. at 38,226 (proposed 42 C.F.R. § 447.802).

5 Id.

C. CMS Should Confirm that Valuation of the Relative Sales Volume of the Products in a Bundled Arrangement For Purposes of Reallocation Should Be Net of Any Discounts that Are Not Reallocated.

CMS proposes that the total value of all price concessions on all drugs sold under the bundled arrangement "be allocated proportionately according to the dollar value of the units of each drug sold under the bundled arrangement."[6] As discussed in Section I.A above, Novartis requests CMS to confirm that when contingent discounts exist in a contract, the "bundled arrangement" includes (1) only the drugs subject to the contingent discounts and only those discounts that are contingent, (2) no non-contingent discounts provided on the drugs that are subject to contingent discount, and (3) no drugs that are not subject to any contingent discounts. If CMS determines that the bundled arrangement is limited to category (1) above, manufacturers will need specific guidance on how to value the relative sales volume of each NDC in the bundle.[7] Novartis believes that the most logical approach would be to calculate the sales volume of the products subject to reallocation net of any discounts that are not part of the bundled arrangement. Novartis asks CMS to clarify that this approach to calculating the relative sales volume of products in a bundled arrangement is a permissible means of complying with the Proposed Rule.

D. CMS Should Consider the Impact of the Reallocation Methodology on the Lagged Price Concession Calculation.

In the preamble to the Proposed Rule, CMS invited comment on how the proposed approach for treatment of bundled price concessions for purposes of calculating ASP may impact the estimation of lagged price concessions. Novartis urges CMS to consider how a broad definition of a "bundled arrangement" may transform discounts that currently are not lagged into discounts that are lagged due to the requirement to reallocate such discounts. As discussed in Section I.A above, a contract may include a bundled arrangement as well as other discounts that do not meet the definition of a bundled arrangement. If CMS determines that the Category 2 and 3 discounts in Figure 1 are part of the "bundled arrangement" and therefore must be reallocated, these non-contingent discounts will necessarily be lagged because the universe of sales for purposes of reallocation will not be known until the end of the performance period for the contingent rebate in Category 1. These non-contingent discounts would otherwise have been known at the time of sale and incorporated into the ASP calculation immediately as non-lagged discounts.

CAP Issues

Novartis has participated in the CAP program since its inception in July of 2006, and we presently offer several of our products through this program. Based on feedback that we have heard from our customers, and in keeping with the comments that the agency is seeking in the Proposed Rule, we would like to offer the following comments on the CAP program. First, we support the CMS's decision to allow participating physicians to request to leave the program via the hardship appeals process. The additional opportunity to leave the program, consistent

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6 Id. at 38,226 (proposed 42 C.F.R. § 447.804(a)(2)(iii)).

7 If CMS determines that a bundled arrangement includes the non-contingent discounts in categories (2) and (3) as well, Novartis believes the reallocation methodology should value each product at its Wholesale Acquisition Cost and not net of the discounts subject to reallocation.

with §1847(a)(5)(A)[8] of the Act, would encourage physicians to join the program without fear of being locked-in if they later suffer hardship. We would also support the expansion of the election period to a year-round period to make the program open to the largest number of interested parties. Physicians would therefore be able to join any time during the year, and commit to participate for one year.

CMS has requested comment on the issue of whether to allow CAP vendors to provide bevacizumab to providers for the treatment of Age Related Macular Degeneration. Currently, CMS is allowing the CAP vendor to supply a 100mg single use vial of bevacizumab with which a physician will utilize only 1mg of the vial for the prescribed patient and discard the rest. This is inconsistent with the Medicare Claims Processing Manual[9], which encourages physicians to "use drugs most efficiently" so as to cut down the amount of wastage. We recommend that CMS allow CAP physicians to purchase drugs such as bevacizumab outside of the CAP program to avoid wastage.

In addition, we do not support the policy of allowing CAP vendors to compound or repackage drugs. This practice may make manufacturers less willing to provide their products through the program if they can not control the integrity of the product ultimately reaching the end user.

CORF Issues

Novartis strongly supports the Proposed Rule, which would allow the administration of influenza vaccines to Comprehensive Outpatient Rehabilitation Facilities (CORF) patients in the CORF setting. Although such vaccines have traditionally fallen outside the scope of CORF services, CMS' proposal to revise the conditions of participation at §485.51(a)[10] to permit CORFs to provide to their patients influenza vaccines in addition to CORF services is an important means of ensuring that all Medicare beneficiaries have increased access to flu vaccinations ensuring they receive high quality health care. Increased vaccination rates lead to improved health outcomes and lower costs. Increasing the settings in which Medicare beneficiaries can receive influenza vaccines will increase these positive outcomes.

Drug Compendia

Novartis supports CMS' proposal to create an annual process for updating the list of compendia used to determine medically-accepted indications for drugs and biologicals used in anticancer chemotherapeutic treatment. We understand that pursuant to Section 1861(t)(2) of the Social Security Act, as well as instructions provided in the Deficit Reduction Act of 2005, CMS must continue to recognize the United States Pharmacopeia-Drug Information (USP-DI) and American Hospital Formulary Service (AHFS) and that this proposed annual process is meant to augment the list of recognized compendia. As a pharmaceutical company committed to advancing effective and novel treatments for cancer, Novartis strongly believes that the available resources from which policy makers can draw in developing coverage policies is an essential component to maximizing patients' access to new and innovative therapies. The proposed public process is a transparent and timely step in that direction.

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8 Social Security Act (SSA) § 1847 (a)(5)(A)

9 Medicare Claims Processing Manual, Chapter 17, § 40

10 Balanced Budget Act of 1997, § 485.51(a)

We are concerned however with CMS' proposal that a compendium must be indexed by drug or biological and not by disease-state in order to be recognized for the purposes of determining recognized off-label uses for anticancer treatments. Novartis believes that such a requirement is not reflective of the sources oncologists currently use in determining accepted treatments, and is an arbitrary requirement in that drug-indexed compendia are not in-and-of themselves more scientifically rigorous than those that are disease-indexed.

In the early 1990s when Section 1861(t)(2) was added to the Social Security Act, compendia were more uniformly organized by drug. Over the past decade, however, physicians have increasingly begun referencing disease-based compendia to help guide therapeutic choices; this is particularly true in cancer treatment. Today's treatment of many cancers involves multi-drug regimens and oncologists often turn to compendia that are organized by disease-state to help determine the best and most current regimens for a patient's particular cancer. To allow only drug-indexed compendia to guide coverage policies would mean that oncologists would be expected to cross-reference multiple compendia (those organized by disease-state to those organized by drug) to be certain that *each* drug in a particular regimen will be covered by Medicare. The importance of Medicare coverage in determining oncologist's decisions cannot be underestimated. A 2005 survey of oncologists sponsored by the Pharmaceutical Research and Manufacturers of American (PhRMA) and the Association of Community Cancer Centers (ACCC) found that 53% of oncologists reported Medicare coverage policy frequently or very-frequently influenced their clinical decision making. Given the impact Medicare coverage policy has on treatment decision-making, and the importance of disease-based compendia in providing information to oncologists on accepted regimens, we urge the agency to remove this requirement and to allow compendia indexed by disease as well as drug/biological to be considered as part of the annual, public review process.

TRHCA - - SECTION 101(b): PQRI (Physician Quality Reporting Initiative)

A. Novartis supports the use of physician organizations as "consensus-based organizations" for the purpose of developing performance measures.

We support and applaud CMS for continuing with their use of performance measures to help promote quality and efficiency in the treatment of Medicare beneficiaries. In the Proposed Rule, CMS discusses that MIEA-TRHCA requires the use of consensus-based development processes for future PQRI measures. While we understand this requirement, we believe that CMS is not making proper use of voluntary consensus standards which have been developed and applied by many specialty organizations. These preferred practice standards or guidelines are the standards to which many specialty societies hold their members, and as they should be evaluated as a PQRI measure regardless of NQF endorsement status. Since the Proposed Rule does not require voluntary consensus standards to meet the NTTAA or OMB-119 definition, we would encourage the agency to partner with a broad group of physician organizations in order to seek assistance in developing measures that fit into currently accepted practice patterns.

B. Novartis supports the adoption of three quality measures for influenza vaccination.

Novartis also strongly encourages the adoption of the three proposed quality measures related to influenza vaccination for the 2008 PQRI. These quality measures are:

- Influenza vaccination in patients with End Stage Renal Disease;
- Universal influenza vaccine screening and counseling; and
- Influenza vaccination for patients 50 years and older.

Adoption of these measures will lead to greater screening, counseling, and influenza vaccination, which will, in turn, lead to higher quality of care and avoidance of flu-related costs. As the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) has stated, influenza vaccination is the most effective means of preventing influenza virus infection and the potentially serious complications that can arise. Seasonal influenza infects 15-60 million Americans each year, according the CDC. Of those, more than 200,000 people are hospitalized from flu complications, and about 36,000 people die. Older people are at high risk for serious flu complications. In fact, more than 90 percent of deaths from influenza related complications occur in persons 65 years and older. The National Coalition for Adult Immunization estimates that the total direct and indirect costs of influenza in the United States are more than $12 billion annually.

Healthy People 2010 includes a national health objective of vaccinating at least 90% of persons aged 65 and older. However, preliminary data from the National Health Interview Survey estimated that the national influenza vaccine coverage among this population in the second quarter of 2006 to be just 66%. Reaching the 2010 goal will require further intervention. The PQRI is an important tool in reaching the 2010 goal because it provides health professionals with the incentives and information needed to reach the people who are remaining unvaccinated.

Given the effectiveness of influenza vaccines, and the incredible potential for the prevention of medical complications and death, vaccinating Medicare beneficiaries against influenza is a smart and effective means of increasing health care quality and reducing health care costs.

We understand that MIEA-TRHCA requires that quality measures must be adopted or endorsed by a consensus organization, such as the National Quality Forum (NQF) or AQA. One of the influenza vaccine measures we are encouraging CMS to include – influenza vaccination for patients 50 years and older – has already been endorsed by the NQF and reflects ACIP recommendations since 2000. Analysis of 2006 Medicare fee-for-service data shows that there were more than 30,000 hospitalizations involving influenza in beneficiaries 45 and older (89 percent of these involved individuals 65 and older). These hospitalizations, and their associated costs, could have been mitigated with a simple, effective and inexpensive influenza vaccine. Since this measure already meets the standard set by the Act, CMS should face no barriers to the adoption of this measure.

The other influenza vaccine measures are currently under development by organizations dedicated to, and expert in health care quality standards, but have yet been adopted by the NQF. We encourage CMS to adopt these measures since we believe that they will promote greater quality of care for Medicare beneficiaries. We encourage CMS to adopt the "universal influenza vaccine screening and counseling" quality measure. Studies have shown physician recommendation is one of the strongest determinants of an individual seeking vaccination and proper screening helps health professionals identify and advise individuals who might not

otherwise have considered vaccination. The proposed measure is currently under development by Quality Insights of Pennsylvania and would provide a strong incentive for health care providers to expose their patients – Medicare beneficiaries and others – to the health care benefits of influenza vaccination.

The measure "influenza vaccination in patients with End Stage Renal Disease" is currently under development by the American Medical Association's Physicians Consortium for Performance Improvement (PCPI). CMS has proposed to select measures under development by the PCPI based upon several factors, including whether the measure will be sufficiently developed and refined for 2008 PQRI implementation, the degree to which they meet the needs of the Medicare program, and their functionality in terms of their ability to be collected and calculated in the PQRI program. PCPI has already published a detailed description of the measure, including information on the numerator, denominator and denominator exclusions, thus showing that the measure is sufficiently developed for use in the 2008 PQRI. The measure is also easily collected and measured since the measure involves a series of yes/no questions that can be answered through medical records and claims data. Most importantly, despite the CDC recommendation that patients with renal dysfunction receive yearly influenza vaccines, a review of Medicare billing data has shown that the ESRD population had a less than 50 percent vaccination rate for the 1997 and 1998 flu seasons. Adopting this measure will be an important step towards better quality of care for ESRD patients.

We thank CMS in advance for its serious consideration of these comments and look forward to working with you to ensure accurate Medicare price reporting. Please feel free to contact me at 202-662-4378 if you have any questions regarding our comments or need additional information.

Sincerely,

Bonnie Washington
Vice President, Health Policy
Novartis Pharmaceuticals

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August 31, 2007 **MARYLAND PATIENT CARE AND ACCESS COALITION**

VIA COURIER

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Room 445-G
Hubert H. Humphrey Bldg.
200 Independence Ave., SW
Washington, DC 20201

Re: CMS-1385-P; Comments on Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule

Dear Mr. Kuhn:

I am President of the Maryland Patient Care and Access Coalition, Inc. ("MPCAC"). MPCAC is comprised of 14 medical practices with more than 140 physicians with offices in 15 different Maryland counties. Combined, we treat tens of thousands of Maryland patients every year. MPCAC's member practices specialize in orthopaedics, urology and emergency medical care. We all, however, are members of MPCAC for one reason: to promote a high quality of patient care, including the improvement of patient access to (1) state-of-the-art diagnostic imaging technology such as magnetic resonance imaging ("MRI") and computed tomography ("CT"), (2) cancer treatment technology such as intensity-modulated radiation therapies ("IMRT") and (3) physical therapy services in a convenient and patient-friendly environment.

On behalf of MPCAC, I thank you for the opportunity to comment on the proposals by the Centers for Medicare & Medicaid Services ("CMS") to change certain aspects of the Medicare Purchased Diagnostic Tests Rule, the Reassignment Rule and the federal physician self-referral law and implementing regulations (the "Stark Law") that were published on July 12, 2007 as part of the CY 2008 Medicare Physician Fee

Schedule (the "Proposed Rule").[1] Although we commend CMS on its continuing efforts to develop clear and comprehensive regulations that implement the Stark Law, I write to express the concerns of the MPCAC and its member practices about the nature of the discussion in the Preamble to the Proposed Rule about in-office ancillary services and to state, in response to the CMS solicitation for related comments, that MPCAC does not believe that material changes to the in-office ancillary services exception to the Stark Law are necessary. Moreover, MPCAC's member practices are opposed to the changes to the Purchased Diagnostic Tests and Reassignment Rules to the extent that such changes would impose financial disincentives for our members to engage part-time or contract radiologists or physical therapists. In fact, MPCAC would consider such changes to the Purchased Diagnostic Tests and Reassignment Rules and/or any significant narrowing of the in-office ancillary services exception to pose an unwarranted barrier to the ability of our members to furnish quality patient care services to the various communities they serve.

A. Background

MPCAC's member practices furnish their patients with integrated orthopedic care services, including in-office diagnostic imaging services and physical therapy services in full compliance with the Stark Law in its current form. Quality of care, and the convenience with which we furnish it to our patients, is dependant upon our ability to continue to do so.

1. Diagnostic Imaging Services

MRI and CT technology has evolved into the normal, cost effective and expected standard of care throughout the country in diagnosing a wide variety of injuries and ailments in the medical specialties of orthopaedics, urology, cardiology, neurosurgery and emergency medicine, among others. These technologies, once considered expensive, cumbersome and difficult to use, have advanced into available, affordable and indeed indispensable patient diagnostic tools. Rather than questioning the provision of MRI and CT scans, many insurers require them as a prerequisite to surgery and other treatments because of the value of such scans in ensuring an accurate diagnosis. On the flip side, the failure to utilize such state of the art diagnostic technology in real time may cause the relevant physician(s) not insignificant malpractice exposure.

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

The rapid advance in MRI and CT technology, followed by the reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to make multiple appointments in different venues to have MRI and CT services performed outside of their own doctor's offices. During the last decade, physicians throughout Maryland, just like their counterparts across the nation, have been able to incorporate affordable MRI and CT technologies into their practices to provide more effective and cost efficient diagnosis and treatment to patients. MPCAC's member practices are no exception. It is important to note that no matter where a patient goes for his or her MRI or CT scan (e.g., to a radiology practice group; non-radiology practice group; multi-specialty physician practice group, with or without radiologist members of the group; freestanding imaging center; or hospital), two facts about the way in which such services are furnished remain constant: (1) the actual images will be taken by trained, licensed technicians (not radiologists) using the appropriate imaging technology, and (2) a Board-certified radiologist will read and interpret the images. In those instances where the diagnostic imaging services are furnished in the offices of the patient's non-radiology specialist, thereby making it more convenient for the patient, the images still are read by a radiologist who may be inside or outside of the group, but who bills the appropriate payor for his or her professional services.

There is, therefore, no clinical, quality of care reason to change the Purchased Diagnostic Tests or Reassignment Rules or to narrow the in-office ancillary services exception so as to eliminate the ability of MPCAC's member practices to furnish state-of-the-art diagnostic imaging services in settings that are most convenient for their patients and most expedient with respect to their ability to make a diagnosis, provided such services are performed in full compliance with the in-office ancillary services exception, in its current form, and are performed in the "same building" (as opposed to a "centralized building"). Any such changes to current law would preclude patients from receiving MRI and CT services from their own doctors with whom they have developed a physician-patient relationship and require the patient to go to another facility (and generally another location) to have a necessary service performed, thereby creating what would in effect be a monopoly for certain radiologists and hospitals at the expense of patient access to necessary care.

2. Physical Therapy Services

Several of MPCAC's member practices also furnish physical therapy services to their patients in the office setting. In concert with an expanding national trend to assemble multi-specialty physician group practices to enhance the quality and

convenience of patient care, these services are provided by qualified therapists who have entered into bona fide employment and/or independent contractor arrangements with MPCAC member practices. These therapists are part-time employees, full-time employees and independent contractors, in much the same way that therapists typically align themselves with hospitals. The salaries and fees that MPCAC's member practices pay to their therapists are the product of arms-length negotiations and are consistent with fair market value.

The ability of our MPCAC member practices to affiliate with the best therapists is critical to their ability to furnish the highest quality care to their patients. Rather than improving quality of care, material changes to the in-office ancillary services exception, the Purchased Diagnostic Tests Rule or the Reassignment Rule likely would take away the practice's ability to provide to patients the benefits of practicing with physical therapists, thereby effectively compromising quality and convenience. Moreover, the therapists with whom MPCAC members work clearly are exercising their prerogative to affiliate with our practices, something that would be prohibited under some circumstances by the Proposed Rule.

B. Effect of Proposed Changes to the Purchased Diagnostic Tests and Reassignment Rules

Under current law, a physician or medical group may purchase the technical component ("TC") and/or the professional component ("PC") of a diagnostic test from another physician or supplier (the "Purchased Diagnostic Tests Rule")[2] but may not mark up the TC of such tests when billing the Medicare program (the "Anti-Markup Provision").[3] The Anti-Markup Provision does not, at present, apply to a purchased or reassigned PC of any such diagnostic test. As a result, CMS has expressed concern that the lack of an anti-markup prohibition with respect to the PC of diagnostic tests has given rise to a proliferation of potentially abusive "revenue-driven" arrangements.[4] In an attempt to remedy this situation, CMS proposes the following changes:

- With the exception of clinical diagnostic laboratory tests, the Anti-Markup Provision set forth in the Purchased Diagnostic Tests Rule would apply to both the TC and the PC of a diagnostic test performed by, and purchased

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[2] 42 U.S.C. § 1395u(n)(1); 42 C.F.R. § 414.50.
[3] Id.
[4] 72 Fed. Reg. 38,122, 38,181 (July 12, 2007).

from, an "outside supplier"[5] — i.e., anyone other than a full-time employee.[6]

- The Reassignment Rule would be amended to prohibit a medical group or physician from marking up the TC or the PC of a diagnostic test performed and then reassigned to the group or physician by someone who is not a full-time employee at the time the service at issue is performed.[7]

As such, a MPCAC member practice would be permitted under the Proposed Rule to mark up the PC of a reassigned diagnostic test only if the service was performed by a full-time employee of the practice. Services performed by a bona fide part-time employee or an independent contractor of a MPCAC member practice would have to be charged at cost without any markup to cover the member practice's overhead expenses in furnishing the service. MPCAC submits that these changes to the Purchased Diagnostic Tests and Reassignment Rules are unnecessarily broad and put at risk a host of non-abusive and beneficial relationships. By removing the financial feasibility of such purchasing and reassignment arrangements, CMS will make it more difficult for physicians and medical groups to furnish these types of services, thereby creating potential access issues for our patients.

A presumably unintended effect of the Proposed Rule is its potentially adverse impact on physicians who (1) specialize in medical fields that involve the interpretation of diagnostic tests (such as radiology, pathology and cardiology), and (2) need (or prefer) to work on a part-time basis (for reasons relating to child care, age, health or otherwise). If the changes to the Purchased Diagnostic Tests and Reassignment Rules are finalized, medical practices will be required to accept the "net charge" of their part-time employee or contractor without taking into account the overhead practice expenses associated with that employee or contractor, and one or both of two socially regressive things may happen: (1) there will be fewer part-time jobs, and/or (2) part-timers and contractors will be paid less than they are paid at present in order for the medical group to recoup its overhead costs, thereby inadvertently (and unhelpfully) creating additional pay scale differentials.

Consequently, MPCAC requests that the Propose Rule be revised to, at a minimum, allow medical groups to use part-time and contracted employees without being subject to the Anti-Markup Provision, provided the medical group satisfies a Stark

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[5] 72 Fed. Reg. 38,122, 38,225 (July 12, 2007) (42 C.F.R. § 414.50).
[6] 72 Fed. Reg. 38,122, 38,225 (July 12, 2007) (42 C.F.R. § 414.50 (a)(3)(ii)).
[7] 72 Fed. Reg. 38,122, 38,229 (July 12, 2007) (42 C.F.R. § 424.80(d)(3)).

Law exception and furnishes the services in the medical group's offices. CMS should carve out from the definition of an "outside supplier" not only full-time employees of the billing physician or medical group, but also part-time employees and independent contractors. Similarly, in regard to the reassignment of the TC or PC of a diagnostic test, we urge CMS to except not only full-time employees, but also part-time employees and independent contractors of the billing physician or medical group.

C. Comments on the In-Office Ancillary Services Exception

In the Proposed Rule, CMS calls the in-office ancillary services exception "[o]ne of the most important exceptions to the physician self-referral prohibition,"[8] yet solicits comments on, among other things:

- Whether certain services should be excluded from the in-office ancillary services exception (e.g., therapy services that are not provided on an incident to basis, services that are not needed at the time of the office visit in order for the physician to make his or her diagnosis or plan of treatment, or complex laboratory services).

- Whether (and if so, how) the definitions of "same building" and "centralized building" should be amended.

- Whether to impose any other restrictions on physician ownership or investment in services that would curtail program or patient abuse.[9]

In so doing, CMS expresses concern about physician-contractors "who have virtually no relationship with the [purchasing] group practice" who may be furnishing services "in a building that is not physically close to any of the group practice's other offices,"[10] indicates that these types of arrangements "appear to be nothing more than enterprises established for the self-referral of DHS,"[11] and notes, seemingly critically, the installation of "sophisticated and expensive imaging or other equipment" in physician offices.[12]

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[8] 72 Fed. Reg. 38,122, 38,181 (July 12, 2007).
[9] 72 Fed. Reg. 38,122, 38,181-82 (July 12, 2007).
[10] 72 Fed. Reg. 38,122, 38,181 (July 12, 2007).
[11] Id.
[12] Id.

As noted above, MRI and CT technologies have evolved and become so much more affordable in the recent past that in-office MRI and CT services have, indeed, become nearly ubiquitous and are exactly the type of services that the in-office ancillary services exception was designed to address, namely "DHS that are ancillary to the physician's core medical practice in the location where the core medical services are routinely delivered."[13] They are *the* standard of care and routinely are handled in this way throughout Maryland and the United States.

The in-office ancillary services furnished by MPCAC's member practices are critically important to our ability to provide effective and convenient patient care and do not in any way implicate CMS's stated concerns. MPCAC's member practices must retain the ability to provide diagnostic imaging and physical therapy services in their own offices. As such, the in-office ancillary services exception should not be limited in any way, provided the services are furnished in the "same building," as that term is currently defined. MPCAC recognizes that CMS may need to redefine "centralized building," however, to curtail certain abusive practices. MPCAC does not oppose such changes.

Finally, the Proposed Rule suggests that the new Anti-Markup Provisions do not apply to the TC of diagnostic tests performed in compliance with the in-office ancillary services exception. It is not entirely clear, however, if this inference is correct. The confusion arises from a proposal made in 2006 that in order to bill Medicare for the TC of a diagnostic test, the billing physician or medical group also would have to "directly perform" the PC.[14] The CY 2007 final rule did not incorporate this proposal and, in the Preamble to the Proposed Rule, CMS observes that the provision "may be unnecessary."[15] The actual text of the proposed regulation, however, 42 C.F.R. § 424.80(d)(3)(iii), states that "[t]o bill for the [TC of the] service, the physician or medical group must directly perform the [PC] of the service."[16] Given the unequivocal nature of CMS' Preamble, this regulatory text may have been included in error. If it was not included in error, and the phrase "directly performs" does not include services performed by contractors or part-time employees, then the net effect of this provision would be to shutdown many in-office ancillary services. Given the confusion over this issue, CMS should clarify its current policy and/or the Proposed Rule regarding whether

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[13] 66 Fed. Reg. 856, 888 (Jan. 4, 2001).
[14] 71 Fed. Reg. 48,982, 49,056 (Aug. 22, 2006).
[15] 72 Fed. Reg. 38,122, 38,180 (July 12, 2007).
[16] Id. at 38,229. (42 C.F.R. § 424.80(d)(3)(iii)) (proposed).

the billing physician or medical group would have to "directly perform" the PC in order to bill Medicare for the TC of a diagnostic test.

Under current law, the in-office ancillary services exception recognizes that certain employment and contractual relationships among practitioners are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the acknowledgment that certain arrangements not only are appropriate, but also are necessary to enhance the efficient delivery of quality health care. This balance acknowledges the importance of enabling physicians to offer diagnostic imaging and physical therapy services that are good for patients.

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MPCAC understands that the proposed changes to the Purchased Diagnostic Tests and Reassignment Rules, and the comments solicited on the in-office ancillary services exception, are motivated by a concern that certain specialists will make improper and medically unnecessary patient referrals for diagnostic imaging and physical therapy services in order to maximize their own financial gain. Although we support the goal of ensuring that quality care is provided to Medicare beneficiaries free of conflicts of interest, the Proposed Rule will have the opposite effect by impeding health care practitioners from providing convenient, quality health care to their patients.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,

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President
Maryland Patient Care and Access Coalition, Inc.

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August 29, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1385-P, Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (Vol. 72, No. 133), July 12, 2007.

Dear Mr. Kuhn:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2008 physician and ambulance fee schedules.

The majority of our comments address the proposed changes to regulations regarding prohibited physician self-referrals under Medicare and Medicaid. **The AHA supports CMS' efforts to modernize how federal laws manage potential physician conflicts of interest.** The physician self-referral law is one of several federal laws focused on prohibiting or limiting interactions between hospitals and physicians that might have monetary value to either party. While the intent is honorable – to avoid conflicts of interest – it is important that the net effect not impede hospitals' and physicians' ability to work together using appropriate incentives to improve quality, patient safety and community access to services. **We urge CMS to view the application of physician self-referral prohibitions not only from the perspective of controlling abusive behavior, but also from the perspective of encouraging care improvement initiatives that would benefit patients, hospitals and physicians.**

PHYSICIAN SELF-REFERRAL PROVISIONS

All health care is about teamwork. Hospital care is especially dependent on the ability of hospital leaders and physicians to work together to improve the delivery of health care to get patients the right care, at the right time, in the right setting. The need for collaboration among health care providers has never been more compelling, as collaboration, quality and efficiency are inextricably related.

Federal laws that affect hospital-physician relationships should be applied to recognize and facilitate care improvement initiatives that would benefit patients, hospitals and physicians. They should allow hospitals and physicians to come together, using incentives where appropriate, to not only reduce costs, but also improve access and the efficiency, quality and safety of hospital care. To do that, they should foster hospital-physician incentive arrangements designed to improve or maintain community access to services, or to achieve one or more of the six aims for health care delivery articulated by the Institute of Medicine (IOM) in its report, *Crossing the Quality Chasm*. The six aims are that health care be *safe, effective, patient-centered, timely, efficient and equitable.*

Specifically, the AHA believes the self-referral rules and others should foster hospital-physician incentive arrangements that are designed to:

- Achieve needed improvements in the health care delivery system, even if they do not produce an immediate cost savings.
- Sustain community access to services that are essential. With physicians less dependent on hospitals as a place to practice, new relationships, including financial relationships, should be allowed in order to maintain community access to services (such as trauma and emergency department (ED) services), support community outreach efforts, care for the uninsured and other aspects of hospital operations that require physician support.
- Promote the integration of clinical care across providers, across settings and over time. Health plans and purchasers often adopt different approaches to payment for hospitals and physicians that in turn create differing and sometimes conflicting incentives. As more purchasers move toward pay-for-performance methods, the need to align hospital and physician payment incentives becomes critical.
- Enhance institutional or practitioner productivity or achieve other efficiencies.

The AHA urges CMS to reconsider its proposed changes to meet both the goals of the self-referral laws and the equally important public policy goal of evidence-based, patient-centered and systems-oriented care delivery.

Our specific concerns and comments on this proposed rule follow three overarching themes:

1. The percentage-based compensation proposal would work against achieving clinical integration and coordination.
2. The proposals do not adequately facilitate the coordination and cooperation needed to

serve communities, especially in rural areas.
3. The proposed expansion of the exception for subsidizing obstetrical (OB) malpractice insurance is too narrow.

However, at least twice in the proposed rule CMS alludes to changes it may be making in another rule that are related to the same topics. To the extent later proposals affect AHA's views, we may provide additional concerns or comments at that time.

1.) THE PERCENTAGE-BASED COMPENSATION PROPOSAL WOULD WORK AGAINST ACHIEVING CLINICAL INTEGRATION AND COORDINATION.

The proposal to limit percentage-based compensation solely to "revenue directly resulting from personally performed physician services" is too limiting and fails to recognize the important role financial incentives play in achieving the goals that the IOM has set for all of health care. It would appear to prohibit payment arrangements based on achieving quality measures, patient satisfaction or efficiencies. It also focuses on an individual physician in a vacuum. Achieving many of the public policy goals for patient care and the delivery system change requires more than what a hospital or a physician can do alone. To be effective, the incentives must drive individuals to work together to achieve the kind of outcomes expected (e.g., achieving immunization goals across a group of children or getting beta blockers to a heart attack victim).

The AHA believes that percentage-based payments should be permitted for certain types of arrangements when: they are designed to achieve an acceptable purpose; there are mechanisms in place to protect the quality of care provided to beneficiaries and avoid inappropriate influence on physician referrals; and the incentive arrangements are transparent to patients. The types of arrangements that should be permitted include:

- sharing of cost savings from efficiencies;
- incentives to meet quality indicators – even when cost savings do not accrue to the hospital;
- incentives to clinically integrate services and coordinate care across settings;
- sharing of pay-for-performance bonuses from payers;
- service contracts to build new service capacities; and
- management contracts.

These arrangements can improve the care provided, and while they may not yield tangible savings to a *hospital*, they may yield savings to the health care system overall.

As proposed, the change in regulation is much too limiting and out of sync with the relationships that are developing and need to evolve to meet the public policy goals for health care delivery. Recognizing the challenges set out by the IOM, and responding to the use of financial incentives by the government and other payers, the financial model for integrated care delivery has come to rely on sharing revenue in appropriate ways as a mechanism to incent appropriate behavior. These efforts will be frustrated if the only factor that may be taken into account is physician-

performed services.

Unlike anti-kickback law safe harbors, which do not preclude the evolution of financial relationships, the self-referral law requires strict compliance with exceptions. CMS should be careful it does not limit appropriate innovations designed to achieve the IOM goals. An important consideration in developing the contours of this exception is to keep in mind the companion anti-kickback law, which can be the ultimate protection against abuse. **Just as CMS "stepped back" to develop rules related to information technology (IT) that recognized larger public policy goals for IT in health care, the AHA urges the same perspective regarding the use of appropriate financial incentives to achieve evidence-based, patient-centered, systems-oriented health care.**

2.) THE PROPOSALS DO NOT ADEQUATELY FACILITATE THE COORDINATION AND COOPERATION NEEDED TO SERVE COMMUNITIES, ESPECIALLY IN RURAL AREAS.

The AHA supports narrowing the in-office ancillary services exception to cover only those services "necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office." The current expansive use of the exception has led to the duplication of services and technology and, as reported by the Medicare Payment Advisory Commission, to over-utilization, higher expenses and unnecessary procedures for patients. In today's environment, overuse of the in-office ancillary exception is one of the many forces driving hospitals and physicians apart and frustrating achievement of the IOM goals.

The negative effects are particularly acute in rural communities. While narrowing the in-office exception is a good beginning, it does not adequately address the access issues created for members of rural communities**. The rules for the "rural provider" exception also should be revised.** As currently applied, it can be used without regard to whether there is unmet need in the community or there will be reduced access for the overall community to needed health care services. Anecdotally, turn-key arrangements between manufacturers and physicians and physician-only owned technology often result in the steerage of more lucrative patients away from the community hospital to physician offices or owned entities. In rural communities where the volume of needed services is not sufficient to support both hospital-based and physician practice-based duplicative services, it is always the hospital-based service that will suffer because physicians control where their patients go. The ultimate effect is to potentially jeopardize the viability of the local hospital and that community's around-the-clock access to needed health care services. It also can jeopardize access to a particular service for less lucrative patients who do not have access to physician practice-based services.

The AHA supports CMS' effort to assure that services provided "under arrangements" meet a community need, and that individual patients receive care in the setting most medically appropriate to their medical needs. Consistent with the IOM goals, only those arrangements that foster needed improvements in the delivery system, sustain community access to essential services, promote clinical integration or enhance efficiencies should be enabled. **However, the proposal for services furnished "under arrangements" may unintentionally**

eliminate hospital-physician joint ventures designed to achieve the IOM goals.

3.) THE PROPOSED EXPANSION OF THE EXCEPTION FOR SUBSIDIZING OBSTETRICAL (OB) MALPRACTICE INSURANCE IS TOO NARROW.

As suggested in the rulemaking, maintaining OB services in some communities is an increasingly difficult challenge. Multiple factors contribute, including the cost of malpractice premiums in some areas. Fewer physicians are training for the specialty, and physicians with training and experience have left the field or are considering leaving that area of practice. Permitting malpractice insurance subsidies under a broader range of circumstances may help minimize the loss of OB services in some communities.

The current preconditions for subsidizing coverage – that the physician practice is in a primary care health professional shortage area (HPSA) and that 75 percent of those served live in a primary care HPSA or be medically underserved – are too limiting. Non-HPSA areas may have a high indigent population, and an increase in primary care physicians may take an area out of the primary care HPSA designation without any increase in physicians providing OB services. The combination of the relatively low payment for OB services and the high cost of insurance premiums works against a physician agreeing to maintain 75 percent of his or her OB practice for the underserved. Another limitation of the current exception is that it only addresses shortages in connection with the medically underserved. In some communities, the shortage is much broader. In relatively affluent areas, a mismatch between increasing insurance premiums and other practice expenses with relatively low payments for OB services is leading to OB shortages for the general community. The net effect can be "OB-underserved" communities. Permitting subsidies in those communities may similarly help minimize the loss of OB services. **The AHA recommends that this exception be allowed in any area where there is a shortage of physician OB services.**

AMBULANCE – BENEFICIARY SIGNATURE

CMS also proposed revisions in the ambulance fee schedule portion of the rulemaking. While the AHA believes that CMS was attempting to minimize the burden on ambulance providers in obtaining a signature during emergency transport, the resulting proposal in actuality would increase the administrative and compliance burden. Ambulance providers face significant hardships in complying with the beneficiary signature requirements because a large portion of the beneficiaries transported are not in a condition to sign a claims authorization form. Many beneficiaries are in physical distress, unconscious or of diminished mental capacity due to age or illness – the very reason they need ambulance transportation rather than arranging their own transportation. **Thus, we urge CMS to abandon the proposed approach, and to instead eliminate the beneficiary signature requirement for ambulance services entirely.**

Guidance on what steps must be taken when a beneficiary or authorized patient representative is not available already is included in the CMS manuals. This guidance requires the ambulance

provider or supplier to document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary. In addition, the regulations currently permit an ambulance provider to submit a claim signed by its own representative when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf.

Under the proposed rule, a provider would only be reimbursed for a claim when the beneficiary did not sign for the service if a series of requirements are met. The proposal mirrors the existing requirements, but *adds* additional documentation requirements. Two of the requirements proposed are already always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. A third proposed requirement that these items be maintained for four years from the date of service is also reasonable. However, we do not believe it is necessary to formally include these in the regulation as they are already required and standard practice.

The AHA would support the adoption of the amendment to 42 C.F.R. §424.36(b)(6) to include subsection (i), which requires that no authorized person was available or willing to sign the claim on the beneficiary's behalf at the time the service was provided in order for an exception to apply. This would formally adopt an exception under those circumstances that would allow ambulance providers to bill Medicare without a beneficiary's signature.

The proposed rule also would add a requirement that an employee of the receiving facility (i.e., hospital) sign a form at the *time of transport*, documenting the name of the patient and the time and date the patient was received by the facility. The AHA does not support this new requirement as it adds burden for both facilities and ambulance providers during a particularly hectic period of service delivery when all of the focus should be on the patient. Treatment and care of the beneficiary should be the overriding focus of all parties, not another form signed by already overburdened ED personnel.

The beneficiary signature is no longer necessary given that it is not required for the assignment of benefits or the authorization of records release. In addition, almost every covered ambulance transport is to or from a facility (i.e., a hospital or a skilled nursing facility). These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service."

The AHA urges CMS to withdraw the proposed beneficiary signature requirements for emergency ambulance transports and instead eliminate the beneficiary signature requirement for ambulance services entirely if the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf.

If you have any questions about these comments, please feel free to contact me or Maureen Mudron, Washington counsel, at (202) 626-2301or mmudron@aha.org regarding the physician self-referral provisions, or Danielle Lloyd, senior associate director for policy, at (202) 626-2340 or dlloyd@aha.org regarding the beneficiary signature provisions.

Sincerely,

Rick Pollack
Executive Vice President

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American Medical Rehabilitation Providers Association

Kathleen C. Yosko, MS, MBA
President and C.E.O.
Marianjoy Rehabilitation Hospital
AMRPA Chairman of the Board

August 30, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

cc: 445-G Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, DC 20201

Delivered by Courier and Electronically

Ref: CMS –1385-P, 72 F. R. 133, July 12, 2007 - Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Ms. Norwalk:

These comments are submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA). AMRPA is the national voluntary trade association which represents over 550 freestanding rehabilitation hospitals, rehabilitation units of general hospitals, and a number of outpatient rehabilitation service providers. Many, if not most, of our members provide outpatient therapy services either through the outpatient departments of hospitals or though outpatient clinics, Comprehensive Outpatient Rehabilitation Facilities (CORFs), or rehabilitation agencies. We have reviewed the proposed rule in-depth and our comments follow.

A. TRHCA—SECTION 101(b): — PQRI, pg 38197

The Tax Reform and Health Care Act of 2006 (TRHCA) created the Physician Quality Reporting Initiative (PQRI) under which eligible professionals who successfully report a designated set of quality measures on claims for dates of service from July 1 to December 31, 2007, may earn a bonus payment, subject to a cap, of 1.5% of total allowed charges for covered Medicare physician fee schedule services. The Act also directed CMS to

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THE AMERICAN SOCIETY OF HEMATOLOGY
1900 M Street, NW, Suite 200, Washington, DC 20036 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

August 28, 2007

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

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for CY 2008, and Other Part B Payment Policies for CY 2008; CMS-1385-P

Dear Sir or Madam:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the proposed physician fee schedule changes for 2008. ASH represents approximately 11,000 hematologists in the United States who are committed to the care and treatment of patients with blood-related disorders. Society members include hematologists and hematologist/oncologists who frequently render services to Medicare beneficiaries under the physician fee schedule. ASH would like to offer some general comments and some comments on issues that specifically impact hematologists:

Coding—Additional Codes from 5-Year Review--Work Adjustor

In this proposed rule, CMS announces that the Five-Year Review Work Adjuster will increase from -10.1% to -11.8%. ASH recommends that CMS eliminate the work adjuster. While cognizant of the legal requirement to adjust for budget neutrality when changes in relative values cause projected expenditures to change by more than $20 million, the Society believes that adjustments for budget neutrality should be applied to the conversion factor rather than to all work relative values.

Factors in favor of eliminating the work adjuster include:

1. It would minimize confusion on the part of other payers whose payments are based on the Medicare Relative Value Scale.
2. It would make the fee schedule more transparent and understandable to physicians and members of the public.
3. It would mitigate adverse impact on the values for evaluation and management services. The increases in the work values for E/M services achieved through the 3rd five year review were substantially diluted by the reduction in work values for 2007 and by the further reduction proposed for 2008.
4. It would be more consistent with the manner in which budget neutrality has been maintained throughout most of the history of the physician fee schedule.

For all of these reasons, and considering that the budgetary impact is identical, ASH strongly recommends that CMS eliminate the separate work adjustment and provide for budget neutrality by adjusting the conversion factor.

TRHCA-Section 101(d): PAQI

ASH is understandably concerned about the potential 9.9 percent reduction in the conversion factor for 2008 that results from the impact of the Sustainable Growth Rate (SGR) system. While the Congress may intervene to enact a positive update for 2008, the law authorizes CMS to use the $1.35 billion from the Physician Assistance and Quality Initiative (PAQI) Fund to lessen the reduction in the conversion factor if the Congress does not intervene. Thus far CMS plans to use those funds for incentive payments under the Physician Quality Reporting Initiative (PQRI) for 2008 services.

ASH remains an active supporter of the PQRI program. Quality indicators developed by ASH were among the initial menu of PQRI indicators published by CMS in January 2007 and will also be included in the 2008 program. However, in the event that legislative relief on the conversion factor reduction is not forthcoming, ASH urges CMS to redirect the PAQI funds toward lessening the draconian impact of SGR on payment for all physicians instead of using them for bonus payments to a minority of physicians.

Coding-Payment for IVIG Add-on Code

ASH applauds CMS' decision to continue the additional payment for the administration of Intravenous Immune Globulin (IVIG). This decision applies to 2008 only. Based on informal reports from our members, we understand that users of IVIG are still experiencing difficulties in obtaining the appropriate product at the allowed payment rates. Even though the addition of the add-on payment does not make the reimbursement for IVIG whole, ASH requests that CMS continue this payment in years after 2008 until there is hard evidence that the marketplace is more stable than is currently the case.

Coding-TRHCA-Section 110: Anemia Quality Indicators

ASH will continue to work with CMS on developing evidence-based standards for the use of erythropoiesis stimulating agents (ESAs) for management of anemia related to cancer treatment. The Society has recommended needed improvements to the recent National Coverage Decision (NCD) that we trust will be given due consideration. Among the concerns expressed to CMS is the potential impact of the NCD on the need for red blood cell transfusion in chemotherapy patients. ASH hopes to collaborate with CMS in collecting claims-based data in order to analyze this and other related issues. ASH understands the NCD requires the reporting of anemia quality indicators in 2008 when claiming payment for ESAs although the precise form of the reporting is left to the discretion of CMS. We urge CMS to closely consult ASH and other interested parties concerned with the treatment of cancer patients to assure that the reporting requirement for physicians does not become burdensome. ASH further hopes that CMS will agree to eliminate the requirement for routine reporting of hemoglobin levels over time and consider exploring alternatives for assuring compliance with the NCD. These might include sample reporting or reporting only by physicians whose utilization of ESAs identifies them as potential outliers compared to their peers. Another option could be the promulgation of quality indicators for the use of ESAs in cancer treatment that could be used to improve compliance with the NCD through the PQRI process.

Drug Compendia

ASH continues to support the use of designated compendia in determining the acceptability of off-label uses of drugs in anti-cancer chemotherapy. However the Society believes that local carriers should retain the flexibility to approve such off-label uses of drugs whether or not they

are listed in an approved compendium. As is noted in the rule, hematologists and medical oncologists do not rely solely on published compendia in determining drug treatment but may also use published guidelines, clinical trial protocols and, on occasion, consultation with peers. This should be done only when medically necessary, i.e. when a malignancy is resistant to standard treatment or when a particular drug protocol is not appropriate for a particular patient and there is reason to believe that the off-label drug is more likely to be efficacious or better tolerated.

Thank you for the opportunity to offer these comments. If ASH can provide any further information, please contact Carol Schwartz, ASH Senior Manager, Policy & Practice, at cschwartz@hematology.org or 202-292-0258.

Sincerely,

Andrew Schafer

Andrew I. Schafer, MD
President

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Roche

August 29, 2007

VIA HAND DELIVERY AND EMAIL
www.cms.hhs.gov/regulations/eRulemaking

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

RE: [CMS-1385-P] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Acting Deputy Administrator Kuhn:

Hoffmann-La Roche Inc. ("Roche") appreciates this opportunity to submit comments regarding the proposed rule *Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008.*[1] As a company dedicated to bringing innovative, effective, high quality therapies to patients, Roche supports updating payment policies under the Medicare Physician Fee Schedule (the "MPFS") to reimburse the provision of important services in a fair and equitable manner.

Roche understands the challenges the Centers for Medicare and Medicaid Services ("CMS") faces in advancing the healthcare system for the millions Medicare beneficiaries and thousands of its participating providers so that they receive and provide high-quality services at an appropriate cost. While we generally support most of the efforts proposed by CMS to promote fair prescription drug[2] reimbursement practices, we offer comments and recommendations regarding the following issues raised under the proposed MPFS rule. In brief:

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

[2] The term "drug" refers to both drugs and biologicals.

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- Roche recommends that CMS adopt the Medicare Payment Advisory Commission's ("MedPAC") option for defining bundled price concessions under the average sales price ("ASP") methodology that would parallel bundling requirements under the Medicaid Drug Rebate Program.
- Roche supports the easing of the existing restriction on transporting Part B Competitive Acquisition Program ("CAP") drugs, where it is permitted by State law and other applicable laws and regulations.
- Roche applauds CMS's efforts to create a public process and standard criteria for adding and revising the list of approved compendia.
- Roche requests that CMS amend the proposed quality measure, number 73, to include planning for both oral and intravenous ("IV") chemotherapy.
- Roche recommends the addition of telehealth services to monitor and manage patients on oral chemotherapy.

ASP Issues

Under its current guidance, CMS permits pharmaceutical manufacturers to exercise discretion in allocating discounts across "bundled arrangements" in calculating average sales price ("ASP"). In its CY 2007 Physician Fee Schedule Rule, CMS states in part:

> "we believe it is important to be cautious in establishing a specific methodology that all manufacturers must follow for ASP purposes. Consequently, we are not establishing a specific methodology that manufacturers must use for the treatment of bundled price concessions for purposes of the ASP calculation at this time. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices. Our intent in not being prescriptive in this area at this time is to allow manufacturers the flexibility to adopt a methodology with regard to the treatment of bundled price concessions in the ASP calculation that, based on their particular circumstances, will best ensure the accuracy of the ASP calculation and not create inappropriate financial incentives."[3]

For CY 2008, CMS now proposes a standard definition for "bundled arrangement," and to specify that, "all price concessions on drugs sold under a bundled arrangement must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement."[4] Although Roche continues to believe that the flexible approach that CMS adopted for CY 2007 was appropriate given the unique attributes of the ASP price reporting methodology (including use of a rolling average methodology

[3] 71 Fed. Reg. 69624, 69675 (Dec. 1, 2006).

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for lagged price concessions), Roche strongly agrees with CMS that, if a methodology is to be adopted, consistency where possible with the Medicaid Drug Rebate Program methodology for allocating bundled sales would be preferable to a methodology that is specific to ASP.

In the CY 2008 proposed rule, CMS offers two scenarios for consideration, both of which were first offered by Medicare Payment Advisory Commission ("MedPAC") in its January 2007, Report to Congress.[5] The first option would require manufacturers to allocate discounts for bundled arrangements in proportion to the sales of each drug sold under the bundled arrangement. This approach would parallel bundling requirements under the Medicaid program and therefore would be more convenient for manufacturers to administer. The second option would require manufacturers to allocate any increased discounts under a bundled arrangement to the sales of the drug that the higher discount was intended to increase (e.g. discount on drug A is offered if customer purchases drug B; then the discount on drug A is allocated to drug B for purposes of ASP).[6]

Roche strongly recommends that, if CMS determines that a standard allocation methodology should be developed for ASP calculations, CMS should adopt the first option outlined in the MedPAC January 2007 Report to Congress, requiring pharmaceutical manufacturers to allocate bundled discounts in proportion to the sales of each prescription drug sold. We believe that this option promotes CMS's goal for reporting consistency between ASP and AMP, thereby, allowing for more accurate reporting, which in turn stabilizes prescription drug prices. We also believe that this methodology would achieve the goal desired by MedPAC's recommendation to CMS, which was for ASP to reflect the average transaction price for each drug.

In addition to supporting implementing option one for reporting bundled price concessions, Roche seeks clarification regarding how the new guidance on bundled arrangements would interrelate with the rolling average methodology for estimating lagged price concessions. The adoption of any methodology for bundled arrangements can require adjustment to the rolling average methodology. Roche seeks clarification from CMS on this issue and urges CMS to allow manufacturers to use the same approach for ASP as for average manufacturer's price ("AMP"), which will also permit a rolling average methodology for lagged price concessions, effective October 1, 2007.

Competitive Acquisition Program ("CAP") Issues

Roche supports the easing of the existing restriction on transporting Part B Competitive Acquisition Program ("CAP") drugs, where it is permitted by State law and other applicable laws and regulations. We

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Footnote continued from previous page

[4] 72 Fed. Reg. 38122 (July 12, 2007).

[5] Report to Congress: "Impact of Changes in Medicare Payments for Part B Drugs," MedPAC, January 2007.

[6] Id. page 8-9.

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believe that physicians understand the need for drug stability and are capable of ensuring proper handling when transporting drugs. This action would enable physicians to administer treatments from their satellite offices or in patients' homes to better meet the scheduling needs of both patients and healthcare providers. This easement would allow flexibility in re-scheduling patient visits, leading to enhanced care and better compliance for Medicare beneficiaries.

Roche agrees that proper safeguards should be put into place so that no drug products are compromised during transport. We ask that the safeguards not be overly cumbersome nor impose additional costs or reporting burden for physicians, thereby nullifying the policy's intent. We strongly urge CMS to allow the public the opportunity to comment on any additions to the CAP requirements, such as adding safeguards, in a future rulemaking prior to implementation.

Drug Compendia

Roche applauds CMS's efforts to create a public process, with standard criteria, for adding or revising the list of approved compendia for determination of medically-accepted indications for off-label use of drugs in anti-cancer chemotherapeutic regimens. We agree that broad accessibility by the general public to the information contained in the compendia is beneficial to beneficiaries, their caregivers and providers -- many of whom rely on compendia as they research cancer therapy options.

Furthermore, Roche supports the Medicare Evidence Development and Coverage Advisory Committee's ("MedCAC") list of desirable characteristics for compendia. The need for a "(d)etailed description of the evidence reviewed for every individual listing" and "(u)se of pre-specified published criteria for weighing evidence" is clear based on the Agency for Healthcare Research and Quality ("AHRQ") assessment of leading compendia, which found the organizations' to be discordant in methodology and information.[7] Roche supports a transparent and evidence-based approach in putting forth specifications for desirable characteristics of recognized compendia.

We would like further clarification from CMS regarding "other reasonable means" by which CMS may notify the public regarding determinations involving requested changes to the list of compendia. Specifically, if CMS determines to utilize a means other than notification via the CMS website, what are the likely avenues of public notification regarding compendia changes? We believe that the process for requesting changes should be transparent and should not involve unexpected or unusual communication pathways as the sole notification of proposed changes. For example, CMS should dedicate a section on its website on Drug Compendia that includes a fact sheet, guidelines, and process for updating compendia.

[7] See "Compendia for Coverage of Off-Label Uses of Drugs and Biologics in an Anti-Cancer Chemotherapeutic Regimen" Final Report, Agency for Healthcare Research and Quality, May 2007.

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Lastly, Roche supports the inclusion of the National Comprehensive Cancer Network ("NCCN") as a recognized compendium under the Medicare program and we understand that NCCN, like any approved compendia, would need to meet all the desirable characteristics set by CMS.

TRHCA – Section 101(b): PQRI

Roche supports CMS efforts to encourage the improvement of quality health care for Medicare beneficiaries. The Physician Quality Reporting Initiative ("PQRI") is taking important steps to help ensure that physicians and other eligible professionals are armed with knowledge regarding the most appropriate care for beneficiaries depending upon their unique clinical care circumstances. Roche is pleased to comment on the "implications of including any given measure(s) proposed herein in the final 2008 PQRI quality measures."[8]

We believe, however, that PQRI measure #73 "Plan for Chemotherapy Documented Before Chemotherapy Administered" needs to be amended to explicitly include planning for *both* oral and IV chemotherapy. The denominator for this measure in its current form includes all cancer patients who were administered IV chemotherapy. Treating cancer patients has evolved from what was once largely exclusive to intravenous administration to a range of new chemotherapy products for oral administration. The omission of oral chemotherapy suggests that oral administration requires less planning or provides a lesser therapeutic option. Undoubtedly, when a patient undergoes any chemotherapy regimen, be it oral or IV, detailed and comprehensive planning is necessary to ensure that the patient experiences optimal health outcomes and the best possible quality of life. Therefore, we urge CMS to revise this measure to include both oral and IV chemotherapy in the denominator and to ensure that oral chemotherapy is represented in all corresponding denominator codes.

Medicare Telehealth Services

CMS maintains an established process for adding services to or deleting services from the list of Medicare telehealth services under the Social Security Act section 1834 (m)(4)(F). Services fall under two categories: Category #1 for "services that are similar to office and other outpatient visits, consultation, and office psychiatry services"; and Category #2 for "services that are not similar to the current list of telehealth services."

Roche is pleased to have the opportunity to submit a request to add telehealth services, such as telephone triage, delivered by physicians, nurses, nurse practitioners or physician assistants, to manage and monitor patients on oral chemotherapy. We believe that telecommunication systems used to manage patients on oral chemotherapy meet Category #1 requirements, as such services are similar to office and outpatient visits or consultations to monitor patients on IV chemotherapy. Roche feels strongly that patients

[8] 72 Fed. Reg. 38196 (July 12, 2007).

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and providers should not be discouraged in the selection and delivery of oral versus IV chemotherapy treatment options. Providing access to equitable telehealth services for each type of chemotherapy treatment allows patients living in rural and other underserved geographic regions an important avenue to achieving better health outcomes and quality of life as a result of these vitally important consultations.

Conclusion

Roche appreciates the opportunity to provide our comments and recommendations. We hope that our suggestions will assist CMS in its mission to provide Medicare beneficiaries continued access to high quality therapies. Thank you for your attention to this matter. Please feel free to contact me at 973-562-2010 if you have any questions, or need additional information.

Respectfully submitted,

Mary Sibley
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SVU
SOCIETY FOR VASCULAR ULTRASOUND
The VOICE for the Vascular Ultrasound Profession since 1977

August 27, 2007

Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Subject designation: Coding—Reduction in TC for Imaging Services

Dear Administrator Weems:

On behalf of the Society for Vascular Ultrasound ("SVU"), we appreciate the opportunity to comment on certain aspects of the Physician Fee Schedule Proposed Rule ("Proposed Rule") for CY 2008.[1] We focus our comments on the mandate in § 5102(b)(1) of the Deficit Reduction Act of 2005 ("DRA") that Medicare reimbursement for the technical component of imaging services performed in a physician office setting must be capped at the lesser of the Physician Fee Schedule ("PFS") or the Hospital Outpatient Perspective Payment System ("HOPD") payment for the service.[2]

Specifically, we are requesting that the Current Procedural Terminology ("CPT") codes for transcranial doppler ("TCD") be removed from the list of codes subject to the HOPD cap because TCD does not meet the statutory definition of "imaging." The five codes we are requesting be removed are as follows:

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[1] CMS-1385-P; Medicare Program; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions. 72 Fed. Reg. 38122 (Jul. 12, 2007).

[2] Pub. L. 109-171, § 5102(b)(1)

- 93886 Transcranial Doppler study of the intracranial arteries; complete study
- 93888 Transcranial Doppler study of the intracranial arteries; limited study
- 93890 Transcranial Doppler study of the intracranial arteries; vasoreactivity study
- 93892 Transcranial Doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection
- 93893 Transcranial Doppler study of the intracranial arteries; emboli detection with intravenous microbubble injection

Additionally, a CMS- commissioned study proves that the costs of certain imaging procedures within the hospital radiology cost center are systematically under-estimated by CMS in the hospital setting. Thus, we believe that it is incumbent upon the Secretary to make appropriate adjustments to the PFS imaging cap for imaging procedures known to have an understated cost-estimate in the hospital setting.

We have communicated with the Centers for Medicare and Medicaid Services ("CMS") on these issues and other related issues in the past, and we would appreciate the opportunity to address the very negative and disproportionate effect of the DRA on ultrasound services.

SVU is the only professional organization completely dedicated to the advancement of noninvasive vascular technology used in the diagnosis of vascular disease. Our more than 4,300 members are committed to providing quality, noninvasive diagnostic services to patients; including Medicare beneficiaries. We respectfully request your consideration of our perspective on these important issues.

In summary, SVU presents comments on the following issues related to the HOPD cap for imaging services under the Proposed Rule:

- Since the DRA mandated reimbursement reductions to imaging procedures and TCD cannot be properly classified as an imaging procedure, TCD cannot lawfully be subject to these reductions.

- In the 2007 PFS Final Rule, CMS removed certain codes from the list of codes subject to the HOPD cap because they did "not involve the generation of an image."[3] The 2008 Proposed Rule contains additional language. Since TCD also does not necessarily or inherently involve the generation of a image, TCD codes must be removed from the list of codes subject to the HOPD cap. At a minimum, CMS must identify and direct its carriers to recognize a modifier that providers can use when providing TCD services without any imaging service to prevent those providers' appropriate reimbursement from being inappropriately reduced by the misapplication of the DRA caps.

- A recent study proves that CMS systematically under-estimates the costs of certain imaging procedures in the radiology cost center. We urge the Secretary

[3] Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; 71 Fed. Reg. 69624, 69661 (Dec. 1, 2006).

to, in the short term, adjust HOPD hospital outpatient rates by making appropriate adjustments to the HOPD methodology based on the consultant's cost-to-charge ratio findings for "other radiology services."

I. CMS Must Adhere to the Plain Language of the DRA, and May Not Reduce Payment for Services That Are Not Clearly Imaging Such As TCD

A. Brief Background on TCD Procedure

A paper by clinicians at the American Academy of Neurology ("AAN") described TCD as "a non-invasive ultrasonic technique that uniquely measures local blood flow velocity (speed and direction) in the proximal portions of large intracranial arteries."[4] This is known as conventional TCD, which the AAN Paper specifically states is "non-imaging."[5] We understand that there is also a procedure called Transcranial Doppler Imaging ("TCDI")[6] which does involve the generation of an image, but the image is primarily used to determine correct placement of the doppler probe, not necessarily to diagnosis any medical condition. Different equipment is used to perform TCD and TCDI. Although TCD and TCDI are referenced in the CPT system using the same codes, the services are distinct and different and CMS cannot properly apply an "imaging" payment restriction to a non-imaging service.

B. TCD Cannot Be Subject to the Reductions Mandated by § 5102(b)(1) Because TCD is Not an Imaging Procedure Within the Meaning of the DRA

§ 5102(b)(1) of the DRA defines the imaging services subject to the HOPD cap as,

> imaging and computer-assisted imaging services, including x-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.

Thus, the HOPD cap can only be applied to "imaging services," including the enumerated services. It is a well established principle of administrative law that the plain language of a statute must be honored by a regulatory agency.[7] Regulatory agencies do not have the discretion to deviate from the plain language of a statute. However, we respectfully

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[4] Sloan, Michael A. et. al., Background Paper to the Official AAN Assessment of TCD (2004) at 3, *available at* http://www.aan.com/professionals/practice/guidelines/tcd_tta_0404.pdf (hereinafter AAN Paper).

[5] *Id.*

[6] A study published in 2002 stated that TCDI, "uses a duplex technique to simultaneously generate a gray-scale and color image, as well as a Doppler waveform." By contrast, the same study described TCD as, "a nonimaging pulsed Doppler technique that genrate[s] a waveform." Neish, Ariane S., MD et. al, *Screening for Stroke in Sickle Cell Anemia: Comparison of Transcranial Doppler Imaging and Nonimaging US Techniques*. Radiology, 222: 709-714, 710-11 (2002).

[7] "[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161, 120 S.Ct. 1291, 1315 (2000) (internal quotations and citations omitted). Accordingly, a regulatory agency "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 2781 (1984) (footnote omitted).

submit that CMS has improperly deviated from the plain language of the DRA in this case because conventional TCD, as opposed to TCDI, involves no imaging component whatsoever.

The description of TCD provided in the introduction to the cerebrovascular arterial studies section of the CPT codebook is illustrative. It states,

> A complete transcranial Doppler (TCD) study (93886) includes ultrasound evaluation of the right and left anterior circulation territories and the posterior circulation territory (to include vertebral arteries and basilar artery). In a limited TCD study (93888) there is ultrasound evaluation of two or fewer of these territories. For TCD, ultrasound evaluation is a reasonable and concerted attempt to identify arterial signals through an acoustic window.[8]

Importantly, the term "image" or "imaging" is not used in this description. Conventional TCD typically does not involve imaging. TCD is basically a tool used to measure the speed and velocity of blood flow though arteries in the brain. Additionally, at least one study has found non-imaging TCD to be more clinically effective than TCDI. A 1994 study compared conventional (non-imaging) TCD to TCD involving imaging in assessing intracranial hemodynamics in a patient population with an average age of 65 years.[9] The researchers found transtemporal success rates of 76 percent for traditional non-imaging TCD, versus 52 percent when using imaging.

In June of this year, SVU partnered with the American Society of Neuroimaging to conduct a survey of the members of our respective organizations about transcranial studies. Specifically, we sought data on how many members perform transcranial studies, and if they perform these studies with or without imaging. Significantly, the results showed that 71.2% of the respondents performed TCD studies without using imaging at all.

Further, the five TCD codes that we are asking to be removed from the HOPD cap all refer to the procedure as a "study" and do not use the word "image" or "imaging" anywhere in the description. Therefore, since conventional TCD is not an imaging service within the meaning of the DRA, it cannot be subject to the HOPD cap.

II. CMS Has Twice Determined That Certain Diagnostic Procedures Must be Excluded From the HOPD Cap Because They Are Not Imaging, and This Same Reasoning Must Be Applied to TCD Procedures

CMS received comments in response to the CY 2007 PFS Proposed Rule requesting that certain CPT codes be excluded from the HOPD cap because they contained no imaging or were predominately non-imaging in nature.[10] The Agency did not comply with all the requests to exclude codes, but did remove five codes because they "do not involve the generation of an image."[11] As discussed earlier, conventional TCD does not involve the generation of an image.

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[8] Current Procedural Terminology Professional edition 2007, AMA at 388.
[9] Fujioka K, Gates D, Spencer M: *A comparison of Transcranial Color Doppler Imaging and Standard Static Pulsed Wave Doppler in the Assessment of Intracranial Hemodynamics.* JVT 18(1)29-35, 1994.
[10] 71 Fed. Reg. at 69661.
[11] *Id.*

The CY 2008 Proposed Rule provides additional support for our argument why TCD codes should be excluded from the HOPD cap. CMS stated that it,

> excluded any service where the CPT code describes a procedure for which fluoroscopy, ultrasound, or another imaging modality is included in the code whether or not it is used, or for which an imaging modality is employed peripherally in the performance of the main procedure[.][12]

In the case of TCDI, the image is typically only used to determine proper placement of the doppler probe on the skull. Thus, the image is only employed peripherally to the main procedure and is not used to diagnose any medical condition. In conventional TCD, an image is not generated at all.

The Proposed Rule further states that certain codes were excluded because,

> we are unable to clearly distinguish imaging from non-imaging services because, for example, a specific procedure may or may not utilize an imaging modality, or the use of an imaging technology cannot be segregated from the performance of the main procedure.[13]

We agree with CMS' determination that that CPT codes must not be subject to the HOPD cap where it is unclear if the procedures represented by the codes are truly "imaging" within the meaning of the DRA. The codes at issue may or may not involve any use of imaging. This is precisely a case where, as CMS has said, the "specific procedure may or may not use an imaging modality." As such, the codes at issue should be excluded from the cap. It would be arbitrary and capricious for CMS to exclude some services based on this rule and then not exclude the services at issue here on that same basis.

III. The DRA Imaging Cap is Distorted by HOPD Cost-Estimates Known to be Inaccurate

We also believe that it is incumbent upon the Secretary to make appropriate adjustments to the PFS imaging cap for those affected imaging procedures where costs used to set the HOPD rates are known to be understated because of the application of a single "radiology" cost-to-charge ratio ("CCR") instead of an "other radiology service" CCR. CMS recently commissioned a report from RTI International[14] (the "RTI study") that definitively shows that the costs of certain imaging procedures within the hospital radiology cost center are systematically under-estimated by CMS in the hospital setting. These under-estimated costs translate into under-calculated payment rates in the HOPD setting.

By referencing lower hospital outpatient payment rates in setting PFS payment rates on imaging procedures, the DRA cap acts to import hospital-based cost and payment data into the PFS setting. The RTI report has definitively shown, and CMS has sufficiently acknowledged that hospital-based cost data is inaccurate with respect to certain radiology procedures. And

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[12] 72 Fed. Reg. at 38145.

[13] *Id.*

[14] RTI International, A Study of Charge Compression in Calculating DRG Relative Weights (January 2007), *available at* http://www.cms.hhs.gov/Reports/Reports/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=ascending&itemID=CMS1196854&intNumPerPage=10.

while such inaccuracies may be alleviated by other factors in the hospital setting, these inaccuracies present a pressing and immediate problem with respect to the PFS.

A. HOPD Cost-Estimates for the Radiology Cost Center

HOPD reimbursement is premised, in part, on cost estimates derived from charges that have been adjusted by a CCR. For radiology services, CMS uses a single CCR to derive costs and calculate payment. The national aggregate CCR for the radiology cost center is 0.19. However, the RTI study found that, within the radiology cost center, magnetic resonance imaging ("MRI") and computed tomography ("CT") procedures have significantly lower CCRs than all other radiology services (0.17 and 0.19, respectively). Removing MRI and CT from the radiology cost center generates a significantly higher CCR of 0.28 for the remaining radiology procedures.[15] A higher CCR indicates that non-MRI and CT radiology procedures carry lower mark-ups than MRI and CT. Thus, on a micro-level, using a single CCR for all radiology services under-estimates the costs of non-MRI and CT procedures and therefore under-pays providers for these procedures. Use of a single CCR over-estimates the costs of these procedures and therefore over-pays providers for these procedures.

B. Impact of Radiology Cost-Estimates on PFS Imaging Services

The impact of different CCRs within a single cost center is mitigated to some extent in the hospital setting as the over-payments and under-payments flow through to the same entity (i.e., the hospital) and, indeed, the same department (i.e., Radiology). However, the DRA cap acts to import the known under-payments for imaging services into the PFS setting. Because the DRA provision references only those HOPD payments that are *lower* than the corresponding PFS payment, the use of CCRs that are known to be inaccurate imposes unfair and arbitrary caps on PFS providers which Congress never intended in passing the DRA. Thus, the under-payments are not balanced by over-payments in the PFS setting as they potentially can be in the HOPD setting.

RTI recommended CMS take a number of short term and long term steps to alleviate the impact of differential CCRs on cost estimates. In the short term, RTI recommended that CMS adopt separate regression-based CCRs for MRI, CT, and all other procedures in the Radiology cost center.[16] Because of the potential impact on other payment methodology changes CMS is adopting in the inpatient hospital setting, CMS declined to implement this recommendation for the 2008 IPPS update.[17] However, CMS acknowledged with respect to ancillary departments such as Radiology that:

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[15] *Id.* at 11.

[16] *Id.* at 16.

[17] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Final Rule with comment period. 72 Fed. Reg. 47129 (Aug. 22, 2007), to be codified at 42 C.F.R. Parts 411, 412, 413, and 489. "Because of concerns that we and some commenters continue to have about premature adoption of the regression-based CCRs without the benefit of knowing how they will interact with other DRG changes, and the arguments in the comments summarized above concerning cost and claims reporting, we have decided to finalize our proposal to not implement the four regression-based CCRs for... radiology (MRI and CT scans) for FY 2008." *Id.* at 47192. "We note that for some categories of hospitals, the impact of adopting MS-DRGs is significant. The RTI work suggests that further changes to the relative weights will also be significant and potentially result in additional redistribution of Medicare payment. In our view, the 'interactions of various components' can be

> "[Such departments] typically include both inpatient and outpatient services within the same department and only a single CCR covering both inpatient and outpatient services can be calculated from Medicare cost reports. Although we believe that applying the regression method used by RTI to only inpatient services is unlikely to have much impact for the adjustments recommended by RTI, the preferred approach would be to apply the regression method to the combined inpatient and outpatient services. The latter approach would ensure that any potential CCR adjustments in the IPPS would be consistent with the potential CCR adjustments in the HOPD. We hope to expand their analysis to incorporate outpatient services during the coming year."[18] (Emphasis added)

We understand and appreciate CMS' hesitation to enact RTI's recommended CCR changes in the hospital-setting without fully understanding the impact such charges would have in conjunction with other changes being implemented simultaneously. And we reiterate our observation that the impact of such inaccuracies is potentially balanced in the hospital setting between overpayments and underpayments to the same entity and department. However, these same concerns are not present in the PFS setting, and we feel it is incumbent upon the Secretary to shield the PFS setting from known inaccuracies in the HOPD rate-setting mechanism for radiology services and adjust the DRA cap to account for the higher CCR of non-MRI and CT imaging procedures in the HOPD setting.

IV. Conclusion

SVU thanks the Agency for its thoughtful consideration of our comments. We believe that the five TCD codes should be removed from the list of codes subject to the DRA cap because TCD is not an imaging procedure within the meaning of the DRA, CMS has previously exercised its authority to remove other codes from this list that do not involve imaging, and a CMS-commissioned study proves that CMS systematically under-estimates the costs of certain imaging procedures in the radiology cost center. Again, we request a meeting to discuss these issues with you in greater detail.

Sincerely,

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determined and before we adopt potential policy options in a final rule, the public should be fully informed on the potential impacts." *Id.* at 47194.

[18] *Id.* at 47191.

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August 28, 2007

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Re: CMS-1385-P: Comments Regarding Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions ("Proposed Physician Fee Schedule Rule")

Dear Acting Deputy Administrator Kuhn:

On behalf of VHA Inc. ("VHA"), I am writing to provide comments to the Centers for Medicare and Medicaid Services ("CMS") with respect to certain proposed changes to the regulations ("Stark Regulations") implementing the federal physician self-referral law ("Stark Law"). These proposed changes are set forth in the subject Proposed Physician Fee Schedule Rule, published in the July 12, 2007 Federal Register (the "Proposed Rule").[1]

Specifically, our comments relate to the proposed change to the definition of the phrase "set in advance" in the Stark Regulations, 42 C.F.R. § 411.354(d)(1).[2] For the reasons set forth below, we believe that this proposed change, if implemented, will adversely and unnecessarily impact the ability of community-based hospitals to work together with local physicians to lower the cost of care, to the detriment of patients, payers and providers alike, including the Medicare program.

Based in Irving, Texas, VHA is a national health care alliance that provides industry-leading supply chain management services and supports and promotes the formation of regional and national networks that help not-for-profit health care organizations improve their clinical and economic performance. With 17 offices across the U.S., VHA has a track record of proven

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1 72 Fed. Reg. 38122, 38179-38187, 38224.

2 Id. at 38184, 38224.

results in serving more than 1,400 hospitals and more than 21,000 other health care providers nationwide.

I. Background & Current Rule

The Stark Law generally prohibits a physician from referring patients to an entity for the furnishing of designated health services ("DHS") covered by Medicare if the physician (or one of his or her immediate family members) has a financial relationship with the entity, unless an exception applies.[3] The Stark Law also prohibits an entity that has provided DHS to an improperly-referred patient from submitting a claim for reimbursement or otherwise billing any person or entity for such DHS.[4]

Because hospital inpatient and outpatient services are DHS — and because the definition of "financial relationship" under the Stark Law is very broad, effectively including any arrangement whereby anything of value flows between a physician and a hospital — it is frequently the case that the only way for a hospital and physician to avoid Stark Law liability is to ensure that each of their arrangements fits squarely into one or more of the exceptions set forth in the Stark Law and/or Regulations.

As CMS notes in the preamble to the Proposed Rule, many of these exceptions require that the compensation flowing from the hospital to the physician at issue be "set in advance" (or "fixed in advance"). In its 2001 Stark II Phase I rulemaking, CMS defined "set in advance" to specifically exclude most percentage-based compensation arrangements.[5] According to CMS, shortly thereafter, "[m]any commenters urged" the agency to "abandon [its] position that percentage compensation arrangements" are not "set in advance" for purposes of the Stark Law.[6] "This was of particular concern," CMS reports, "to academic medical centers and hospitals, which argued that percentage compensation is commonplace in their physician compensation arrangements."[7]

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3 42 U.S.C. § 1395nn(a)(1)(A).

4 Id. § 1395nn(a)(1)(B).

5 66 Fed. Reg. 856, 959 (January 4, 2001) ("Percentage compensation arrangements do not constitute compensation that is 'set in advance' in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.")

6 69 Fed, Reg. 16054, 16068 (March 26, 2004).

7 Id.

In response to this feedback, CMS delayed the January 4, 2002 implementation date of the percentage-based compensation limitation in the "set in advance" definition.[8] Thereafter, as part of its 2004 Stark II Phase II rulemaking, CMS eliminated the limitation altogether, concluding that its "original [2001] position was overly restrictive."[9] Specifically, CMS modified the definition of "set in advance" to permit percentage-based compensation arrangements, provided (1) the "specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid," (2) this formula is "set forth in sufficient detail so that it can be objectively verified," and (3) the formula is not "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."[10] This definition of "set in advance" has been in effect since 2004.

II. Proposed Rule

In the preamble to the Proposed Rule, CMS states that "[d]espite our intent that percentage compensation arrangements could be used only for compensating physicians for the physician services they perform," it has come to the agency's "attention that percentage compensation arrangements are being used for the provision of other services and items, such as equipment and office space that is leased on the basis of a percentage of the revenues raised by the equipment or in the medical office space."[11] According to the preamble, CMS is "concerned that percentage compensation arrangements in the context of equipment and office space rentals are potentially abusive."[12] In addition, the agency states:

> we believe there is the potential for percentage compensation to be utilized in other areas as well. Therefore . . . we are proposing to clarify that percentage compensation arrangements [1] [m]ay be used only for paying for personally performed physician services; and [2] must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a

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8 68 Fed. Reg. 74491 (December 24, 2003); 68 Fed. Reg. 20347 (April 25, 2003); 67 Fed. Reg. 70322 (November 22, 2002); 66 Fed. Reg. 60154-55 (December 3, 2001).

9 69 Fed. Reg. at 16068.

10 Id. at 16068, 16134.

11 72 Fed. Reg. at 38184.

12 Id.

> percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided).[13]

As revised, the new definition of "set in advance" would provide that "[p]ercentage-based compensation, other than compensation based on revenues directly resulting from personally performed physician services . . . is not considered set in advance."[14]

III. Comment

VHA respectfully opposes the proposed modification to the definition of the phrase "set in advance." VHA is concerned that if the proposal is implemented, hospitals and physicians will be unable to maintain, develop and implement many arrangements that are designed to lower the cost of delivering hospital services. These innovative arrangements often involve a hospital paying a physician or a physician practice group a set percentage of the savings that the hospital achieves due to the physicians' agreement, for example, to follow a product standardization and conservation protocol (such as a recommendation that cardiac surgeons utilize certain types of stents for certain interventional procedures).[15]

Because these arrangements are based on a reduction in expenses incurred by the hospital in furnishing hospital services — and not on "revenues" that result from "personally performed physician services" — these arrangements would not appear to meet the new "set in advance" definition proposed by CMS. As a result, these arrangements could not meet the personal services, fair market value, or academic medical center exceptions (among others), each of which includes a "set in advance" requirement.[16] Consequently, hundreds (and perhaps thousands) of painstakingly negotiated (and now longstanding) hospital-physician arrangements that are specifically designed to lower provider — and, ultimately, patient and payor — costs may need to be terminated in order for the parties to avoid liability under the Stark Law.

This result would be inconsistent with the position taken by CMS' sister agency, the U.S. Department of Health & Human Services' Office of Inspector General ("OIG"), and is not necessary to achieve CMS' stated objective (i.e., preventing abusive percentage-based compensation arrangements that are tied to hospital savings). The OIG has reviewed a number

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[13] Id.

[14] Id. at 38224 (proposed 42 C.F.R. § 411.354(d)(1)).

[15] OIG Advisory Opinion 05-03 (February 10, 2005), at 3-4.

[16] 42 C.F.R. §§ 411.357(d)(1)(v) (personal services), 411.357(l)(3) (fair market value), 411.355(e)(1)(ii) (academic medical center).

of these arrangements[17] and concluded that, if properly structured, they do not pose a material risk of program abuse under the federal health care program anti-kickback law ("Anti-Kickback Law")[18] or the services reduction civil monetary penalty statute ("Services Reduction CMP").[19] According to the OIG, the arrangements at issue "are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies."[20]

> Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals. Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes.[21]

Because these cost savings arrangements must comply with the Anti-Kickback Law (which, like the Stark Law, is intended to prevent overutilization of covered items and services), and must comply with the Services Reduction CMP (which is intended to prevent underutilization of covered items and services) — and because the OIG has concluded that such arrangements, if properly structured, do not raise material issues under either of these statutes — effectively prohibiting such arrangements, through application of the strict liability Stark Law, would, in our view, be counterproductive and contrary to good public policy, especially at a time when CMS continues to pursue a variety of gainsharing demonstration projects.

This is particularly so where, as here, the underlying statute — i.e., the Stark Law — already has a large number of existing, overlapping safeguards and requirements that are specifically designed to achieve the policy objective behind the proposed modification. As a threshold matter, the existing definition of "set in advance" only permits percentage-based compensation arrangements if:

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[17] See, e.g., OIG Advisory Opinion 06-22 (November 9, 2006), OIG Advisory Opinion 05-06 (February 18, 2005), OIG Advisory Opinion 05-05 (February 18, 2005), OIG Advisory Opinion 05-04 (February 10, 2005), OIG Advisory Opinion 05-03 (February 10, 2005), OIG Advisory Opinion 05-02 (February 10, 2005), OIG Advisory Opinion 05-01 (January 28, 2005).

[18] 42 U.S.C. § 1320a-7b(b).

[19] Id.. § 1320a-7a(b)(1).

[20] See, e.g., OIG Advisory Opinion 05-03 (February 10, 2005), at 6.

[21] Id.

- the "specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid,"

- this formula is "set forth in sufficient detail so that it can be objectively verified," and

- the formula is not "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."[22]

Moreover, each of the exceptions that include a "set in advance" requirement also includes a number of additional conditions that are specifically designed to safeguard the Medicare program from fraud and abuse. In order to fit into the Stark Regulations' personal services exception, for example, not only does the compensation at issue have to be "set in advance," but the following requirements (among others) also must be met: (1) the arrangement at issue must be set out in writing, (2) this writing must be signed by the parties, (3) this writing must specify the services covered by the arrangement, (4) the arrangement must cover all of the services to be furnished by the physician, (5) these services cannot exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement, (6) the arrangement must be for at least one year, (7) the compensation under the arrangement must not exceed fair market value, and (8) the services at issue cannot involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.[23]

In sum, the proposed modification to the definition of "set in advance," if adopted, will have an adverse impact on many non-abusive hospital-physician cost-saving programs. As the OIG has noted, these programs, if properly structured, "can serve legitimate business and medical purposes." Nor is the proposed modification necessary in order to achieve CMS' objectives, given the existence of the Anti-Kickback Law, the Services Reduction CMP, and the various other requirements that must be met — above and beyond the "set in advance" requirement — under the relevant Stark Law exceptions. For all of these reasons, VHA respectfully requests that CMS not adopt the proposed modification to the "set in advance" definition. In the alternative, VHA respectfully requests that CMS revise the proposed definition of "set in advance" to insert the words "or savings" after the word "revenues" and to insert the words "or indirectly" after the word "directly" so that the new definition would read as follows: "[p]ercentage-based compensation, other than compensation based on revenues **or savings**

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[22] 42 C.F.R. § 411.354(d)(1).

[23] Id. § 411.357(d).

directly **or indirectly** resulting from personally performed physician services . . . is not considered set in advance."

* * * *

In closing, on behalf of VHA and its members, I would like to thank CMS for providing us this opportunity to comment on the Proposed Rule. Please feel free to contact me at (202) 354-2607 if you have any questions or if VHA can provide any assistance as you consider these issues.

Respectfully submitted,

Edward N. Goodman

Edward N. Goodman
Vice President, Public Policy
VHA Inc.

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MILLENNIUM

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August 29, 2007

Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: [CMS 1385-P] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

"DRUG COMPENDIA"

Dear Acting Administrator:

Millennium Pharmaceuticals, Inc. is pleased to comment on the section entitled "Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen" in the referenced proposed rule. Millennium, one of the world's leading biopharmaceutical companies, focuses on developing therapeutics in oncology and inflammatory diseases that significantly improve patient outcomes in challenging conditions.

Because of our commitment to anti-cancer research and development, we take a keen interest in drug compendia that may be used by physicians in determining the medically-accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen. Appropriate access to a full complement of anti-cancer drugs sanctioned by a functioning compendia system can have life and death consequences for cancer patients. Consequently, we believe that there is an urgent need for the Department of Health and Human Services, and the Centers for Medicare and Medicaid Services, to recognize additional functioning compendia for the off-label use of oncology drugs under the Medicare program now, while at the same time officially updating the process to naming new compendia over time.

DESIRABLE COMPENDIA CHARACTERISTICS

On March 30, 2006, the MedCAC (formerly the Medicare Coverage Advisory Committee) met in public session to advise CMS on evidence regarding the desirable characteristics of compendia to determine medically-accepted indications of drugs and biologicals in anti-cancer therapy and the degree to which the currently listed and other available compendia display those characteristics. During that public session, the MedCAC identified a

list of ten desirable compendia characteristics. CMS cited these characteristics in the proposed Medicare physician fee schedule rule for CY 2008,[1] and Millennium is pleased to have the opportunity to present our comments regarding four of the characteristics. Specifically, Millennium would like clarification regarding the following characteristics and requests that CMS address these matters as it proceeds:

- *Use of prescribed published processes for making recommendations* - Millennium would like CMS to provide detailed information regarding how the Agency would evaluate the acceptability of compendia organizations' plans to use a "prescribed published process for making recommendations" for various drugs and biopharmaceuticals listed in respective compendia. We also ask CMS to provide a clear interpretation of how this "desirable characteristic" will be applied in deciding upon the addition or deletion of a compendium from the list.

- *Explicit "Not recommended" listing when validated evidence is appropriate* - Millennium would like further clarification regarding what CMS considers "validated evidence" to support the inclusion or exclusion of an off-label use under the Medicare program. In addition, we would like the Agency to elucidate upon what constitutes an "appropriate" situation in which "validated evidence" would support a product to be "not recommended."

- *Explicit listing and recommendations regarding therapies* - Millennium recommends that CMS provide further guidance to compendia organizations regarding the establishment of therapy grading recommendations. Consistent and clearly articulated recommendations will minimize the interpretative latitude of those evaluating compendia recommendations for Medicare coverage purposes; thereby moderating coverage inconsistencies among Medicare beneficiaries.

- *Process for public identification and notification of potential conflicts of interest of the compendia's parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts* - We recommend that one way to address potential conflicts of interest among interested parties is to implement rolling membership for the data review committees, thereby disallowing any one or more organizations or individuals from having a prolonged

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

influence over the interpretation of incoming data utilized to make medically-indicated use recommendations for products for compendia listing purposes.

CMS states that it will "consider a compendium's attainment of the MedCAC-recommended desirable characteristics of compendia...in reviewing requests" for additions or deletions to the list of compendia. CMS further states that it "may consider other reasonable factors in making a determination." Millennium urges the Agency to publish these additional factors in a form that allows for public comment before they become effective.

REQUEST FOR ACTION

As a developer of innovative oncology medications, Millennium is particularly concerned that the quality of compendia listings for anti-cancer chemotherapeutic regimens be comprised of the most accurate, thorough and timely information.

Waiting indefinitely for the addition of new authoritative compendia is contrary to the public interest because beneficiaries in every region of the United States need immediate access by way of Medicare coverage to the most complete armamentarium of supported cancer chemotherapy available. Medicare beneficiaries battling cancer rely in significant part on these compendia listings for coverage of their oncology drugs.

As you know, Section 1861(t)(2)(B) of the Social Security Act (SSA) provides the Secretary of Health and Human Services with the authority to revise the list of compendia that are used to determine Medicare Part B coverage of oncology drugs for "off-label" uses. In the United States, off-label use is regulated by the Food and Drug Administration, and policies permit physicians to prescribe approved medications for use other than for their labeled indications.

Cutting edge therapies are particularly important in oncology, where patients desperately need access to a wide spectrum of medications for life saving purposes. This system was put into place by Congress in 1993 to provide additional rigor and review to coverage of innovative therapies. However, shortly after the system was instituted, two of the compendia merged. This left the system envisioned by Congress incomplete. As you are aware, on December 27, 2006, the U.S. House of Representatives directed the Secretary to act as soon as possible to update the list of three compendia and report back to the House no later than January 30, 2007.[2] The Secretary has not responded to this request.

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[2] *Congressional Record*—Extensions of Remarks E2247, December 27, 2006.

Therefore, Millennium urges CMS to announce a specific timeline and provide *a date certain* when the Secretary will recognize additional compendia. While we applaud CMS for proposing to create a process that incorporates public notice and comment to receive and make determinations regarding requests for additions or deletions to the list of approved compendia, Millennium remains concerned that without a specified date by which CMS will announce changes to the current list of compendia, Medicare beneficiaries who are battling various forms of cancer will continue indefinitely to be denied access to the most wide-ranging, effective array of products available. Naming/recognizing additional compendia now would not obviate or alter the Agency's authority to update or review compendia moving forward.

Millennium looks forward to working with CMS to advance the addition of compendia in a timely fashion for off-label uses of drugs and biologicals in anti-cancer chemotherapeutic therapy. If you have any questions concerning our comments, please feel free to contact me on (202) 289-6837.

Sincerely,

Michael J. Eging
Vice President
Government Relations and Public Policy

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Federation of
American
Hospitals®

August 31, 2007

VIA HAND DELIVERY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Re: Comments on Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule (CMS-1385-P)

Ladies and Gentlemen:

The Federation of American Hospitals ("FAH") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural parts of the United States, as well as rehabilitation, psychiatric, long-term acute care, and cancer hospitals. We appreciate the opportunity to provide our comments on the July 12, 2007 proposed rule with comment period issued by the Centers for Medicare & Medicaid Services ("CMS") related to the 2008 update to the Medicare Physician Fee Schedule ("Proposed Rule"). (*See* 72 *Fed. Reg.* 38,122.)

In addition to physician payment policy provisions, the Proposed Rule contains certain proposed changes to the regulations implementing section 1877 of the Social Security Act ("the Act"), which generally prohibits Medicare payment for physician "self-referrals" for designated health services. FAH has followed the development of federal law in this area, and commented on related regulations, for many years. On behalf of our members, we welcome the opportunity to comment on the current physician self-referral proposals and requests for comment. We also provide comments on the proposed changes related to independent diagnostic testing facilities.

COMMENTS RELATED TO PHYSICIAN SELF-REFERRAL

We commend CMS for continuing to review and suggest proposed changes to the physician self-referral regulations in order to respond to the constantly evolving arrangements for health care items and services. For example, we fully support the goals underlying the proposed "Alternative Criteria for Satisfying Certain Exceptions," which we believe reflects CMS' growing appreciation that

lawful, legitimate arrangements may fail, from time to time, to fit neatly within all of the technical requirements of existing physician self-referral exceptions. Below, FAH provides detailed responses to CMS' proposals and requests for comment. In several instances, FAH supports CMS' proposals, while in other instances we express concerns with particular proposals.

FAH also notes that, in addition to the Proposed Rule, CMS recently issued a final rule addressing additional aspects of the physician self-referral regulations (*i.e.*, the "Stark II, Phase III Final Rule"). While FAH's comments provided here address only the issues in the Proposed Rule, we also identify certain areas where our views are impacted by our initial reactions to the Stark II, Phase III Final Rule.

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

CMS proposes to impose an anti-mark up prohibition on the technical component and professional component related to diagnostic tests, including technical component services furnished in a centralized building. (*See* 72 *Fed. Reg.* at 38,180.) FAH supports CMS' proposed changes.

II. Burden of Proof

CMS proposes that, when a claim is denied by Medicare due to a prohibited referral and that denial is appealed, the burden of proof should be on the entity which submitted the claim to show that the claim was not related to a prohibited referral. (*See* 72 *Fed. Reg.* at 38,180-81 (proposed 42 C.F.R. § 411.353(g).) FAH opposes this proposed regulatory change, and instead believes that the burden of proof should be placed on CMS and its contractors. Although it may be common for the provider to have the burden of proof that services it provided are covered by Medicare and were medically necessary, we believe that physician self-referral compliance is different, given the significant potential consequences to noncompliance and the different Congressional intent underlying the statute.

Accordingly, once a provider has demonstrated these threshold coverage requirements, the burden should be on CMS to prove a physician self-referral violation. We believe that a party, who is presumed innocent under the United States Constitution, should never have the burden of proving that it did not violate a law.

Furthermore, more than a dozen physician self-referral exceptions require compliance with the anti-kickback statute (*e.g.*, recruitment, fair market value compensation, indirect compensation arrangements, medical staff incidental benefits, etc.) (*See* 42 C.F.R. § 411.357(e), (l), (m) and (p).) This means a provider would have the burden of proving that the arrangement: (1) meets an anti-kickback statute safe harbor; (2) has received a favorable advisory opinion; or, (3) otherwise does not violate the anti-kickback statute (an intent-based statute). As you know, anti-kickback statute advisory opinions are rare. Thus, unless an arrangement fully complies with a safe harbor, providers will have the challenge of "proving a negative" under uncertain anti-kickback statute standards. In other words, providers would have the burden of proving they lacked the intent necessary to violate the anti-kickback statute, even though it is the government that has the burden of proof under the anti-kickback statute. This anomalous result supports our counter-proposal to place the burden of proof on CMS or its contractors to prove the existence of a physician self-referral violation. Moreover, given that neither CMS nor fiscal intermediaries normally determine compliance with the anti-kickback statute, we question both the practical ability and legal basis for them to do so in these instances.

Should CMS decide to maintain the current proposal in the final rule, the agency should provide clarification regarding the policy. What would be the factual basis used for initially denying a

claim on these grounds? Also, providers have several levels of appeals when contesting a claim denied based on a physician self-referral violation. Would the proposed regulatory policy place the burden of proof on the provider at every level of appeal? Would the regulation trump other evidentiary rules that may exist elsewhere, including under the False Claims Act? A specific concern relates to the exception at 42 C.F.R. § 411.353(f), which includes a requirement that the entity not have knowledge of the referring physician. Regardless of the proposal, if the entity claims it did not have knowledge of the identity of the referring physician, the government should have the burden of showing that the entity did, in fact, have such knowledge (otherwise the entity is in the position of having to prove a negative). This new policy would present similar concerns under other sections of the physician self referral regulations. (*See, e.g.*, 42 C.F.R. § 411.354(b)(5)(B) and (c)(2)(iii).)

III. In-Office Ancillary Services Exception

CMS is considering modifying the in-office ancillary services ("IOAS Exception") to make it more consistent with Congress' original intent, although the Proposed Rule contains no specific proposal. (*See* 72 *Fed. Reg.* at 38,181-82.) FAH has reviewed the concerns raised by CMS regarding the current IOAS Exception, and we believe there is good reason for CMS to propose changes to this exception. We suggest that the definition of "centralized building" in 42 C.F.R. § 411.351 should be revised to delete the following statement: "[a] group practice may have more than one centralized building." We believe that deleting this portion of the definition will address CMS' concerns that Congress did not intend for group practices to have more than one centralized facility.

In administering this exception, policy makers should focus on ensuring that safe and high quality health care is furnished to Medicare beneficiaries. The health care marketplace is increasingly experiencing the desire of physicians to provide care in non-hospital settings, including their physician offices. While the delivery of health care is ever evolving, certain types of health care services should only be rendered at sites of service where safe and high quality care can be best provided. In many cases, this will be a hospital, not a physician office. CMS should keep quality of care and patient safety concerns in mind as it finalizes its changes to the IOAS exception, which affects what types of care can be furnished in a physician office.

For this purpose, we also urge CMS to consider additional refinements to the IOAS Exception to guard against the risk of Medicare program and patient abuse, including:

- A diagnostic service should only qualify for the IOAS Exception if the physician billing for the service, or a member of that physician's group practice, performs the professional services (*i.e.*, the interpretation) related to the diagnostic service.

- Return to the statutory "direct supervision" requirement, *i.e.*, to qualify for the IOAS Exception, the services must be furnished: (1) personally by the referring physician; (2) personally by a physician who is a member of the same group practice as the referring physician; or, (3) personally by individuals who are directly supervised by the referring physician or another physician in the same group practice.

- Eliminate the option at 42 C.F.R. § 411.355 (b)(2)(i)(B) for qualifying for the "same office" requirement.

- To qualify for the IOAS Exception, the services must be medically necessary at the time of the patient's office visit to assist the physician in his or her diagnosis or plan of treatment in connection with that visit.

- To qualify for the IOAS Exception, any therapy services must be provided and billed as an incident-to-service.

These refinements will address the concerns that group practices are benefiting financially from referrals for services that are not closely related to the physician's office practice. CMS should also incorporate a requirement to ensure an adequate relationship between the referring physicians and the furnishing of ancillary services. This could be achieved through a requirement that the ancillary service providers be employees, as defined under federal income tax law, of the physician or group practice.

IV. Obstetrical Malpractice Insurance Subsidies

CMS is concerned that the current obstetrical malpractice insurance subsidies exception is overly restrictive and seeks comments on how the exception can be made more beneficial, while honoring the intent of the physician self-referral law. (*See* 72 *Fed. Reg.* at 38,182.) FAH agrees with CMS' assessment and shares the following thoughts on improving the current exception.

First, FAH urges CMS to expand the existing exception to cover all physicians, not just obstetricians. While the malpractice crisis for obstetricians has been well documented, many other physician specialties are also experiencing difficulties obtaining affordable malpractice insurance. As CMS is well aware, malpractice premiums are a significant expense for physicians, and states which have not enacted some form of tort reform (and therefore have higher malpractice insurance costs for physicians) have experienced increased difficulty in attracting physicians due to the cost of malpractice insurance and the risk of related liability. Furthermore, the absence of affordable malpractice in certain states is causing physicians to "go bare" without coverage, which hurts patients and other providers. When physicians forego malpractice insurance coverage in these states, injured patients (including Medicare beneficiaries) may not have adequate recourse when they are negligently treated, or misdiagnosed, by a physician. Also, the burden of defending claims and paying judgments in these cases often is disproportionately shifted to other providers, such as hospitals.

To address these issues, we believe it would be good public policy to expand this exception beyond obstetrics. Expanding the obstetrical malpractice insurance subsidy exception to all specialties is likely to increase availability of physicians in some regions that are experiencing shortages, and prevent situations where physicians are taking the risky path of forgoing malpractice insurance coverage altogether.

Second, FAH recommends the following potential changes to the current exception:

- Eliminate the health professional shortage area ("HPSA") or medically underserved area ("MUA") or being part of a medically underserved population ("MUP") requirement and instead cap a hospital's malpractice premium subsidy to the amount by which the average malpractice premium for that specialty in the hospital's community exceeds the national average malpractice premium for that specialty;

- Eliminate the HPSA, MUA, MUP requirement and instead allow hospitals to subsidize a specialty if an independent third party expert who assesses community needs determines in a written report that there is a demonstrable shortage of that specialty in the hospital's geographic service area; or

- Reduce the current requirement regarding the volume of the patients who reside in a health professional shortage area ("HPSA") or medically underserved area ("MUA") or

be part of a medically underserved population ("MUP"), from 75 percent to 25 percent. (*See* 42 CFR § 1001.952(o)(2)(i), (ii).)

Each of these recommendations would increase the number of physicians who could potentially receive malpractice subsidies, thereby advancing a strong public policy goal of ensuring adequate numbers of physicians in hospital service areas, as well as helping to ensure that physicians maintain adequate malpractice insurance. Furthermore, allowing hospitals to subsidize malpractice premiums is often a more cost-effective solution to physician shortages than the alternative, which often entails having existing physicians leave or retire, and then having to replace them with new physicians using expensive recruitment packages. Finally, to prevent any misuse of an expanded malpractice insurance subsidy exception, we propose adding a requirement that hospitals may not provide malpractice subsidies in a targeted, preferential or discriminatory manner based on the volume or value of the physician's referrals, and that a physician cannot make obtaining a malpractice insurance subsidy a condition to referring or continuing to refer to the hospital.

V. Unit-of-Service (Per Click) Payments in Space and Equipment Leases

CMS proposes to change the regulations to restrict space and equipment leases from including unit-of-service-based (commonly known as "per click") payments to a physician lessor for designated health services rendered by a lessee entity to patients referred by the lessor. (*See* 72 *Fed. Reg.* at 38,182-83 (proposed 42 C.F.R. §§ 311.357(a)(5), (b)(4).) FAH understands CMS' concern with these arrangements and supports the proposed change. In fact, we believe that CMS needs to go one step further, and prohibit unit-of-service based rental payments when they reflect services provided to patients referred by the lessor *or any physician owner or investor in the lessor*. However, if this proposed change were finalized, FAH urges CMS to provide an appropriate grace period before these changes take effect, which would allow parties time to restructure or unwind existing leasing arrangements. We believe that if an appropriate transition period is not provided, patient access to important services will be jeopardized and hospitals could be subject unnecessarily to potential liability for services rendered immediately after the effective date.

Further, CMS seeks comment on whether the regulations should be revised to prohibit unit-of-service or time-based rental payments to the extent that such payments related to services referred by a physician lessee to a lessor entity who furnishes designated health services. (*See* 72 *Fed. Reg.* at 38,183.) Similar to our comments above, we believe unit-of-service rental based payments should be prohibited when those payments relate to services referred to a lessor entity by a physician lessee.

However, FAH views the idea of applying this policy to time-based rental payments to be much more problematic. First, we are unclear as to how this would work, what the intended result would be, and what benefit could be achieved. Time-based rental payments do not reflect the amount of services referred; they reflect the period(s) of time for which the equipment or location is leased. To the extent that the value of referrals or services provided is incorporated into the lease payment, we believe this is already prohibited under the current office space and rental of equipment exceptions. (*See* 42 CFR §§ 411.357(a), (b).)

Furthermore, time-based rental payments are ubiquitous in leases. A lease that provides for a fixed rental payment for a period of one year involves a "time-based" rent because a year is a period of time. Likewise, leases with monthly, weekly, daily or hourly rental payments all provide for time-based rent, although some of those may look like per-service agreements. Prohibiting such leases would require parties to unwind countless leasing arrangements at significant transaction costs, with no practical alternative means to calculate rent (other than usage, which CMS, appropriately, is curtailing), and no corresponding benefit in reducing the risk of fraud and abuse. Finally, the

Proposed Rule's preamble does not describe CMS' particular concerns with respect to time-based lease payments. Thus, it is not clear what risks these arrangements present to federal health programs and patients, if any.

In our view, CMS should only consider prohibiting time-based rental arrangements when they essentially permit payment for the use of leased space or equipment "on-demand." We believe that time-based rent can be problematic in these situations. For example, if the aggregate amount of time for which space and equipment are leased is not set in advance, yet such space and equipment are available to the physician on demand, then the physician can pay to lease the space and equipment only when the physician needs it to provide specific patient care services. On the other hand, if the total amount of time leased by the physician is set in advance, then we believe the arrangement should be permitted, because it would not fluctuate based on referrals, and the physician would have financial responsibility for the rental payments without regard to the volume of services the physician provides using that space or equipment.

Finally, FAH seeks clarification regarding how the Proposed Rule would impact per service lithotripsy leases. As you know, lithotripsy and its treatment under the physician self-referral law have been subject to judicial scrutiny and were held not to constitute designated health services in the District of Columbia. (*See Am. Lithotripsy Soc. v. Thompson*, 215 F.Supp.2d 23 (D.D.C. 2002).) In earlier physician self-referral rulemakings, CMS did not address this court decision and how it impacts physician self-referral enforcement policy going forward. We assume that the above federal court decision is binding only for lithotripsy services provided to Medicare beneficiaries in the District of Columbia, and that outside of that jurisdiction, lithotripsy services remain a designated health service, because they are billed as "inpatient or outpatient hospital services." However, there remains some confusion as to the current rules regarding lithotripsy service contracts. Given the types of policy changes being contemplated here and the normal structure of lithotripsy arrangements, the final rule would seem to be an appropriate place for CMS to address this court decision and to express its current views on lithotripsy.

VI. Period of Disallowance for Noncompliant Financial Relationships

CMS seeks comments on how it might, to the extent practicable, set forth the period of disallowance for arrangements that implicate, but fail to satisfy the requirements of one or more of the various exceptions. (*See* 72 *Fed. Reg.* at 38,183.) FAH believes that providers should be permitted to self-correct noncompliant financial arrangements and that the period of disallowance should end once the noncompliant financial arrangement has been remedied. For example, if a hospital were to identify a noncompliant professional services agreement, the period of disallowance should end once: (1) the hospital corrects or terminates the arrangement; and (2) the physician repays to the hospital any compensation in excess of what is permitted by the physician-self referral law and regulations.

Alternatively, if the physician does not (or cannot) repay any excess compensation, then the period of disallowance should end once the hospital pays to the Medicare Trust Fund the amount of compensation that it paid to the physician in excess of what is permitted by the physician self-referral law and regulations, and the hospital is prohibited from paying any future compensation to the referring physician unless and until the physician reimburses the hospital for the amount of such excess compensation."[1]

[1] We note that payments to CMS based on compensation received by the referring physician is consistent with the Office of Inspector General's "An Open Letter to Health Care Providers" (April 24, 2006), in which Inspector General Daniel R. Levinson stated that OIG tends to settle self-referral and kickback self disclosures for a multiplier based on the value of compensation conferred on the physician. (*See* Office of Inspector General, U.S. Department of Health and Human Services, An Open Letter to Health Care Providers (April 24, 2006).)

This approach is beneficial in several ways for both CMS and hospitals. First, it encourages hospitals to review and remedy any noncompliant arrangements, because the sooner a noncompliant arrangement is remedied, the sooner the physician could refer to the hospital and the hospital could bill for the services provided pursuant to those referrals. Second, there would be certainty for the industry regarding their obligations when noncompliant arrangements are identified. In contrast, a suggested "case-by-case" approach is inconsistent with the purpose of the physician self-referral law, which is to establish "bright lines" for compliance, to the extent feasible. Third, CMS would receive repayment of compensation in some instances, which could be used to benefit program beneficiaries. Fourth, self-correction by hospitals would spare CMS the enormous time, effort and expense of reviewing countless arrangements with potential technical issues under the physician self-referral law and regulations.

VII. Ownership or Investment Interest in Retirement Plans

CMS proposes to revise the regulations to provide that "ownership" and "investment" interests do not include an interest in a retirement plan offered by the DHS entity to the physician or immediate family member as a result of the physician's or immediate family member's employment with the facility. (*See* 72 *Fed. Reg.* at 38,183-84 (proposed 42 C.F.R. § 411.354(b)(3)(i).) FAH supports CMS' proposed change.

VIII. "Set in Advance" and Percentage-Based Compensation Arrangements

CMS propose to clarify that percentage compensation arrangements (1) may only be used for paying personally performed physician services, and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor. (*See* 72 *Fed Reg.* at 38,184 (proposed 42 C.F.R. § 411.354(d)(1).) FAH is sensitive to the potential abuses that CMS is attempting to address with the proposed change. However, we believe that the proposed change would result in the elimination of many common percentage arrangements that present no risk of program or patient abuse, including practice management agreements (in which a manager provides administrative and other management services to physicians, typically in exchange for a percentage of the physician's revenues or collections, which could include ancillary revenue), and leases with cost sharing for common space (in which tenants pay their respective percentage of costs associated with common areas of the property).

Likewise, many pay-for-performance and quality of care initiatives provide physicians with the potential to earn percentage-based compensation to the extent certain quality of care benchmarks are achieved. There are other common arrangements that involve compensation based on a percentage of something other than professional fees generated, including physician practice expense sharing arrangements, and billing and collection agreements, to name just a few.

FAH urges CMS to adopt a more narrowly tailored approach, and prohibit percentage-based compensation arrangements only to the extent the compensation is based on a percentage of revenues, collections, charges, receipts, profits or other amounts that reflect DHS-designated health services referred by the physician receiving the compensation. This approach would be consistent with CMS' proposal with respect to unit-of-service (per click) payments in space and equipment leases. Furthermore, we believe this prohibition should be included in the special rules on compensation addressing when compensation does or does not take referrals into account, and ***not*** the definition of "set in advance." Finally, we also recommend any changes to percentage-based compensation arrangements be phased in over time to allow parties to end or modify their existing compensation arrangements.

IX. Stand in the Shoes

CMS proposes to amend the regulations to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would "stand in the shoes" of the entity that it owns or controls, and would be deemed to have the same compensation arrangements with the same parties on the same terms as does the entity it owns or controls. (*See* 72 *Fed. Reg.* at 38,184.) FAH understands the concerns underlying CMS' proposed changes, but we believe such concerns have already been adequately addressed in the Stark II, Phase III Final Rule. Furthermore, in CMS' example, because the entity owned or controlled (the "Subsidiary") by the DHS entity (the "Parent") provides DHS itself, the Subsidiary's financial relationship with the referring physician(s) presumably would already need to meet an exception. Therefore, it is unclear what is gained by having the Parent stand in the shoes of the Subsidiary, and use the same exception the Subsidiary is using.

Other practical issues also arise. For example, what degree of ownership is required to trigger the "stand in the shoes" analysis -- is it any ownership interest, a majority, or 100% of the Subsidiary? What is meant to be in "control" of another DHS entity? Is it the power to appoint board members (if so, what percent of the board) or officers, or contractual control, or some other method? We are concerned that these additional "stand in the shoes" provisions would only contribute to confusion in this area, and it would be unclear in many situations whether an arrangement should qualify as an indirect compensation arrangement, by virtue of an unbroken chain of financial or compensation relationships, or as a direct relationship, by virtue of the "stand in the shoes" rules.

X. Alternative Criteria for Satisfying Certain Exceptions

CMS seeks comments on whether to amend certain exceptions to provide an alternative method for satisfying those exceptions. (*See* 72 *Fed. Reg.* at 38,185.) FAH applauds CMS for its responsiveness to concerns expressed by providers about the dilemma of technical violations under the physician self-referral law and regulations. As CMS notes in the Proposed Rule, providers potentially could experience technical physician self-referral violations due to missing signatures, expired contracts, or missing documentation. Although many providers are diligent in their record keeping and compliance efforts, innocent mistakes still occur, and the strict liability construct of this statute makes this dilemma very serious.

However, we find CMS' current proposal to be too limited. Given that these violations are only technical, we believe it is cumbersome, time-consuming and unnecessary for CMS to undertake a case-by-case review. An alternative to formal compliance should be permitted if the provider (1) can identify contemporaneous written documentation (*e.g.*, cancelled checks, invoices, email or other correspondence) evidencing that the key terms of the arrangement complied with the substantive elements of the applicable exception (although perhaps not the procedural requirements for a single written agreement, signed by both parties), and (2) promptly brings the arrangement into compliance with both substantive and procedural requirements of the applicable exception.

If the provider is unable to identify contemporaneous written documentation, then it should correct or end the arrangement and (1) seek repayment of compensation from the physician of the amount that was paid to the physician in excess of what was permitted under the physician self-referral law, or (2) if the physician will not repay the compensation, submit an amount to CMS equal to the payments made to the physician in excess of what was permitted under the law and regulations. (*See above,*. § VI. Period of Disallowance for Noncompliant Financial Relationships.) In these cases, after the repayment of excess compensation, the provider could then submit a notice to CMS that a

noncompliant arrangement has been identified and remedied and maintain a file evidencing the corrective action that could be reviewed later, if necessary.

In addition, we have specific comments regarding certain of the requirements listed in the alternative criteria for satisfying certain exceptions:

- **Disclosure of the facts and circumstances of the arrangement to CMS.** Requiring the "facts and circumstances" of the situation to be disclosed to CMS upon the occurrence of technical violations will require scarce resources to be allocated to the process by both the providers and CMS. Would CMS establish reasonable time frames for a response so that providers are not left in limbo awaiting an uncertain government decision? We are concerned that CMS could be flooded with disclosures of technical violations. We believe our proposal is far more efficient and effective, and is not susceptible to abuse and could be audited by the government.

- **CMS determines that the arrangement satisfied all but the prescribed procedural or "form" requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS.** It is unclear how CMS will determine some of the more subjective requirements of the exceptions, such as whether compensation is fair market value, or the services provided exceed those services that are reasonable and necessary for the legitimate business purposes of the arrangement. Determining compliance or noncompliance with these types of requirements would appear to be outside of the normal course of business for CMS, and would require enormous and costly resources, potentially including the use of outside experts.

- **The failure to meet all the prescribed criteria of the exception was inadvertent.** CMS indicates that it would consider an "inadvertent" failure only when there is an innocent or unintentional mistake, but does not provide any substantive guidance regarding what constitutes an "innocent or unintentional mistake." This could cause confusion for providers seeking to make a disclosure. It also appears to be somewhat inconsistent with the knowledge standard, discussed below.

- **The referral for DHS and the claim for DHS were not made with knowledge that one or more of the exception's prescribed criteria were not met.** First, it is unclear whose knowledge would be relevant. Second, we question how CMS would determine if this requirement was satisfied especially given it proposes to use the scienter standard of the Civil False Claims Act. How would someone demonstrate, for example, that it did not know and should not have known that a signature was missing on a lease? Would CMS interview all personnel involved at the entity, in addition to the referring physician? Such an approach would require significant resources, and effectively create a mini-trial for each minor, technical violation brought to CMS' attention. If any knowledge requirement were retained by CMS, it should be an *actual* knowledge standard in order to provide more certainty with respect to this exception.

- **No more than a set amount of time had passed since the time of the original noncompliance with the prescribed criteria.** Because many physician self-referral violations are unintentional, they are not discovered immediately. Requiring that not more than a set amount of time pass would exclude many arrangements that otherwise properly fit within the alternative criteria. In order to maximize the effectiveness of these alternative criteria, FAH urges that this condition be removed.

We note the Stark II, Phase III Final Rule makes it even more important for CMS to adopt a workable policy in this area as soon as possible. The Phase III Final Rule implements policy changes in certain areas which may increase instances where alternative criteria for compliance would be beneficial to protect arrangements that do not pose a risk of patient or program abuse. While the need for policy on this has been longstanding, the need will increase when Phase III Final Rule goes into effect in December.

Finally, we note that the existing regulatory refund obligation adds to the provider community's trepidation over how to handle technical physician self-referral violations. (*See* 42 C.F.R. § 411.353(d).) Compliance analyses regarding whether to refund arise in a variety of situations and can often present complex questions. For physician self-referral purposes, we believe the current refund regulation goes beyond CMS' statutory authority in this area, and therefore creates additional risks for parties for enforcement actions related to physician self-referral arrangements. The statute provides expressly that "[i]f a person collects any amounts that were billed in violation of [the physician self-referral law], the person shall be liable ***to the individual*** for, and shall refund on a timely basis ***to the individual***, any amounts so collected." (42 U.S.C. § 1395nn(g)(2)(emphasis added).)

Thus, the statute's plain wording requires only repayments to individuals, and does not create any obligation on the part of any provider to refund any payments received from Medicare on claims submitted in violation of physician self-referral law. Instead, general federal debt collection authorities provide the federal government with the authority to recoup identified overpayments. The physician self referral statute's refund authority should be viewed as complimentary to the general federal recoupment authority, and is intended to ensure that beneficiaries receive refunds of their co-payments when a Medicare overpayment is recouped. For these reasons, we believe the implementing regulation at 411.353(d) exceeds the authority granted by section 1887(g)(2) of the Act, and presents an impermissible interpretation of the statute. Accordingly, we request that CMS revise this regulation to properly reflect Congressional intent.

XI. Services Furnished "Under Arrangements"

The Proposed Rule expresses CMS' concern with the current state of affairs involving "under arrangement" services and their relationship to physician self-referral. (*See* 72 *Fed Reg.* at 38,187.) To address these concerns, CMS proposes to revise its definition of "entity" to include both the entity that furnishes the DHS and the entity that bills for the DHS. (*Id.* (proposed 42 C.F.R. § 411.351).) FAH supports CMS' goals with respect to "under arrangements," and recognizes the legitimate concerns that may exist when a physician-owned joint venture provides the same services to a hospital "under arrangements" that the hospital previously provided directly, without expanding the type of services provided, upgrading the facility or equipment, or otherwise contributing to health care quality or accessibility in the community.

The concept of "under arrangement," which originally was solely a payment concept, has been used in recent years as a way to work around the strict rules of the physician self-referral law. Under arrangement transactions have proliferated as growing numbers of physicians and hospitals have exploited what amounts to a "loophole" in the existing self-referral regulations. We believe CMS is appropriately clamping down on these abusive arrangements, which, when unraveled, are quite often just a sophisticated way of circumventing the basic purpose of the physician self-referral law. For these reasons, FAH is fully supportive of CMS' policy goals.

However, we are concerned that CMS' proposal does not concisely address the problem it seeks to remedy. For example, the proposed revisions to the definition of "entity" are confusing and

may be over-broad. Specifically, the phrase "has performed the DHS" could lead to different interpretations—does this include individuals, management companies, lessors and/or vendors? Likewise, the term "caused a claim to be presented" is also ambiguous and could be interpreted as including a number of unintended entities, including billing companies, consultants, or even individual billers and coders. CMS should be mindful that when closing this loophole, it does not inadvertently create ambiguity and confusion in other areas.

FAH believes it is far better to pursue a more focused solution, and proposes the following: First, add the following sentence to the definition of "entity" in 42 C.F.R. § 411.351: "An entity providing services 'under arrangements' is also an 'entity' for purposes of this subpart." Second, delete "under arrangements" as an exception to an "ownership or investment interest" (*see* 42 C.F.R. § 411.354(b)(3)(iv)) and include it instead as an ownership or investment interest under 42 CFR § 411.354(b). Third, clarify in 42 C.F.R. § 411.354(c) that an "under arrangements" contract might also create an ownership or investment interest, in addition to an indirect compensation arrangement.

We believe that these changes would accomplish the same goal as CMS' proposed changes, but in more targeted fashion and without making any broadly sweeping and potentially confusing changes to the definition of "entity." As with "per-click" leases and percentage compensation, we urge CMS to consider a phase-in of any changes in this area, which will permit the termination and/or restructuring of existing relationships and arrangements before absolute compliance is triggered.

The Stark II, Phase III Final Rule contains several provisions that will affect under arrangement transactions. However, those provisions will only affect how such arrangements can be structured; they are not sufficient to address CMS' overarching concern about the proliferation of these types of arrangements. Therefore, it is critical for CMS to redefine "entity," as that approach is the only way to address fully properly the valid concerns that CMS expresses in the Proposed Rule.

COMMENTS RELATED TO INDEPENDENT DIAGNOSTIC TESTING FACILITIES

Under this proposed rule, CMS is advocating changes to the already existing independent diagnostic testing facilities ("IDTF") performance standards as well as recommending two new standards. FAH offers comments concerning the proposed changes in three areas: (1) applying existing and newly proposed performance standards consistently to all freestanding imaging services regardless of how they are enrolled; (2) the proposed changes to existing standards; and (3) the new CMS proposed standards.

I. Consistent Standards

FAH believes the consistent adoption of performance standards for all freestanding imaging services, whether enrolled as an IDTF or as a physician directed clinic, would continue to support CMS' intent to ensure that minimum quality standards are met to protect Medicare beneficiaries. As CMS states in the December, 2006 Federal Register[2], "these standards are merely good business practices that will help to ensure that suppliers are providing quality care to Medicare beneficiaries." CMS also noted that it received several comments recommending the expansion of the IDTF performance standards to all imaging services, including those enrolled as a physician directed clinic rather than as an IDTF. The response from CMS was that this will be considered in future rulemaking processes. FAH encourages CMS to follow through on its commitment to consider, and more

[2] Federal Register: December 1, 2006 (Volume 71, Number 231)]

importantly ensure quality care for the Medicare beneficiaries by requiring consistent standards in all settings that provide imaging services.

II. Changes to Existing IDTF Standards

A. Liability Insurance – § 410.33(g)(6)

We appreciate and support CMS' decision to remove the requirement of listing the serial numbers of any and all diagnostic equipment used by the IDTF. However, the FAH is concerned about the proposal to revise the performance standard to include the requirement that an IDTF must list the CMS designated contactor as a Certificate Holder on the liability insurance policy. The stated rationale for this new requirement is so the CMS designated contractor can, at any time, directly verify with the IDTF's insurance underwriter and agent that the IDTF is maintaining the required liability insurance. The FAH opposes this new requirement. This would create an undue administrative burden on the IDTF and its insurer and would set an unnecessary precedent of listing a governmental agency on an insurance policy.

B. Enrollment Changes – § 410.33(g)(2)

FAH supports the changes in this standard to lessen the administrative burden for the IDTF and the carrier/Medicare administrative contractor ("MAC"). This demonstrates CMS' commitment to requiring those items that are deemed to be substantive changes to be submitted within 30 days.

C. Beneficiary Questions and Complaints – §410.33(g)(8)

FAH recognizes the need to clarify the requirement to maintain documentation of the interactions with the beneficiaries regarding complaints. However, is it the intent of this standard that every question is logged? For example, if a beneficiary has a question about their bill or a scheduled appointment time, it would not be feasible that each and every question be logged. We respectfully request that the beneficiary's complaint (rather than global questions) and corresponding follow up be subjected to the outlined documentation requirements. Although it is our opinion that this is CMS' intent, the final rule offers the opportunity to provide further clarity of this intended purpose.

D. Supervising Physicians – § 410.33(b)(1)

FAH supports the proposed revisions to this standard.

III. Proposed New IDTF Standards

A. Initial enrollment date for IDTF

We recognize CMS' efforts to establish a more uniform enrollment standard to confirm that an IDTF is in compliance with the Medicare standards prior to billing. To address this, CMS has proposed to allow the effective date of billing privileges to be the latter of (1) the date of filing of a Medicare enrollment application that was subsequently approved by the contractor; or (2) the date an IDTF first started rendering services at its new location. In order to effectively manage this requirement and ensure the availability of the services provided to the beneficiaries, there must be a shared and joint responsibility between the IDTF and the CMS enrollment contractor.

We applaud the fact that the enrollment process will be moving to a web-based solution, specifically the Provider, Enrollment, Chain, and Ownership System (PECOS Web). We are hopeful that this new system will streamline the enrollment process and address many of the timeliness issues that the industry has experienced related to the processing of IDTF enrollment applications. One of our members recently reported that it has taken the contractor more than a year to process and approve a completed enrollment application on several IDTFs in one region.

We have reviewed the Functional Requirements Document[3] for the Medicare Administrative Contractor (MAC). Within the outlined scope of work (SOW), there is reference to the Contractor's timeliness responsibilities. The SOW for paper enrollment applications describes timely as when 80% of the applications are processed within 60 calendar days of receipt, 90% in 120 calendar days of receipt, and 99% of applications are processed within 180 calendar days. In the web-based enrollment process, the SOW describes timely as 90% of applications are processed within 45 days of receipt, 95% in 60 calendar days, and 99% within 90 calendar days of receipt. Based on these timelines, the FAH recommends an accelerated rollout of the PECOS to expedite the process.

It is our suggestion that Medicare ensure these timelines are adhered to by their contractors so that beneficiaries have access to quality and convenient healthcare delivery offered at the IDTF.

Furthermore, we believe it is critical that CMS develop and require their contractors to follow a protocol that outlines the items that will require a contractor to reject or deny an enrollment application. Even with the best of intentions, an incidental oversight may occur when completing the enrollment application. When this occurs, the decision to reject or deny the claim (which will now impact billing privileges) must be weighed against the information that is lacking. For example, there have been instances in which an application was returned to add a "comma" or an unintentionally omitted 9 digit of a social security number. These omissions need to be corrected; however, these elements do not constitute substantive items that would render the enrollment application rejected. In other words, the rejection or denial of an application should be based on substantive elements. These other notable items should be identified as a deficiency or as an incomplete application and returned to the applicant with a request to update or complete the application. Under such circumstances, the application should not be rejected or denied in such a way that would adversely affect the IDTF's effective date to bill for it services to Medicare beneficiaries. This would constitute an arbitrary and capricious denial of the IDTF's ability to appropriately bill for its services back to the date it submitted a materially complete application.

B. Prohibition on Sharing

In general, FAH supports CMS' desire to prohibit IDTFs from sharing space, equipment or staff or subleasing its operations to another individual or organization. The industry recently appears to be experiencing a proliferation of shared use arrangements between IDTFs and physicians who refer diagnostic services to those IDTFs. Such arrangements can be structured in a variety of ways, which vary widely in terms of legal and compliance risk. As such, leveling the playing field, so to speak, by prohibiting any such shared use arrangement with these types of physicians would be supported by FAH under the following circumstances. First, as referenced in Part (1) above, this standard needs to be applied consistently in all imaging centers, whether enrolled as an IDTF or as a physician-directed

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[3] Centers for Medicare & Medicaid Services Office of Acquisition and Grants Management R -- RFI to RFP 2 Cycle 2 Part A/B MAC RFI to RFP 2 Cycle 2 Part A/B MAC 01, Synopsis http://www.fbo.gov/spg/HHS/HCFA/AGG/Reference%2DNumber%2DAB%2DMAC%2DRFP%2D2%2DCycle%2D2%2DRFI%2D1/listing.html

clinic. Otherwise, two distinct compliance and regulatory standards will emerge depending on how the same imaging center is enrolled. Second, space sharing should not be prohibited when done with an adjoining physician practice or radiology group that is an owner of the IDTF. The prior CMS Transmittal 187 (issued on January 26, 2007 and later rescinded) stated that an IDTF "[m]ay not share space with another active Medicare supplier. (Note: Physicians owning an IDTF and sharing space are exempt from this requirement)." For example, it is common for IDTFs to share waiting room, common area space, or other space within the IDTF with the adjoining physician practice or radiology group that is an owner of the IDTF. We do not think it was CMS' intention to adopt a standard that is more restrictive than the proposed Transmittal 187 that was rescinded.

It is also unclear as to how this prohibition would be implemented in terms of the supervising physician. For example, if the supervising physician is "shared" by an IDTF and that physician's own group practice.

In addition, CMS requested comments on whether this shared use prohibition should be extended to mobile services used by IDTFs. On this point, FAH would not be in support of extending this prohibition to the mobile IDTF setting. IDTFs routinely use mobile services to provide a full range of diagnostic services to its patients. Often staff from the IDTF will provide patient services within the mobile unit, since the IDTF assumes responsibility and oversight for the mobile services provided on the IDTF's premises. Also, the mobile provider often shares space within the IDTF to operate the equipment. These mobile services are provided in a cost effective way and enable the IDTF's patients to receive a broader array of services than would be available if the IDTF had to secure such services through fixed equipment provided solely by the IDTF. Prohibiting such legitimate sharing arrangements would limit beneficiary access to necessary mobile services and increase the costs of providing necessary diagnostic care.

INDEPENDENT BILLING FOR PATHOLOGY SERVICES

As we have stated in previous comments letters, we do not agree that Medicare is currently paying twice for the technical component (TC) of pathology services provided to hospital inpatients as these services were not included in the base cost for grandfathered hospitals when the DRG system was first established. CMS did include pathology services performed by the hospital laboratory in the base year cost but CMS instructed fiscal intermediaries that where hospitals used an independent laboratory that billed the Part B carrier that "these costs should not be included in the hospital's base period costs". Thus, CMS is not paying twice for laboratory services performed and billed by independent laboratories for grandfathered hospitals (those hospitals that were not permitted to include such costs in their base year).

Also, hospitals that have historically not had to make payment nor bill for these services, will now incur additional administrative costs related to these functions.

FAH recommends that CMS continue to permit grandfathered hospitals to use independent laboratories and to permit independent laboratories to bill for such services to the Part B carrier.

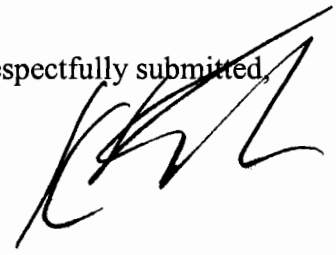
In summary, FAH recommends applying the existing and the newly proposed performance standards consistently to all freestanding imaging services regardless of how they are enrolled; that the proposed changes to existing standards be evaluated based upon our comments; and, as stated above, the FAH strongly suggests a comprehensive assessment and clear implementation guidance be provided in the event that the new standards are implemented. In addition, the new standards should

include the assurance that enrollment applications are rejected or denied only for substantive reasons and that consideration is given for legitimate shared use arrangements.

* * * * *

FAH appreciates the opportunity to comment and looks forward to reviewing your response. If you have any questions about our comments or need additional information, please contact me or Jeff Micklos of my staff at 202.624.1500.

Respectfully submitted,



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August 31, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Physician Self-Referral Provisions

Dear Mr. Kuhn:

The American College of Osteopathic Surgeons (ACOS) and the American Osteopathic Academy of Orthopedics (AOAO) appreciate the opportunity to provide written comments on the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008", as published in the *Federal Register* on July 12, 2007. Specifically, we wish to comment on the proposed changes to the physician self-referral rules and the Medicare reassignment and anti-markup provisions that apply to diagnostic tests.

In general, we are very concerned that the proposed changes will add yet another layer of unnecessary complexity and confusion in an area where physicians are simply trying to provide patients with the highest quality of services in an efficient manner in one centralized location. For example, the proposed rule questions whether there should be new restrictions on "pod" labs located in physician offices. Yet, the Centers for Medicare and Medicaid Services (CMS) provides no evidence of any existing abuse in this area. There has been no evidence demonstrated of over-utilization of services or other abuses occurring because of these arrangements.

Indeed, we believe that these pod labs, conveniently located in the physician offices, have increased the quality of patient care and perhaps reduced the overall costs to the Medicare system by providing efficient and more timely care. We urge CMS to seek further data in this area to confirm whether abuses are occurring prior to making any policy changes that might in fact lead to lower quality of care and even greater costs to the system.

Also, under the proposed rule changes, the only professional or technical components of a service that a physician group could mark-up would be those performed by a full-time employee of the group. This proposed change does not reflect real-world situations. There are many cases where the physician group hires other professionals for interpretations or technical services as

independent contractors or part-time employees, particularly in rural areas. In addition to paying these professionals for these services, the physician group also incurs overhead expenses and assumes the risk in billing for these services because some services will not be paid. If the physician group is prohibited from billing more than the amount actually paid to the independent contractor or part-time employee, the physician group would actually lose money on providing the service. Thus, these services will no longer be provided in the physician office, resulting in less efficient care for the patient and perhaps even lower quality of care and increased costs.

Further, the law currently allows time-based or per-click payment arrangements, as long as the payment is set in advance at fair market value and does not change during the term of an agreement in a manner that reflects the volume of referrals. The term of the agreement must be at least for one year. However, CMS is proposing that space and equipment leases, personnel leases, billing service agreements, or management services agreements between a physician and a billing entity may not be based on per-click payments to the physician or on a percentage of collections for services referred by the physician to the billing entity. Such a change would require physicians and hospitals to restructure or terminate many arrangements, when once again there is no substantive evidence of abuse in this area.

Lastly, the proposed rule would change certain indirect compensation relationships between physicians and hospitals into direct relationships and would prohibit physician ownership of entities that provide equipment or services to hospitals. The proposed changes would require the restructuring or termination of many physician-hospital joint ventures and lease and management arrangements, including those where the compensation already is based on fair market value and the arrangements foster competition, lower costs, and better care.

In closing, we urge CMS to reconsider its proposed changes in these areas and instead gather more data to determine if these truly are arrangements where program abuse and/or over-utilization is actually occurring.

Respectfully Submitted,

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President, ACOS

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August 31, 2007

VIA ELECTRONIC SUBMISSION
AND HAND DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Rm 309-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS – 1385-P
Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008

Comments Concerning Proposed Physician Self-Referral Provisions

Dear Centers for Medicare and Medicaid Services:

This letter is submitted in response to the Proposed Rule published by the Centers for Medicare and Medicaid Services (referred to herein as "CMS") in the July 12, 2007 Federal Register (referred to herein as the "Proposed Regulations") regarding physicians' referrals to health care entities with which they have financial relationships under the Medicare and Medicaid programs (referred to herein as the "Stark Law").

We are submitting these comments on behalf of several of our clients including not only physicians and physician groups but also other stakeholders, such as hospitals and health systems, physician-owned non-designated health service suppliers and other health care entities furnishing designated health services.

The overarching comment we have is our surprise and dismay that CMS is taking a piecemeal and hurried approach to issuing regulations under the Stark Law, which is a highly complex area

of the law. The Proposed Regulations, which suggest significant and sweeping changes to a number of provisions set forth in the final Stark II Phase II Regulations, are buried within a 273-page issuance largely focused on physician fee schedule issues. This is in contrast to the traditional promulgation of Stark regulations as a separate rulemaking devoted exclusively to the self-referral law which puts all stakeholders on notice of new rules, not just physicians. This is especially important because the entity subject to penalties for Stark Law violations is the DHS entity, not typically the physicians.

In addition, the Proposed Regulations provide the public with less than 60 days to submit comments. This is in contrast to the expectation of a meaningful comment period for Proposed Regulations of this significant nature. We are especially dismayed by the fact that CMS has used the Proposed Regulations to reopen long settled areas of interpretation, like the scope of the in-office ancillary services exception, as well as the definition of what constitutes a DHS, now 3 years after the publication of final Phase II regulations.

CMS issued the final Stark II regulations three years ago with a great deal of fanfare touting that it had resolved all significant areas of overreaching that were reflected in the prior versions of the regulations. In referring repeatedly in these Proposed Regulations to its positions in the 1998 proposed regulation, CMS appears to have completely forgotten the controversial nature of that earlier proposal and the substantial efforts undertaken by the health care community to convince CMS that it would be prudent to scale back its overly expansive interpretation of the Stark law. Yet, just three years after issuance of the Phase II Stark II final regulations which definitively resolved these controversies, and based only on "anecdotal reports" of abuse, this new proposal now contemplates a return to decade-old interpretations that would involve massive restructuring in the health care community. In addition, if the Proposed Regulations, along with the issues in which CMS seeks public comment, were to be finalized, then it could result in wholesale elimination of the delivery of services that have been furnished in group practice settings for many years.

We fail to understand (or be able to explain to our clients that seek to comply with these requirements) why CMS is not addressing all of the issues relating to the Stark Law in a consolidated process of rulemaking, by publishing a single comprehensive set of proposed regulations that are easily identified to all relevant stakeholders, and which allow a time period that is long enough for meaningful comments to be crafted and submitted. This is further evidenced by the fact that CMS is scheduled to issue in next week's Federal Register the Stark II Phase III Final Regulations, which are being issued without a comment period and which will become effective 90 days after publication in the Federal Register.

Various areas addressed in the Proposed Regulations are merely broad "solicitations" for comments based only on anecdotal evidence, *e.g.*, the discussion of various in-office ancillary services exception issues involving pathology, clinical laboratory, occupational and physical therapy services and referrals among specialists; also the discussion of the period of disallowance for noncompliance financial relationships. These areas cannot be considered as true "proposed" regulations that give the public a meaningful opportunity to comment on an articulated CMS proposal. As such, these areas require issuance of a true proposed regulation

with proposed language for the public to react to and comment on. This is particularly important when comments on this proposed rule are due before the final Stark II Phase III regulations have even been officially published in the Federal Register, meaning that the public has not had an opportunity to assess the implications of the final regulation on these proposals. A further complicating factor is that the final Stark II Phase III regulations are alluded to throughout the Proposed Regulations yet not addressed directly.

We are also dismayed by the fact that so many concepts and positions originally proposed by CMS in the 1998 Stark II proposed regulations, which were ultimately modified in Phases I and II in 2001 and 2004, have been reincorporated into this set of Proposed Regulations. Specifically, in the preamble to the Phase I and Phase II regulations, CMS acknowledged that there are good reasons for maintaining flexibility in the Stark regulations. The Stark law is black and white, so that any overly restrictive Stark law interpretations mean that services cannot be furnished to Medicare patients, even if the patients want those services in that setting or from that physician. Moreover, any abuse that arises from any particular physician financial relationship can always be prosecuted as an anti-kickback violation, or a breach of the various Medicare payment and coverage rules. Similarly, abuses perceived in site of service, quality, or reimbursement can be remedied through modifications to those underlying Medicare rules, not the Stark Law. However, in these Proposed Regulations, CMS is proposing to eliminate some of this flexibility based upon perceived abuses.

For these reasons, we urge CMS to abandon the notion of issuing the Final Medicare Physician Fee Schedule with the Stark Law sections included in the Final Rule, but instead postpone publication of these aspects of the Proposed Regulations until such time as it publishes a consolidated proposed rule on the physician self-referral law (*i.e.*, "Phase IV Regulations").

As we have done in the past, we welcome the opportunity to meet with you to discuss these issues in greater detail and/or provide some supplemental information related to the topics addressed below.

Services Furnished Under Arrangements

In an attempt to address what it considers a problem of potential over-utilization of services by physicians who have an ownership interest in an entity that performs tests or procedures pursuant to an "under arrangements" relationship with a hospital, CMS proposes to expand the current definition of "entity" (to which a physician is prohibited from making a referral if he or she has a financial relationship with the entity), from only that entity which bills for the designated health service ("DHS") to now include the entity that actually provides the DHS in an "under arrangements" relationship.

This proposed interpretation of the Stark Law contradicts the position taken by CMS in the Stark II Phase I Final Regulations in 2001, where CMS stated that it "would treat 'under arrangements' financial arrangements between hospitals and physician-owned entities as compensation and not ownership relationships." At that time, comments were made by individuals concerned that the definition of inpatient and outpatient hospital services would impact hospitals that purchase

services "under arrangements" from entities owned in whole or in part by referring physicians. In 2001, CMS stated that it would not interpret the statute to consider "under arrangements" to be "ownership interests" because to do so, given the high volume of these arrangements, would "disrupt patient care" and that "*bona fide* "under arrangement" relationships could easily be structured to comply with the personal services arrangement exception, or, in some cases, the fair market value exception" and that there was precedent in the statute for treating them as compensation. *See* 66 Fed. Reg. at 942.

In proposing this change, CMS treats as one and the same services furnished "under arrangements" that are themselves on the list of DHS with services that are not DHS. An "under arrangements" contract should not convert a service that is not a DHS to a DHS simply because there is a contract with a hospital and the service appears on the hospital bill. The law and Stark regulations already constrain physicians from owning entities that furnish DHS (*e.g.*, lab, therapy, radiology, etc.) absent a relevant exception. Treating the entity that furnishes a service that has not been designated by Congress as a DHS as if it is a DHS entity merely because that the entity has a contractual arrangement with a hospital that bills it as an inpatient or outpatient hospital service is an unwarranted expansion of the Stark Law.

Despite CMS's receipt of "anecdotal reports" of hospital/physician joint ventures that now provide services formerly provided by the hospital itself, there remain many legitimate reasons for a hospital contracting with an entity to provide services on an "under arrangements" basis. Specifically, we have been informed by health care entities that many of these services can often be provided on a more efficient, clinically appropriate basis by an entity that specializes in the provision of a particular type of services. For example, a free-standing ambulatory surgery center ("ASC") focuses only on the provision of outpatient surgeries and procedures. Because the ASC does not have the multiple departments with their conflicting interests and demands, it can often provide surgical services more effectively and efficiently than can a general acute care hospital. This leads to greater patient satisfaction because of less rescheduling and delays of surgery due to emergency/unscheduled surgeries. This is very important since most patients are transported to and from the ASC by family or friends who must take off work to perform this task. Cancellations and delays only lead to more days off of work for these transporters with a resulting negative effect on the economy and employers. In addition, ASCs allow for block scheduling which inpatient facilities are less able to do. This allows surgeons a greater efficiency which assists them in accepting low-paying Medicare patients, thus giving these patients access to a wider and more readily available group of specialists.

Hospitals that enter into "under arrangements" relationships are relieved of the burden of maintaining or expanding a particular service line, while still being able to provide much needed services to the members of its community. This frees up hospital capital to be spent on other much needed services and space and other resources within the hospital to be used for other services. It has been our experience that hospitals have found themselves unable to keep up with the demand for outpatient surgery capacity and have found that investing in ASCs to be a better use of their resources as compared to building and staffing larger outpatient surgery areas within

the hospitals. In addition, the partnered ASCs are not taxable entities providing tax revenues that would not be forthcoming from a nonprofit inpatient hospital.

Another advantage of having outpatient surgeries performed in the ASC setting is that in a hospital surgical patients are exposed to other patients with chronic illnesses or infectious diseases, making the post-operative patient susceptible to nosocomial infections. Microorganisms and pathogens can thrive in a hospital setting and can be transmitted by food and water, transfused blood and intravenous fluids, medications, air, direct human contact, linens and other carriers. ASCs pose less risk of infection because patients spend relatively little time in these facilities and have only minimal exposure to other patients and staff. In fact, the Institute for Healthcare Improvement has estimated the inpatient rate of surgical site infections to be between two and five percent (2-5%) for patients undergoing clean extra-abdominal operations and up to 20% in patients undergoing intra-abdominal procedures. This is compared to a post-surgical infection rate of 0.18% for ASCs (data taken from the Outcomes Monitoring Project Report, 1st quarter 2007).

From CMS's comments, it appears that it believes that entities only provide services "under arrangements" that are "medically less intensive." However, this is not accurate. Many ASCs provide a full range of surgical services, including complicated surgeries and procedures, that are comparable to hospital outpatient surgery units. We believe that CMS should research and compare the types of surgeries and procedures performed in hospital outpatient surgery units and those being performed at ASCs before concluding that ASCs are performing medically less intensive services than hospital outpatient surgery units.

CMS's concerns about the potential for over-utilization are already addressed, at least in part, by the "under arrangements" regulations that require that the provider of the services ensure that the procedures being performed are medically necessary. These requirements are summarized in CMS's General Information Eligibility and Entitlement Manual which states that "the provider (other than a SNF) must ensure that the medical necessity of such services is reviewed on a sample basis by the utilization review (UR) committee if one is in place, the facility's health professional staff, or an outside UR group. (CMS Pub. 100-1 Chapter 5) § 10.3. CMS may be in a better position to end abuses without negatively affecting legitimate providers of services under arrangement by enforcing the "under arrangements" requirements such as this one.

Instead of reversing Congress' and its own prior stance on this matter and trying to "fix" under arrangement violations by casting a wide net through the use of the Stark Law, CMS should instead focus its efforts on revising the "under arrangements" regulations to put a halt to the abusive arrangements. By doing so, CMS is much more likely to stop the abuses while allowing legitimate, non-abusive "under arrangements" relationships to continue.

Stand in the Shoes

In the Proposed Regulations, CMS suggests amending §411.354(c) to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS

entity would "stand in the shoes" of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties on the same terms as does the entity owned or controlled.

CMS's rationale for this proposal is that it believes that it is necessary to "collapse" these relationships to safeguard against "program abuse by parties who endeavor to avoid the application of the physician self-referral requirements by simply inserting an entity or contract in a chain of financial relationships linking a DHS entity and a referring physician." However, CMS has already addressed this concern in how it has defined expansively "indirect ownership interests" in §411.354(a)(1)(b)(5) and "indirect compensation arrangement" in §411.354(a)(1)(c)(2). This expansion of the definition of "indirect" interests in the final Stark II regulations captured many more layers of financial relationships for purposes of Stark law analysis and compliance than were previously thought to be implicated by the Stark law. We believe no further expansion or "stand in the shoes" concept is necessary to prevent parties from avoiding the application of the physician self-referral requirements.

Also troubling with respect to CMS's "stand in the shoes" notion is the concept of a DHS entity standing in the shoes of an entity it "controls." The Stark Law and implementing regulations always have been concerned with ***financial*** relationships, *i.e.*, ownership interests and compensation arrangements. The Proposed Regulations unduly expands the relationships implicating the Stark Law beyond the statute to control among affiliated organizations. Again, the expanded definition of "indirect" should be sufficient to capture any such affiliations where there are financial relationships among the organizations. No further expansion to "control" is warranted. Nowhere in the Stark statute does it mention "control." Moreover, "control" is a fuzzy notion that has no place in the Stark Law, where clarity and precision are essential. What would constitute control? A membership interest? A management/contractual arrangement? Board seats? If so, how many?

Even ownership under a "stand in the shoes" concept is difficult. Does it only apply to wholly owned entities? If some lesser percentage of ownership than wholly owned, is a majority interest necessary to trigger "stand in the shoes?" If the DHS entity owns a 40% interest, is that sufficient "ownership" to require the entity to "stand in the shoes?"

We believe that the adoption of the "stand in the shoe" concept contradicts CMS's position concerning the applicability of the exception for physician ownership interests in hospitals (at §411.356(c)(3)) and DHS entities owned by the hospitals. In the March 26, 2004 Phase II Interim Final Regulations, CMS stated that this exception would not permit physicians who own an interest in a hospital to refer patients to a DHS entity owned by the hospital. However, if CMS is unwilling to collapse a wholly owned subsidiary into its parent hospital for purposes of allowing a physician to satisfy an exception, then how can CMS argue that it should be able to interpret the Stark Law as requiring a DHS entity to be collapsed into a non-DHS entity for purposes of implicating the Stark Law in the first instance? We understand and support commenters' request for permission to use a "stand in the shoes" concept to qualify for an exception, but we take issue with CMS's proposal to mandate that "stand in the shoes" means that many indirect arrangements must now qualify as if they were direct arrangements.

If CMS adopts a stand-in the shoes concept, it must apply equally to exceptions as it does to the trigger. Moreover, CMS must think through the applicability of exceptions to all potential arrangements captured by stand-in-the-shoes. CMS's use of the medical foundation example is illustrative. While there are a number of exceptions that medical foundations may rely upon when they compensate physicians – in office ancillary services exception, personal services, employment, academic medical center exception – it is not clear that all of these exceptions would apply to hospital arrangements with physicians when they are deemed to "stand in the shoes" of the medical foundation. This could unintentionally upset many existing structures. CMS should limit the stand in the shoes concept to the area in which it makes the most sense – physician ownership of their group practices.

We further want to confirm with CMS that the "stand in the shoes" concept would not apply to faculty physicians who provide academic and clinical teaching services within an academic medical center. The AMC exception was carefully crafted by CMS in recognition of the unique circumstances and symbiotic relationship among faculty physicians the other components of the AMC, and nothing in the Proposed Regulations should affect the provisions that are reflected in that exception.

Unit of Service (Per Click Payments) in Space and Equipment Leases

CMS proposes to revise the space and equipment lease exceptions so that these leases may not include unit-of-service or "per-click" payments for services furnished when the physician who leases space or equipment to an entity refers patients to the entity for those services. This is in direct contrast to CMS's prior discussion of this very same topic. In Phase I of the Stark Regulations, CMS stated that it had "reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals." 66 Fed. Reg. at 876. CMS now appears to be proposing to ignore the intent of Congress and its own prior publicly stated position on the issue, on grounds that "such arrangements are susceptible to abuse." However, CMS does not explain what factors have changed in such arrangements to make them more susceptible to abuse now than they were when Congress passed the Stark Law and when CMS put its stamp of approval on such arrangements back in 2001.

Moreover, we believe that there is insufficient support for CMS's position that this compensation methodology for space and equipment leases results in abusive practices and that the current requirements under the Special Rules on Compensation in 411.354(d) includes sufficient safeguards in that the rental payments must reflect fair market value and that the equipment/space being leased is reasonable and necessary for the legitimate business purposes of the lease. These protections are more than adequate to protect the federal health care programs from abuse while allowing legitimate business arrangements between physicians and entities to exist and, therefore, CMS should not adopt these changes to the space and equipment lease exceptions.

In addition, medical equipment in general is very expensive and becoming more and more specialized. It may not be possible or desirable for a hospital or other entity to use precious capital on specialized equipment. The same is true for some entities when it comes to finding space for the variety of services it provides. It may be much more cost effective for the hospital or other entity to lease equipment/space from a physician lessor who also has a need for the equipment or space, or to lease equipment or space to a physician who needs are sporadic in nature. This is especially true for equipment purchases. For example, a specialize surgeon may purchase a piece of equipment that she uses several times a month primarily during outpatient surgeries. A hospital to which the physician refers patients may have an occasional need for this equipment for use on inpatients or for use by another surgeon performing the same or similar procedures at the hospital on a sporadic basis. It would make no sense for the hospital to spend scarce resources on a piece of expensive equipment it has a need for only occasionally. It makes much more sense to rent the equipment on a per-use basis from the physician owning the equipment. This is also true for arrangements in which the equipment is leased to the physician for occasional use.

CMS is trying to make it more difficult, if not impossible, for legitimate business arrangements for expensive space and equipment rentals between physicians and hospitals to exist. Prohibiting these types of arrangements will make expensive equipment less available to those health care entities and providers already struggling for their financial lives. It can be argued, of course, that these types of arrangement may still be permissible, but that a hospital would need to pay the physician leasing the equipment to or from the entity a set fee or in some other manner for the use of the equipment on his/her referred patients. Once again, CMS is putting an unnecessary administrative burden on health care providers to categorize use of the equipment based on the referring physician.

Set in Advance and Percentage Based Compensation Arrangements

In the Phase I Final Regulations promulgated in 2001, CMS took the position that percentage based arrangements did not satisfy the "set in advance" standard, which is a requirement of many of the exceptions applicable to compensation arrangements. However, given the prevalence of percentage-based compensation and the outcry by various segments of the industry, CMS subsequently postponed the adoption of this provision in the Phase I Final regulations. Finally, in the Phase II Interim Final Regulations promulgated in 2004, CMS reversed its stated position stating that it was "persuaded that our original position was overly restrictive" 69 Fed. Reg. at 16068. CMS then proceeded to modify the set in advance definition to allow percentage arrangements, provided that the percentage compensation is established with specificity prospectively, is objectively verifiable and is 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.

In the Proposed Regulations, CMS has once again reversed its current position on percentage arrangements by now proposing that percentage based compensation can apply only to pay

physicians for personally performed physician services. This is a surprising reversal given the attention that was previously given to percentage compensation arrangements in the Phase II regulations, as described above. Further, this proposed position makes meaningless the existing statutory exception for "physician services" (42 U.S.C. §1395nn(b)(1) and corresponding regulations (at 42 C.F. R. § 411.355(a)).

Under the Stark Law, it is only necessary to determine whether compensation is "set in advance" for referrals by a physician who has a compensation arrangement with an entity that needs to qualify under a Stark law exception that includes the "set in advance" requirement. However, CMS has defined the term "referral" to exclude any DHS "personally performed or provided by the referring physician." See 42 C.F.R. §411.351. As a consequence, any financial relationship that is related to services that the physician personally performs would not be subject to the Stark Law in the first place, since the provision of those services by the physician would not constitute a "referral" by definition. Thus, by limiting the definition of "set in advance" to allow only percentage compensation arrangements in connection with the services "personally performed" by the physician, CMS will be adopting a superfluous provision. It would never be necessary for a physician who receives compensation related to services that he/she is personally performing to even need to take advantage of an exception that includes a set in advance requirement.

We also believe that CMS's proposal creates an unwarranted restriction on compensation that rewards the achievement of certain milestones not directly related to physician services in a hospital. This proposal would seemingly overturn favorable advisory opinions issued by OIG in this area as well as other initiatives underway by Congress and CMS to reward physicians based on departmental quality and cost savings.

For these reasons, we do not believe that in 2004 CMS intended for the definition of "set in advance" to only permit percentage arrangements for services personally performed by a physician. We request that CMS withdraw its proposal to prohibit percentage based compensation arrangements to such services. We believe that the current standard for set in advance adequately protects CMS's interests because it requires percentage arrangements to be reflected formally in agreements, set the furnishing of the items or services and be stated in sufficient detail so that it can be objectively verified.

Burden of Proof

In the Proposed Regulations, CMS clarifies that in any appeal of a denial of payment for a DHS that was made pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the services was not furnished pursuant to a prohibited referral. CMS explains that this burden of proof posture is consistent with its policy governing claims denials. This provision on burden of proof for claims involving Stark covered services should not affect the burden of proof otherwise applicable in connection with other governmental sanction and enforcement provisions, such as civil monetary penalties, exclusions and other possible civil penalties.

In-Office Ancillary Services Exception

Although CMS declines to issue a specific proposal for amending the in-office ancillary services exception in the Proposed Regulations, it asks for comments as to whether changes are necessary and also asks for comments to four specific questions relating to (1) whether services not furnished on an incident to basis should be protected, and whether services not needed at the time of an office visit to assist the physician in diagnosis or plan of treatment should be protected, (2) whether changes to the definitions of "same building" and "centralized building" should be made, (3) whether nonspecialist physicians should be able to use the exception to refer specialized services to refer patients for specialized services involving use of equipment owned by the nonspecialists, and (4) whether other restrictions on the ownership or investment in services would curtail program or patient abuse.

In response, CMS should consider that the Stark Law was not intended to address physician scope of practice. We read CMS's discussion in the Proposed Regulations about pathologists, specialists, and physical therapy and occupational therapy services being furnished under the in-office ancillary services exception to reflect CMS's interjecting itself into "turf battles" between specialists, which is an area outside of the Stark Law. If CMS has a concern based on quality of care that a specialized service needs to be performed by a particular kind of physician, then CMS should address the issue in the coverage guidelines, not in self-referral regulations.

CMS also suggests amending the in-office ancillary services exception to limit the exception to services needed at the time to assist the physician in diagnosis or treatment. We believe that it is beyond CMS's statutory authority to promulgate a temporal restriction on the scope of the in-office ancillary services exception, and that such a provision would pose an unwarranted restriction on the scope of the in-office ancillary services exception. The in-office ancillary services exception was plainly intended to confirm the broad authority of physicians to practice medicine in a group practice setting where services can be performed on a cost-effective and patient-convenient basis. It is unclear why CMS would want Medicare and Medicaid patients to have to endure multiple appointments in disparate locations instead of obtaining one-stop shopping in a physician office setting. It also is unclear what precisely is the "cut-off" of services anticipated by the "needed at the time" restriction. Does this mean that services not essential to that particular physician office visit would no longer qualify for protection? What does this mean for courses of treatment now carried out more conveniently and cost-efficiently in a physician's office, such as chemotherapy? Are patients to be sent back to the more costly treatment venue of the hospital for such services?

With respect to adopting a limitation applying the exception to incident-to services only, it is clear that the statute does not limit the exception to only incident to services. Indeed, the term "incident to" is never mentioned in the statute, and the statute calls for "direct supervision" rather than the more stringent "direct personal supervision" of the incident-to standard. Moreover, this is resurrecting an issue that was put to rest long ago in the previous final Stark regulations. In the 2004 final regulations, CMS confirmed and restated definitively its position from the 2001 final regulation that the Stark law supervision standard is merely "the level necessary to meet the Medicare program payment and coverage rules applicable to the particular designated health

service." Thus, the Stark law supervision standard is "incident to" when Medicare requires it for coverage purposes, but a less stringent standard when Medicare coverage provisions allow general physician supervision for the service. This standard has been clear since 2001, and any modification absent clear and convincing evidence of abuse (not just "anecdotal reports") is plainly unwarranted.

Obstetrical Malpractice Insurance Subsidies

We applaud CMS's moving away from strict safe harbor compliance as the measure of Stark compliance. However, we believe that the exception should not be limited geographically to medically underserved areas or HPSAs. The problem that CMS described in the preamble for obstetrical malpractice insurance subsidies is not limited to HPSAs or MUAs. This issue over access to care can appear in any geographic area where there is unmet need for obstetrical services. We believe that there should be no requirements in the Stark Law exception relating to location of the entity or medical practice.

Period of Disallowance for Noncompliance Financial Relationships and Alternative Criteria for Satisfying Certain Exceptions

We support that CMS is contemplating setting limits on the period of disallowance for Stark law noncompliance as well as allowing "alternative" criteria for satisfying exceptions. This is especially important given the onerous Stark Law penalties involved, even in the event of inadvertent Stark law violations.

Indeed we believe that some circumstances warrant no "period of disallowance" at all. Specifically, if the parties to an arrangement did not realize that they were in violation, they ought to be able to reconcile the arrangement to be in compliance with the exception without any period of disallowance at any time before they are alerted by the government that there is a possible violation. Physicians frequently are not aware of the far reaching implications of the Stark law on their long-standing arrangements until they engage a compliance review which points out certain discrepancies in their longstanding practices. This may occur, for instance, in group practice compensation formulas. In such circumstances, the parties should be able to determine what permissible compensation should have been, alter the methodology on a going forward basis, and make an internal payment reconciliation with the affected physicians to achieve compliance, without violating the Stark law for any period of time whatsoever. Such a provision would encourage health care entities to conduct frequent compliance assessments and remedy any shortfalls in compliance, without being subject to the potentially onerous and far reaching Stark law penalties.

There also should not be any continuing disqualification from using an exception, also in light of the onerous Stark law penalties. In CMS's example, a mere $600 fair market value discrepancy would cause a hospital to be out millions of dollars in revenue from services referred by the physician, in addition to possible fines and penalties. Under such circumstances, CMS should not lengthen the period of time or make it more difficult to qualify for an exception.

We also question why the alternative means of satisfying exceptions for "violations" that are inadvertent and innocent is only upon self-disclosure. In light of the tremendous penalties involved and black and white nature of the prohibitions, there ought to be a means specified in the regulations for the parties to "fix" inadvertent "violations" internally or among themselves, and for CMS or any reviewing agency to exercise discretion upon later review without the need to go through the burden and expense of a self-disclosure.

The proposed regulations also contemplates that the "violations" are "self-disclosed to us." The question raised under this language is to what agency the disclosure must be made. Is it to CMS? Would a formal voluntary disclosure through the OIG self-disclosure protocol be required? Could a provider with a Corporate Integrity Agreement self-disclose to its CIA monitor? Would disclosure to the carrier or fiscal intermediary or program safeguard contractor suffice?

In sum, we fail to understand why there is no mechanism for simply fixing inadvertent violations without the burden and expensive of voluntary disclosure. We would recommend that the self-disclosure prerequisite be eliminated. If not, we believe that any reasonable disclosure to any governmental agency or agent should be acceptable.

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We appreciate the opportunity to comment on these proposed regulations, and we look forward to further clarification of these issues. In the meantime, please feel free to contact us if you have any questions or require further information in this regard.

Sincerely,

Marci Handler

David E. Matyas

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THOMSON

August 31, 2007

Centers for Medicare and Medicaid Services
Room 445-G Hubert Humphrey Building
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Washington, D.C. 20201

Re: CMS-1385-P, RIN 0938-AO65
Comments of Thomson Micromedex
DRUG COMPENDIA

Thomson Micromedex respectfully submits the following comments in response to the above captioned notice of proposed rulemaking. Our comments are limited to the portion of the proposed rule entitled "Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen (Sec. 414.930)" (DRUG COMPENDIA).

Thomson Micromedex' comments are organized as follows:

- General Background on Thomson Healthcare and Thomson Micromedex, the products DrugDex® and DrugPoints® Systems, (the latter product is the successor to the United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI®)), and a description of Thomson Micromedex' editorial process, conflict of interest policy, policy on external requests, and the "evidence rating" system employed by DrugDex and DrugPoints.

- An explanation of why the Secretary of Health & Human Services (HHS) should regard DrugPoints as a "successor" to USP DI and not a "substitute."

- A discussion of the Technology Assessment (TA) that was performed by the Agency for Health Research and Quality (AHRQ) acting through two of its Evidence-Based Practice Centers in connection with the Medicare Coverage Advisory Committee's (MedCAC's) review of various compendia. In particular, Thomson Micromedex is clarifying the record regarding errors that occurred in the evaluation of DrugDex.

- Thomson Micromedex' observations, comments and recommendations concerning the "desirable characteristics" that MedCAC identified for compendia.

- Thomson Micromedex' recommendations on changes in the proposed rule with regard to the compendia review process.

I. General Background

The following background supplies the facts necessary to support our subsequent comments and ensure that the Secretary of HHS and the Centers for Medicare and Medicaid Services (CMS) have a baseline of information regarding Thomson Micromedex' compendia.

A. Corporate Structure

The Thomson Corporation is a leading global provider of integrated information solutions for both business and professional customers. Thomson provides "must-have" information, utilizing technologies and applications that help our customers to make better, faster decisions. Thomson is organized into five segments: Legal, Financial, Tax & Accounting, Scientific, and Healthcare. The Healthcare segment "Thomson Healthcare" includes several strategic business units including the Thomson Healthcare business known as Micromedex.

The Micromedex business delivers information solutions into three markets: hospitals, corporate (including managed care organizations), and international. This business has over 9,600 customers worldwide in more than 92 countries and utilizes an international network of 43 distributors. Thomson Healthcare utilizes its Micromedex business to create, market and deliver clinical evidence-based products including DrugDex and DrugPoints. Located primarily in Denver, Colorado, Thomson Micromedex employs over 100 people whose primary role is to develop proprietary content in accordance with documented editorial policies and procedures. These editorial policies and procedures, discussed below and attached as Exhibits A – D, ensure that Thomson Micromedex' evidence-based drug content remains unbiased and supports appropriate drug therapy.

B. DrugDex and DrugPoints

DrugDex was first developed over 30 years ago. It contains comprehensive evidence-based drug information including detailed information on dosing, pharmacokinetics, adverse effects, FDA-approved and off-label uses, comparative efficacy, and other critical information on the appropriate use of drugs. The information is referenced to the underlying studies and intended to provide the healthcare professional with both broad and in-depth review of all aspects of prescription drugs.

DrugPoints was initially developed approximately ten years ago and has been greatly enhanced during the last two years in anticipation of becoming the successor to USP DI. DrugPoints contains summary drug information aimed at the point of care clinician. Derived from the same core drug information as DrugDex, DrugPoints provides evidence-based information delivered in a concise format to enhance readability and ease of quickly finding needed information. Sections include dosing, adverse effects, FDA-approved and off-label indications, interactions, toxicology, and pharmacokinetics.

DrugDex is cited in federal statute as a compendia to be referenced for purposes of conducting drug utilization review (DUR) under the Medicaid program and determining whether, for purposes of the Medicaid program, a proposed use of a drug should be

considered a "medically accepted indication" notwithstanding the absence of FDA approval for the proposed use (commonly referred to as an "off-label" use). (*See* 42 U.S.C. 1396r-8(k)(6); 42 U.S.C. 1396r-8(g)(1)). USP DI (or its successor publications) is also listed as compendia in this same statutory subsection. These statutory provisions are incorporated by reference into the definition of a covered drug employed under the Medicare Part D program (Social Security Act Section 1860D-2(e) (as added by the Medicare Prescription Drug, Improvement and Modernization Act., Pub. L. No. 108-173 (2003)). USP DI (or its successor publications) is also listed in 42 U.S.C. 1395x(t) as a reference compendia for making a similar determination as to whether a proposed off-label use constitutes a "medically accepted indication" for purposes of the Medicare Part B program. DrugDex is not listed under this latter statutory section.[1]

C. Editorial Process

Thomson Micromedex is committed to providing unbiased evidence-based information on drug uses in accordance with the available medical and scientific literature. Its policies and procedures are intended to ensure that the content maintains rigorous scientific integrity. Thus, Thomson Micromedex follows a defined workflow when creating and updating content, utilizes subject matter experts as needed when evaluating off-label indications, complies with a conflict of interest policy consistent with industry standards, and mandates adherence to it policy on external requests when interested third parties seek to influence the content. Furthermore, Thomson Micromedex employs an evidence-based approach to content creation. This approach is consistent with AHRQ and the U.S. Preventive Services Task Force Ratings of the quality of clinical evidence.[2] These policies and procedures, coupled with detailed analysis of the evidence, support Thomson Micromedex' goal of providing products of the highest quality.

1. Editorial WorkFlow

Thomson Micromedex' editorial workflow relies on over 100 full-time editorial staff members, including physicians, clinical pharmacists, nurses, other allied health professionals, and medical librarians. This staff follows a multiple step process to create and review the content of Thomson Micromedex products. (See Exhibit A.) Our editorial staff, under the direction of the Chief Medical Officer, is trained in the identification of relevant literature and critical literature evaluation techniques. These techniques, in combination with clinical judgment, are employed throughout the process of creating and revising content.

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[1] Thomson Micromedex recognizes that the proposed rule is addressing a process to update the list of compendia used for purposes of Medicare Part B, but we are also aware of pending federal legislation that, if enacted, would apply the updating process authorized for Medicare Part B to the Medicaid and Medicare Part D programs as well. *H.R. 3162 (The Children's Health and Medicare Protection (CHAMP) Act), 110th Cong., 1st Sess. Sec. 224* (2007). Thomson Micromedex anticipates that, should this legislative proposal become law, CMS might apply the same process it develops in this proposed rule to Medicare Part D and Medicaid.

[2] U.S. Preventive Services Task Force Ratings: Strength of Recommendations and Quality of Evidence. *Guide to Clinical Preventive Services, Third Edition: Periodic Updates*, 2000-2003. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/3rduspstf/ratings (accessed on 08/21/2007).

The process for identifying topics for research are based on numerous inputs, including literature review, clinical judgment, regulatory standards, healthcare trends, FDA actions, editorial board suggestions, external requests, and policy changes emanating from professional health care societies. The evidence is reviewed and evaluated for appropriate statistical analysis and methodological rigor. The iterative writing, reviewing and editing process allows only the best quality content to be promoted to production and released in our products.

In addition, an internal panel of senior clinical staff reviews all new content. Certain topics may undergo additional review by an external editorial board, which consists of experts in their field of study and practice. Thomson Micromedex supports several external boards with representation from specialties in cardiology, clinical toxicology, emergency medicine, endocrinology, neurology and pediatrics to name a few. Moreover, Thomson Micromedex established an Oncology Advisory Board to assist in the review of off-label drug indications in oncology practice. These external board members provide additional input particularly when documentation is controversial or indeterminate or when evidence ratings for off-label indications are subject to significant change based on new documentation.

2. Off-Label Indications

As discussed above, Thomson Micromedex' editorial workflow includes the review of off-label indications in drug therapy. This information is critical to clinicians in their day-to-day practice and thus our drug information products, DrugDex and DrugPoints, contain off-label indications. Mindful that these drug uses have not been reviewed by the FDA, Thomson Micromedex follows its off-label indication policy (attached as Exhibit B), to ensure that its review of off-label uses is consistent with evidence-based medicine and free from any inappropriate outside influence.

Off-label indications are identified through monitoring of the literature and other accepted sources of medical information (e.g. FDA, NIH, CDC). A thorough literature search is conducted to ensure that all relevant information is identified, including negative or inconclusive findings. External editorial board members including Oncology Advisory Board members review and scrutinize certain off-label indications. These board members must be practicing physicians with board certification in applicable specialty areas or practicing pharmacists with board certification and/or advanced training in applicable specialty areas. All editorial board members must comply with our conflict of interest policy.

3. Conflict of Interest Policy

Thomson Micromedex' conflict of interest policy is consistent with industry standards. (See Exhibit C). The policy is intended to ensure that individuals involved in literature evaluation and content development are not influenced by financial conflicts of interest. It is a three-tiered policy which provides that, for de-minimis levels, disclosure is not required; for additional levels, disclosure is required but is not deemed to be disqualifying; and, finally, disqualification results in situations where there is a significant potential for conflict due to the size or nature of a financial relationship.

4. Requesting Inclusion of Information

In order to accommodate third party requests while at the same time protecting our long-standing reputation as a leading provider of unbiased information, Thomson Micromedex established a process for requesting inclusion of information in Thomson Micromedex products. Our policy on external requests, (attached as Exhibit D), requires third parties that are interested in seeking review of a proposed off-label indication to provide all relevant information, including information on negative or inconclusive studies.[3] We also require the disclosure of information regarding relevant financial relationships.

DrugDex and DrugPoints are first and foremost intended to guide clinicians in the care and treatment of patients. Thomson Micromedex also recognizes that these products are used for determining reimbursement under public and private health care insurance programs, and thus the importance of considering external submissions in a rigorous, evidence-based and timely manner. At the same time, Thomson Micromedex is not structured as a clearinghouse for any and all requests for consideration of possible indications. Thus, while we will acknowledge that an external request has been received, we do not engage in a dialogue or debate with the third party submitting the literature or evidence.

Furthermore, in our experience the majority of these third party requests for consideration of indications have been previously identified by Thomson Micromedex' editorial staff. Nonetheless, regardless of how the indication is identified, it will be addressed through the same editorial workflow described above. Foremost the literature drives the indications that are reviewed. And, consistent with our policies, Thomson Micromedex prioritizes our review of these indications based on clinicians' needs for information, considering factors such as patient safety, break-through therapies, and available alternative treatment options.

D. Evidence-Based Medicine and Indication Ratings

Evidence-based medicine is the foundation for the recommendations that appear in DrugDex and DrugPoints. The need for an evidence-based approach to medical practice is widely accepted. Using an evidence-based rating system brings additional rigor to the assessment of indications, and allows clinicians to make better informed treatment decisions. Many schemas have been devised for the classification of the key elements of evidence-based medicine (e.g., strength of evidence, strength of recommendations, etc.). Thomson Micromedex' classification is patterned after the widely accepted American College of Cardiology/American Heart Association and U.S. Preventive Services Task Force (USPSTF) guidelines.[4] In both systems, well-designed clinical studies are given greater weight and poorly designed studies and case reports are assigned lesser weight. Evidence-based medicine does not negate the role of consensus, or expert opinion, in the

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[3] The policy also applies to parties seeking to change or de-list an off-label indication. For example, the policy requires a drug manufacturer that submits information to certify, among the other items listed in the policy, the inclusion of all findings relevant to that drug.

[4] U.S. Preventive Services Task Force Ratings: Strength of Recommendations and Quality of Evidence. Guide to Clinical Preventive Services, Third Edition: Periodic Updates, 2000-2003. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/3rduspstf/ratings.htm (accessed on 04/04/2007).

evaluation of evidence. Consensus is assigned to the lowest tier of evidence[5] and is superseded by data derived from rigorous, randomized controlled clinical trials.

Thomson Micromedex uses three distinct evidence based rating parameters that are applied to both FDA-labeled and off-label indications: Efficacy, Strength of Recommendation, and Strength of Evidence. All indications are assigned one rating for each of the three rating types. The assigned ratings appear in Drugdex and DrugPoints.[6]

Efficacy ratings are used relative to the general standard of care for the appropriate drug indication or treatment recommendation and are defined as follows:

Efficacy Rating Type	Rating Definition
Class I – Effective	Evidence – and/or expert opinion – suggests that a given drug treatment for a specific indication is effective.
Class IIa – Evidence Favors Efficacy	Evidence – and/or expert opinion – is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence – and/or expert opinion – favors efficacy.
Class IIb – Evidence Is Inconclusive	Evidence – and/or expert opinion – is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence – and/or expert opinion – argues against efficacy.
Class III – Ineffective	Evidence – and/or expert opinion – suggests that the given drug treatment for a specific indication is not effective.

Strength of Recommendation ratings for tests and treatment interventions are defined as follows:

Strength of Recommendation Rating Type	Rating Definition
Class I – Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa – Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb – Recommended, In Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III – Not Recommended	The given test or treatment is not useful and should be avoided.

[5] Methodology Manual for ACC/AHA, Guideline Writing Committees. Methodologies and Policies from the ACC/AHA Task Force on Practice Guidelines, April 2006. http://www.americanheart.org/downloadable/heart/1148391822076Methodology_Manual_for_ACC_AHA.pdf (accessed on 04/04/2007).

[6] Historically, USP DI contained limited information on indications and assigned only one of the following acceptance ratings: Accepted, Acceptance Not Established, and Unaccepted. During the transition to DrugPoints, Thomson Micromedex invested significant resources to revised and improve the simplistic USP DI rating system to a more granular, state of the art rating system.

Strength of Evidence ratings represents the evidence upon which recommendations or evaluations of efficacy are based on and are defined as follows:

Strength of Evidence Rating Type	Rating Definition
Category A	Category A evidence is based on data derived from: • Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies • Multiple, well done randomized clinical trials involving large numbers of patients
Category B	Category B evidence is based on data derived from: • Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies • Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). • Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).
Category C	Category C evidence is based on data derived from: • Expert opinion or consensus • Case reports or case series

Thomson Micromedex' evidence-based rating system provides an appropriately granular view of off-label indications and is designed to assist clinicians in making informed, evidence-based decisions about the proper care and treatment of their patients.

The actual indications included in the two Thomson Micromedex products vary. DrugDex, as the comprehensive in-depth product, includes all indications regardless of the assigned ratings. The concise DrugPoints product includes only those indications that meet the following rating criteria[7]:

1. All FDA-approved indications regardless of rating

2. Indications with a **Strength of Recommendation** rating of Recommended (Class I)

3. Indications meeting the following criteria and containing these ratings:
   (i) **Efficacy** rating of Effective or Evidence Favors Efficacy and **Strength of Recommendation** rating of Recommended in Most (Class IIa)

[7] There are a few cases where there is not yet sufficient supporting evidence for an indication to meet the criteria for inclusion in DrugPoints, but the use of a drug in practice warrants including the indication and providing dosing information. This occurs rarely and is identifiable by low Efficacy and Strength of Evidence ratings.

(ii) **Efficacy** rating of Effective or Evidence Favor Efficacy and **Strength of Recommendation** rating of Recommended in Some (Class IIb) if **Strength of Evidence** is A or B.

Our clinicians use DrugDex when they need to delve deeper into the indications and supporting evidence.

II. DrugPoints is the "successor" to USP DI

CMS indicates in its discussion of the proposed rule that CMS interprets Section 6001(f)(1) of the Deficit Reduction Act of 2005 (adding the phrase "or its successor publications" after the aforementioned statutory citations to USP DI) as explicitly authorizing the Secretary to continue to recognize the compendia currently known as USP DI after its name change if the Secretary determines that it is in fact a "successor" publication rather than a "substitute" publication.

Effective July 2007, Thomson Micromedex is no longer publishing a professional product under the USP DI name and, thus, USP DI is no longer being updated. Thomson Micromedex is publishing its successor product to USP DI, "DrugPoints," and regularly updating this product pursuant to the processes described above. Thomson Micromedex believes that the facts and circumstances make clear that, effective July 2007 DrugPoints is now the successor compendia to USP DI. Thus, the Secretary of HHS should expeditiously issue a determination to this effect and CMS should provide appropriate instruction to its contractors, carriers, States, territories and other relevant stakeholders regarding this determination. We note that this action does not require CMS to utilize the statutory updating process nor to await any updating process that may be created pursuant to this proposed rule, but can and should be done by executive action (e.g. carrier instruction and "Dear State Medicaid Director" letter). Thomson Micromedex is aware that at least one Medicare Part B carrier is currently indicating that it has not received direction to recognize DrugPoints for this purpose and is therefore not doing so. As time goes on, the legacy USP DI product will fall behind the current state of evidence-based medicine with regard to determining medically accepted off-label indications and expeditious action to recognize DrugPoints as the successor to USP DI is therefore warranted and respectfully requested.

CMS does not expand on its view of the difference between the terms "successor" and "substitute" or how that difference is meaningful to the current discussion. Based on a review of the definitions of these terms, Thomson Micromedex understands the distinction as follows: a "successor" is literally that which follows; comes next in time, or replaces another in position whereas a "substitute" is a thing that takes the place of another. [8]

There is ample evidence to support a determination that DrugPoints is the successor publication to USP DI and not a substitute. It is important to recognize that, although

[8] Merrian-Webster http://www.merriam-webster.com/; Oxford Concise http://www.askoxford.com/; Cambridge Advanced Learner **http://www.onelook.com/**; American Heritage http://www.bartleby.com

Thomson Micromedex has published a product under the name "DrugPoints" for several years, it is not simply replacing USP DI with the prior DrugPoints product. Rather, comprehensive changes have been made to DrugPoints as a consequence of its new role as the successor to USP DI.

Thomson Micromedex enhanced the DrugPoints product as of July 2007, specifically to ensure that it would succeed the USP DI product in all essential components, such as the inclusion of indication ratings, references, clinical teaching, toxicology information and common synonyms. The name change is the final step in a long, involved process of transitioning USP DI to DrugPoints. This transition occurred over a two year period and is described below.

In September 1998 Thomson Micromedex purchased the USP DI content and licensed the rights to the "USP DI" trademark from the United States Pharmacopeial Convention, Inc. (USP). For the next 4.5 years, Thomson Micromedex was responsible for the development of the evidence-based content and initial evidence rating review, while USP provided Thomson Micromedex with access to USP's expert committees to review Thomson Micromedex' assigned evidence ratings. In May 2004, complete editorial review responsibility transitioned to Thomson Micromedex and USP expert committees were no longer involved in evidence rating reviews. At that time USP and Thomson Micromedex agreed that the license to the USP DI trademark would cease in 2007 and thereafter neither party would use the mark "USP DI."

Thomson Micromedex continued to develop evidence-based content, as before, following a defined editorial process that, as discussed above, utilizes outside experts. In addition, Thomson Micromedex created the Oncology Advisory Board. Like the USP committee members, these experts are well known in their fields and associated with major organizations and healthcare facilities throughout the nation. Consistent with the USP approach to expert review, Thomson Micromedex has found the Oncology Advisory Board members extremely helpful in contributing the combination of practical experience and clinical research to the review process.

The final step in the transition occurred in early 2007 when Thomson Micromedex began notifying USP DI customers of the pending succession of DrugPoints and the name change from USP DI to DrugPoints pursuant to its contractual obligation to cease using the name USP DI. In July of this year, Thomson Micromedex ceased publication and updating of USP DI.

We would also note that Thomson Micromedex has been briefing CMS and Congress on this transition and the impending name change since at least 2005. Thomson Micromedex actively advocated before Congress to secure inclusion of Section 6001(f)(1) of the DRA and it was understood by lawmakers and staff involved in this amendment that the purpose was to recognize the Thomson Micromedex product that would succeed to USP DI. CMS was also informed of this legislative advocacy and the intent at the time it was underway.[9]

[9] At the time that the DRA was being legislated by Congress, no determination had yet been made as to what the successor product to USP DI would be named. Therefore it was not possible to simply insert the name of the successor product which is why the legislation reads as it does.

III. Comments Regarding the Technological Assessment (TA)

In its discussion, the proposed rule recounts some past activities leading up to the issuance of the proposed rule. The discussion indicates that CMS, acting through the agency for Health Research and Quality (AHRQ), commissioned a technology assessment (TA) on the currently Part B listed compendia as well as several other compendia. AHRQ contracted the TA to two of its Evidence-Based Practice Centers (EPCs) (New England Medical Center and Duke). The proposed rule indicates that the TA "found little agreement between the EPC's independent identification of evidence on 14 examples off-label indications and evidence cited in the drug compendia." We do not believe that this characterization of the TA is accurate with respect to Thomson Micromedex' DrugDex product for two reasons: (1) the New England Medical Center (NEMC) committed a major analytical error in that it did not, in fact, review DrugDex but instead mistakenly reviewed a different Thomson Micromedex product[10]; and (2) DrugDex actually fared quite well in the TA evaluation notwithstanding the NEMC's error and, when adjusted for this error, performed even better.

On the eve of the March 30, 2006, MedCAC hearing, CMS posted the Draft Technical Assessment (Draft Report) conducted by Duke and NEMC EPCs on its website. In reviewing the Draft, Thomson Micromedex found numerous errors in the report's findings regarding the DrugDex and USP DI products. We were therefore concerned by the need to correct the record regarding our provision of the highest quality, unbiased information. It was unfortunate that the MedCAC was presented with, and took action based on, a flawed TA. To the limited extent Thomson Micromedex was able to do so, we attempted to correct the record in our presentation to the MedCAC. Thomson Micromedex also took steps to correct the errors after the hearing and several of the issues we raised were corrected in the final report (Final Report). Unfortunately some of the issues were not corrected or addressed, and those exceptions include the following:

- Issue: Indication specific toxicity reporting. In the 2007 Final Report, there is a discrepancy in the reporting of the indication specific toxicity for DrugDex between what is presented in the tables and what is presented in the discussion section of the report. Four of the 14 tables that summarized the compendia listings for each indication reported that DrugDex listed indication specific toxicities. In contrast, the discussion section stated that DrugDex listed indication specific toxicities for <u>all</u> 14 indications. DrugDex does in fact include all 14 indications.

[10] DrugDex is Thomson Micromedex' drug information product that is a statutorily-referenced compendia for determining off-label uses under Medicaid and Medicare Part D. The NEMC researchers contracted by AHRQ inadvertently analyzed a different then-existing Thomson Healthcare product called "DrugPoints" that, by design, provided less comprehensive information. As a result, their report indicated that DrugDex did not contain information on certain indications when in fact DrugDex did contain such information. It should also be noted that the "DrugPoints" product that NEMC reviewed at that time no longer exists in that form, although the name "DrugPoints" has been retained and is now being used as the name of the successor compendia to USP DI. The use of the same name for an essentially different product could be an obvious source of confusion, and it is important therefore to clarify that the product currently known as DrugPoints is an enhancement and evolution of USP DI and not the same as the discontinued product previously marketed under this name.

- Issue: Reason for discrepancy in references cited. There are two reasons for the discrepancy in the literature cited in the 2007 Final Report and that cited in DrugDex. First is the specificity of the indication. Most of the indications listed in DrugDex were more specific than those listed in the 2007 Final Report. For example, with oxaliplatin, the 2007 Final Report listed lung cancer as the indication whereas DrugDex listed non-small cell lung cancer. Different literature would be cited for the specific indication of non-small cell lung cancer than the general indication of lung cancer. The second reason for the discrepancy is the methodological quality of the studies selected. Unlike the 2007 Final Report, DrugDex cites only studies of the best methodological quality rather than all that were identified through a literature search.

- Issue: Methods for grading and analyzing quality of studies. The 2007 Final Report did not place any importance on the methodological quality of the studies selected. In contrast, Thomson Micromedex views the evaluation of the methodological quality as critical to the evidence-based review process, utilizing an evaluation scheme similar to that of the American Heart Association and the U.S. Preventative Services Task Force. Of all literature identified for an indication, Thomson Micromedex selects those of highest methodological quality whereas the 2007 Final Report selected all studies regardless of methodological quality.

IV. Comments on MedCAC Identified Desirable Characteristics

The proposed rule reviews the March 30, 2006 public session of the Medicare Coverage Advisory Committee and the desirable characteristics identified by the MedCAC for compendia. Thomson Micromedex offers the following comments on whether these characteristics should govern future review of compendia under the process set forth in the proposed rule.

- *Extensive breadth of listings.* Thomson Micromedex agrees that this is an important characteristic.

- *Quick throughput from application for inclusion to listing.* Thomson Micromedex agrees that expeditious review of medical evidence and prompt updating of listings is a highly desirable characteristic. We caution that this desired characteristic should be balanced with the need to accommodate rigorous and judicious review of the evidence and validation by trained and experienced editorial professionals and external experts. Thomson Micromedex further notes that the use of term "application" in the characteristic is problematic because it assumes that the various compendia – both those presently listed under Part B and those not presently listed – follow a process whereby outside parties "apply" for listing. As discussed above, Thomson Micromedex has an off-label request policy for handling information submitted by outside parties but does not operate as an alternative mechanism to the FDA-approval process.

- *Detailed description of the evidence reviewed for every individual listing.* Thomson Micromedex agrees that this is an important characteristic. In addition, Thomson Micromedex acknowledges that to facilitate ease of use by practitioners, it is also valuable to provide summary information at the point of care. This summary information should be linked or supported by some means to more in depth information. Historically, USP DI was a summary database that provided short but concise assessments. Similarly, DrugPoints is a summary database, but in recognizing the needs of practitioners DrugPoints is linked to the robust and comprehensive DrugDex product. This linking allows the users to drill down into the detailed evidence and references for every individual listing.

- *Use of pre-specified published criteria for weighing evidence.* Published criteria is an important characteristic of compendia. Thomson Micromedex' rating system sets forth the criteria it uses to weigh the evidence and has fashioned its evidence based system of efficacy, strength of recommendation, and strength of evidence ratings on well known and accepted methodologies.

- *Use of prescribed published process for making recommendations.* Thomson Micromedex agrees that this is an important characteristic. Our published editorial process complies with this characteristic.

- *Publicly transparent process for evaluating therapies.* Thomson Micromedex' process of evaluating therapies involves a continuous review of the medical literature. We believe our current practice as described in Thomson Micromedex' published policy complies with this characteristic. Thomson Micromedex cautions, however, that this characteristic and the two above (*Use of prescribed published process for making recommendations and use of pre-specified published criteria for weighing evidence)* should not be interpreted or extended to require disclosure of the compendia owner's internal, confidential and proprietary editorial processes.

- *Explicit "Not Recommended" listing when validated evidence is appropriate.* Thomson Micromedex agrees that this is an important characteristic. The statutory language that governs the determination of whether an off-label use is medically indicated requires that a use be "supported" by one or more citations in compendia. It is therefore important that compendia through their rating system disclose when a referenced possible use is not recommended lest an argument be made that the mere inclusion of the possible use in a compendia requires its coverage. Additionally, there must be validated evidence available before any rating will be made – recommended or not recommended. The Thomson Micromedex editorial workflow is literature driven. If there is not sufficient literature available to justify a review of an indication, then the indication receives a lower priority and will be constantly reviewed for prioritization as more literature becomes available. As discussed above, only indications which meet the rating criteria are included in DrugPoints.

- *Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies.* We agree that this is an

important characteristic. Inclusion of sequential or combination therapies is included in DrugDex and DrugPoints and supported by validated research published in the primary literature.

- *Explicit "equivocal" listing when validated evidence is equivocal.* Thomson Micromedex agrees that an explicit "equivocal" listing is appropriate and our rating system is designed to provide information needed to assist clinicians and payers in assessing equivocal evidence on a particular use. As described previously, DrugDex and DrugPoints utilize a Strength of Recommendation category of "recommended in some cases" (tests or treatments that may be useful, and are indicated in some but not most cases) and an Efficacy rating of "evidence is inconclusive" (evidence/expert opinion is conflicting but the weight of evidence argues against efficacy) as well as a Strength of Evidence rating that indicates the type of evidence to support the ratings. Evidence ratings used in DrugDex and DrugPoints include a middle tier rating that includes meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. By analyzing very granular information to make recommendations regarding Efficacy, Strength of Recommendation, and Strength of Evidence, clinicians and payers can assess the information provided to make reasonable determinations regarding appropriate treatment.

- *Process for public identification and notification of potential conflicts of interest of the compendia's parent and sibling organizations, reviewers, and committee members, with an established procedure to recognize conflicts.* As mentioned above, Thomson Micromedex has a carefully developed conflicts policy which we would understand to entirely comply with this desired characteristic. Thomson Micromedex takes its role very seriously and has taken many steps to keep our editorial content development process separate from the influence of outside interests. Like other companies (for profit and not for profit) Thomson Micromedex utilizes conflict of interest policies to ensure that no inappropriate influence touches the editorial integrity of our products. The editorial team responsible for off-label content is operationally independent from editorial departments at other Thomson Healthcare businesses.

V. Comments Regarding the Proposed Process for Updating Compendia Listings

Regarding the proposed process for updating compendia listings that is central to this proposal, Thomson Micromedex offers the following recommended changes:

- CMS needs to provide appropriate instruction regarding the status of DrugPoints as the successor publication to USP DI effective July, 2007. CMS should take immediate steps to inform Medicaid program directors, Part B carriers, Part D plans, providers and other stakeholders regarding this determination.

- Do not make the process an annual process. An annual process for review of the compendia listing is inappropriate and a longer time interval should be adopted (perhaps every three years). We are concerned that it would pose an unreasonable burden in terms of time and expense to participate in such a federal regulatory process on an annual basis. There is not enough change in this field to warrant an annual process.

- Eliminate or modify the Characteristics of Compendia used in the evaluation process as discussed above.

- Establish threshold substantive criteria for de-listing of compendia. Thomson Micromedex suggests that the Secretary of HHS establish in any final regulation a minimum standard of evidence that must be met in order to warrant the removal of presently listed compendia. Specifically, we believe that, in order to de-list recognized compendia, a petitioner or CMS itself should be required to provide substantial evidence demonstrating that there has been a "material change" in currently listed compendia that justifies its removal and to state with specificity the nature of that material change and supporting justification.

VI. Conclusion

The USP DI compendia has been succeeded by DrugPoints, effective July 2007. DrugPoints uses the same evidence-based approach as DrugDex, which has been in use by practitioners as well as included in federal Medicaid and Medicare statutes for a number of years. Thomson Micromedex' evidence-based rating system brings rigor to the assessment of drug indications, and enhances the clinician's ability to make treatment decisions. We have a dedicated editorial team of over 100 professionals, and have invested significant time and resources to refine our content creation processes to be efficient, consistent, and quality-focused.

Thomson Micromedex is committed to providing unbiased, evidence-based information. We appreciate this opportunity to comment on the proposed rules and stand ready to assist the Secretary of HHS and CMS as they evaluate all the comments and issue the final rule.

Sincerely,

Dr. Alan Ying
Chief Medical Officer
Thomson Healthcare Inc.

Editorial Workflow

Over 100 full-time editorial staff members, including physicians, clinical pharmacists, nurses, and other allied health professionals as well as medical librarians, are involved in the multi-step process to create and review the content in Thomson Micromedex products.

Under the direction of the Chief Medical Officer, our editorial staff is also trained in the identification of relevant literature and accepted literature evaluation techniques that assess methodological rigor, appropriateness of statistical analyses, as well as clinical relevance. These literature evaluation skills, in conjunction with clinical judgment, are employed throughout the content creation and review process presented below.

All Thomson Micromedex content in proprietary products is developed in accordance with documented Thomson Micromedex editorial policies and procedures. Our content facilitates the practice of evidence-based medicine whereby the clinician can identify best practices and choose the most appropriate treatment plan for a specific patient.

Internal Medicine
Oncology
Geriatrics
Pediatrics
Emergency Medicine
Toxicology
Clinical Pharmacokinetics
Alternative Medicine

The senior Thomson Micromedex editorial staff considers many factors when selecting subjects for our databases. Topics chosen for further research are based on ongoing review of the world's medical journals, clinical judgment and recommendations, regulatory standards and compliance, national healthcare trends, FDA approvals, editorial board suggestions, external requests, and policy changes in health and disease management from professional health organizations.

The foundation of our ongoing literature surveillance is an automated literature query designed and monitored by an internal medical library staff and senior Thomson Micromedex editorial staff. This literature evaluation process comprises three levels: surveillance, title and abstract analysis, and full-text analysis. This three-step approach supports objective and systematic selection of the most important evidenced-based research.

Selected literature is prioritized and launched into the editorial workflow for content creation.

Primary literature identified in Step 1 is forwarded to a clinical writer to further assess the appropriateness of inclusion in our databases. This additional assessment is based on accepted literature evaluation techniques and includes an analysis of methodological rigor, application of statistics, and clinical relevance.

If deemed appropriate for inclusion, the information is summarized in our proprietary, state-of-the-art Content Management System. Clinical writers adhere to internal style guides, policies, and procedures to create accurate, consistent content.

Once written, new content is forwarded for internal review.

An internal senior clinical staff member reviews new content. The review assesses clinical accuracy and relevance as well as adherence to internal style guides, policies, and procedures.

Content creation and review is an iterative process by which the reviewer provides feedback to the writer. Content may cycle through the creation and review process several times before moving to the next step. This promotes continuous learning and serves to ensure our content is of the highest quality.

The Chief Medical Officer is ultimately responsible for the content output by the Thomson Micromedex editorial team. The senior clinical staff and internal experts regularly meet with the Chief Medical Officer to validate content decisions and to ensure inter-rater reliability within the group.

Certain topics may undergo additional review by a Thomson Micromedex Editorial Board.

An internal senior clinical staff member performs a final review of the content, taking into account any feedback received from the Editorial Board. Content is promoted to production and is available for release in Thomson Micromedex products.

The Thomson Micromedex editorial staff is dedicated to the integrity of our information.

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Off-Label Indications

Thomson Micromedex products contain FDA-approved or "labeled" indications as well as unapproved or "off-label" indications for drug therapy. Discovery and adoption of new uses for marketed drugs often precedes FDA approval of such uses. Furthermore, some manufacturers fail to seek FDA approval of rare indications, as the FDA application process may be cost prohibitive. Nonetheless, this information is critical to clinicians in day-to-day practice. Micromedex understands the importance of including information on off-label indications in its products.

To continue the long-standing reputation of Micromedex as a leading provider of unbiased information and to support best practices in drug therapy, Micromedex adheres to its policy for inclusion of off-label indications in its databases and products.

Cardiology & Nephrology
Clinical Toxicology & Substance Abuse
Critical Care & Emergency Medicine
Dermatology
Endocrinology
Gastroenterology
Hematology & Oncology
Infectious Diseases
Neurology
Nuclear Medicine & Radiology
Nutrition & Electrolytes
Obstetrics & Gynecology
Ophthalmology
Otorhinolaryngology
Pediatrics
Psychiatry
Pulmonology
Rheumatology & Clinical Immunology
Urology

At Micromedex there are two mechanisms for identifying off-label indications. First and foremost, off-label indications are identified through routine monitoring of the primary literature and other accepted sources of medical information such as the FDA, NIH, and CDC. Second, off-label indications may be identified through the consideration of external requests or suggestions for inclusion in Micromedex databases and products. The following are considered in prioritization of indication review:

- Patient safety
- Break-through therapies

Regardless of how the off-label indication is identified, members of the Micromedex editorial staff – in conjunction with the medical librarian – conduct a thorough search of the primary literature and other accepted sources of information to identify additional relevant, published information, including negative or inconclusive findings. This ensures all pertinent articles are considered in the analysis.

Once identified, the evidence is reviewed and evaluated for statistical and methodological validity. If the documentation is deemed sufficient to warrant inclusion, the off-label indication is added to the Micromedex database. In addition to thorough analysis of supporting documentation and internal clinical review, off-label indications meeting the following criteria are reviewed by an internal panel comprising the chief medical officer and members of the senior clinical staff:

- Rare diseases
- New indications with a Strength of Recommendation rating of "Recommended" or "Recommended in Most Cases," or an Acceptance rating of "Accepted"
- Existing indications for which the associated ratings significantly change

Occasionally, the internal panel determines documentation to be controversial or indeterminate. In these cases, the indications are sent to an external Editorial Board maintained by Micromedex. This board is made up of external experts with expertise in a variety of specialties.

Additionally, a separate board, the Oncology Advisory Board – made up of oncology experts, reviews new off-label indications related to oncology as well as revisions that result in a significant change in the associated ratings.

The board members must be practicing physicians with board certification in applicable specialty areas or practicing pharmacists with board certification and/or advanced training in applicable specialty areas. In addition, board members must have at least five years of clinical experience in the applicable specialty area and possess current knowledge of standard practices of care and established clinical guidelines related to drug therapy. All board members must comply with the Thomson Micromedex Conflict of Interest Policy.

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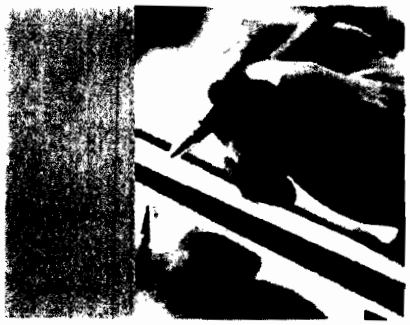
Conflict of Interest Policy



This document sets forth policies and procedures to help ensure individuals involved in literature evaluation and content development for Micromedex databases and products are free from financial conflicts of interest. Micromedex is committed to providing unbiased evidence-based information on drug uses in accordance with the available medical and scientific literature. The policies and procedures outlined herein identify and resolve potential conflicts of interest for Micromedex external advisors involved in the content development process.

Micromedex draws on the expertise of a range of individuals from within and outside the company to evaluate the available evidence on a drug. It is essential that these individuals be impartial and unbiased.

Particularly for outside advisors, the individuals may have affiliations with the drug sponsor or a competing drug sponsor, or may have a direct commercial interest in the drug. For example, a leading researcher in a particular field may act as a clinical trial investigator or as a consultant for the sponsor of a drug covered by a Micromedex database, or may have intellectual property and royalty rights in the drug. Where such financial relationships exist, there is the potential for a conflict of interest.

The drug information contained in Micromedex products may be used by physicians to facilitate prescribing determinations, or by third-party payers or government healthcare programs to facilitate coverage or reimbursement determinations. The content that Micromedex develops thus has a potential commercial impact on drug sponsors and consequently on individuals with financial ties to the sponsors.

Not all financial relationships are disqualifying. Financial relationships vary in type and size, and an overly broad conflict of interest policy would inappropriately preclude individuals with critical expertise from contributing to content development. This document thus sets forth a process to identify and categorize relevant financial relationships. Specific criteria are then applied for each category to determine whether disqualification or disclosure is necessary.

For the remainder of this policy, a drug sponsor will be referred to as a pharmaceutical company, meaning a company that sells and markets a pharmaceutical product.

Collecting Information on Financial Relationships

Before utilizing any external advisor, Micromedex will collect information on the individual's financial relationships with pharmaceutical companies. Information will be collected on the Financial Disclosure Form.

The Micromedex Editorial Department ("Editorial Department") will be responsible for ensuring that the forms are completed and maintained by Micromedex. Forms will be completed upon the beginning of an advisor's term on an advisory panel and annually thereafter. In addition, the Editorial Department will request the advisor to update any financial disclosure information prior to the advisor's work on any new assignment such as review of a particular monograph.

If an advisor or potential advisor refuses to provide information about his or her financial and other relevant interests, the person shall be disqualified from participation in content development for Micromedex.

General Rules for Identifying and Resolving Conflicts of Interest

When a new content development activity begins such as review of a particular indication, the Editorial Department will review the financial relationship information from the potential external advisors to be used and identify any financial relationships. If possible, the Editorial Department will select advisors to assist with the content development without any pertinent financial relationships. Where that is not possible because of the available pool of qualified individuals, the rules in the following section for different types of financial relationships will be applied.

Rules for Specific Financial Relationships

The following interests in pharmaceutical companies are considered to create a potential conflict of interest. In each case, the policy describes the scope of the interest and how it should be addressed. The policy is intended to cover the combined financial interests of the advisor and the advisor's spouse.

Employment or Leadership Positions

An individual who currently or within the past six months (a) is or was an employee, or (b) holds or held a position as a director of, or a partner in, any pharmaceutical company shall be excluded from participation.

Where the individual's spouse is an officer or director of, or a partner in, any pharmaceutical company, the individual shall be excluded from participation.

Equity or Stock Ownership

This section applies only to stock or equity ownership in a pharmaceutical company where the individual or the individual's spouse has direct control over the disposition of that ownership interest. It does not include an interest in stock held via a diversified fund, such as a mutual fund, which is under the control of another.

Where the combined value of the stock or equity ownership in any single pharmaceutical company held by the individual and/or the individual's spouse totals $25,000 or less, the individual shall be allowed to participate.

Where the combined value of the stock or equity ownership in any single pharmaceutical company held by the individual and/or the individual's spouse is greater than $25,000 but less than $100,000, the individual shall be allowed to participate and the individual's interest shall be disclosed.

Where the combined value of the stock or equity ownership in any single pharmaceutical company held by the individual and/or the individual's spouse is greater than $100,000, the individual shall not be permitted to participate

Advisory/Consulting Role; Lecture/Speaking Fees and Payments of Other Sorts

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August 31, 2007

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Acting Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
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Washington, DC 20201

DELIVERED BY MESSENGER

Attention: CMS-1385-P

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

Dear Mr. Kuhn:

I am contacting you on behalf of the 15,000 members of the American Academy of Dermatology Association (AADA) to share our comments on the proposed rule for Medicare payment for physician services in 2008, as published in the *Federal Register* on July 12, 2007. Given the significant, adverse impact of this particular proposal on Medicare patients' access to virtually all medical and surgical dermatology services and upon the practice of dermatology in general, it is our sincere hope that CMS will take the Academy's concerns and recommendations to heart when issuing the final rule for implementing the CY2008 Medicare physician fee schedule.

The Sustainable Growth Rate (SGR) and the Medicare Economic Index (MEI)

Unless Congress takes action to halt yet another projected conversion factor cut resulting from the flawed SGR formula, physicians will face a 10% across-the-board reduction in payments next year. The cumulative impact of several years' worth of projected cuts coupled with short-term legislative fixes to avert them is steadily eroding the fiscal soundness and overall stability of the Medicare Part B program, and thereby puts physicians in an increasingly untenable situation. The Academy therefore strongly favors repeal of the SGR formula and replacing it with
a new payment method that would accurately reflect changes in medical practice costs, such as a method based on the Medicare Economic Index (MEI).

The urgency underlying our request for a more equitable and accurate payment system cannot be overstated. If the SGR remains unchanged, then Medicare reimbursement for physician services will decline precipitously by nearly 40% over the next eight years. Yet during this same period medical practice costs as reflected by the MEI are projected to climb 20%. As millions more Americans become eligible for Medicare coverage, physicians are expected to furnish services while at the same time instituting new quality reporting and measurement requirements and meeting a growing array of compliance demands. The ability to do so is impacted in direct and indirect ways by the Medicare physician fee schedule. It should be no surprise to CMS that as physician reimbursement plummets, it is difficult for practices to comply with so many new demands, modernize practices with emerging technologies, and to see more patients, too.

For these reasons, we urge CMS to work with Congress and the physician community to repeal the SGR formula and replace it with a new formula based on the MEI. Furthermore, we urge CMS to update the MEI itself so it reflects current inputs and assumptions and not just those in place in 1973 when the index was established. Likewise, we urge CMS to reduce the proposed 1.5% MEI productivity adjustment applicable to physicians to 0.65%. This latter percentage is equivalent to the productivity adjustment proposed for all other Medicare providers next year and is also consistent with President Bush's recommendation on this matter. In addition, if CMS chose to exercise authority it already has to do so, the agency could improve the fairness of the system by retroactively removing the cost of drugs administered in physician offices from the Part B physician payment pool, thereby restoring billions of dollars that could be used to stabilize the program while promoting access to healthcare services for Medicare beneficiaries.

Impact – Budget Neutrality Adjustment

In this proposal, CMS plans to reduce all physician work relative value unit (RVU) values by -10.1% to -11.8% to achieve budget neutrality in the fee schedule. The majority of physician specialties opposes application of the budget neutrality adjuster to the work values, and has asked CMS to make this adjustment to the conversion factor. In fact, from 1998 to 2006, CMS applied the adjuster to the conversion factor. Unfortunately, CMS chose to apply the budget neutrality adjustment to work values in 2007 without providing sufficient rationale for doing so. For 2008, the Academy respectfully urges CMS to return to the well-established practice of applying any budget neutrality adjustment to the conversion factor, as supported by organized medicine.

Multiple Procedure Payment Reduction for Mohs Surgery

The proposed rule explicitly withdraws the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures. This exemption for the Mohs Micrographic surgery codes was established in the 1992 Medicare Physician Fee Schedule and maintained by CMS within all subsequent fee schedules since 1992 (see Federal Register, Vol. 56, No. 227, Nov 25, 1991, page 59602). We believe that this CMS action will unduly impact not only those Medicare beneficiaries who have or will be diagnosed with skin cancer but also those surgical dermatologists who provide these services. We also believe that the proposal fails to articulate adequate justification for this action.

First, CMS states that "the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list". This appears to be both irrelevant to the issue at hand and factually incorrect. That the removal of these codes from the exempt list is presented in a notice of proposed rulemaking (NPRM) is merely evidence that CMS recognizes that payment policy formulation responsibility lies within the agency and not CPT. Furthermore, we do not believe that the CPT Editorial Panel explicitly took this action as stated.

Second, the proposal focuses on the AMA/Specialty Society Relative Value Update Committee (RUC) by correctly noting that (1) the RUC valued each Mohs code carefully; (2) the RUC assumed each code is a separate procedure; and (3) the RUC did not consider efficiencies when the procedures are performed on the same day. However, the proposal then inexplicably relies on these very same statements to justify changing the existing and longstanding CMS policy. While these three factors are correct they do not justify the conclusion that the Mohs codes should suddenly now be subject to the Multiple Procedure Reduction Rule. For example, it is no surprise that the RUC dismissed the efficiencies issue since CMS has long recognized that there are no efficiencies inherent in these procedures when performed together. Therefore factors cited as the reason for removal from the exempt list are, in reality, the very same factors that CMS has previously considered and recognized to justify exemption. Simply stating the factors does not provide any insight into the reasoning why such a drastic change is being contemplated at this time. The proposal does not provide any explanation for this proposed change and certainly does not justify the reversal of a previously well considered and long standing CMS payment policy. CMS should therefore defer from making this change, and any proposal for change in the future should be based on a sound rationale and factual data.

CMS agreed at the time the Mohs procedures were introduced that these *"are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be*

paid separately with no multiple surgery reductions." This conclusion is still correct and applicable today.

We are also very fearful that this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. Furthermore, application of the Multiple Procedure Reduction Rule is unlikely to generate significant cost savings and may paradoxically increase the cost of providing care to these patients, precisely for the reasons that CMS originally cited for granting the current exemption.

The fact that in this rule CMS appears to grant RUC policymaking authority is an interesting issue that must be addressed. First, let the Academy state here that we strongly support the RUC process and recognize the value it brings to the annual task of developing the Medicare physician fee schedule. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this, the RUC defied the predictions of critics who claimed that reaching consensus and agreement would not be possible among the various stakeholders.

The RUC and CMS have also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that particular allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. By contrast, all policy decisions affecting the Medicare physician fee schedule have undergone full development by CMS in the public notice and comment process. It does not appear that such an open and fair process has been followed with respect to the MPRR policy and Mohs surgery, as proposed in the NPRM by CMS. To have the RUC thus engaged in these policy formulations-- in a forum which is not open or accessible to the public, as is implied by this propsal--is unfair to the affected Medicare beneficiaries and threatens the RUC process. We disagree with using the RUC for this purpose. However, if CMS believes the RUC role should be expanded to the policy making sphere, it should be done in a direct manner by explicitly giving the RUC a public and well-articulated charge to take on this task.

In light of the concerns raised above, the Academy respectfully requests reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, CPT 17311 and CPT 17313, as appropriately exempt from the Multiple Procedure Reduction Rule as are the other add-on Mohs codes. We therefore request continuation of the exemption from the MPRR.

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

We realize that the Tax Relief and Health Care Act of 2006 (TRHCA) places CMS in the awkward position of expanding the PQRI through the fee schedule rulemaking process although the PQRI pilot project is not yet completed, and the agency is therefore deprived of data on which to base any program expansions. This timeframe leaves no opportunity to evaluate the 2007 PQRI before moving forward with the 2008 PQRI. Because of this situation, we urge CMS to incorporate the provisions of the Voluntary Medicare Quality Reporting Act (S. 1591/H.R. 2749) into the rule for implementing the fee schedule rule next year. This legislation, which can be read by clicking on http://thomas.loc.gov, directs CMS to report the results of the PQRI 2007 to Congress before proceeding with an expansion of the program, to focus the development of measures only on identified gaps in care, and to ensure that any Medicare physicians' quality program is voluntary, among other things..

The Academy also believes that the proposal's requirement that measures for the 2008 PQRI program be developed through the use of a consensus-based process should be clarified to recognize the AMA Physician Consortium for Performance Improvement (PCPI) as the entity for the development of physician-level quality measures.

TRHCA – Section 101(d) Physician Assistance and Quality Initiative (PAQI)

The Academy very strongly supports using the $1.35 billion in the PAQI fund for reducing the impact of the 10% Medicare physician payment cut in 2008. The proposal to use these funds to reward quality reporting activities as part of the 2007 PQRI pilot project is inconsistent with congressional intent, as expressed in the Tax Relief and Health Care Act of 2006. We disagree that there are any legal or operational obstacles to applying the PAQI funds to offsetting the update cut. Furthermore, using these funds to offset the draconian 10% cut will provide tangible relieve for all Medicare physicians whereas only those physicians reporting to the PQRI would realized any benefit under the CMS proposal. Fairness and the looming cut demand that the entire $1.35 billion be applied towards reducing the payment cut.

Medicare Telehealth Services

The Academy appreciates CMS extending the opportunity to submit requests for added telehealth services to the Medicare program. Besides increasing access for patients, telemedicine may also reduce overall costs. The Academy believes teledermatology fits well into telehealth services category 1, for office and other outpatient visits and consultations. Dermatology patients who participate in telemedicine would otherwise likely receive treatment for their skin conditions from a non-dermatologist physician, the accuracy of the diagnoses rendered via telemedicine can be higher and diseases can

be treated effectively and at earlier stages than they would be if a patient waited until complications made a long trip to see a dermatologist imperative. Patients who are spared a long trip also benefit economically from such an arrangement because they do not bear the cost of missing work or traveling. Telemedicine moves information – not the patient.

While making treatment more effective for patients, telemedicine also helps to make optimal use of the short supply of dermatologists. While it will never replace the face to face patient visit, the Academy considers telemedicine a viable method of treatment and one important component of an overall plan to improve patient access to dermatology.

Currently, Medicare reimburses telemedicine for rural patients (defined as patients who live in non-metropolitan statistical areas) if it takes place in a live interactive ("two way") mode. The patient and physician communicate in real time but from different locations using video conferencing technology. Medicare reimbursement currently does not exist for store and forward consultations, which take place when patient pictures and information are forwarded by a referring physician to a dermatologist, who evaluates them and responds with a diagnosis and treatment plan. The AADA and the American Telemedicine Association have reviewed the effectiveness of live interactive telemedicine visits compared with store and forward and found both to be clinically equivalent to traditional face to face patient encounters. Store and forward is more convenient for both the patient and the two physicians, allowing for asynchronous communication that simplifies the amount of coordination required. Therefore, the AADA believes that dermatologic office visits conducted via live interactive or store and forward telemedicine should be covered under the Medicare program and we will actively pursue reimbursement.

Physician Self Referral Issues

Overall, the physician self-referral issue is complex enough that it warrants being extracted from this fee schedule rulemaking proposal and addressed separately. The Academy therefore urges CMS to address physician self-referral issues in a separate proposal.

Notwithstanding this request, we will address the anti-markup provision of this proposal in this comments letter. The Academy appreciates the opportunity to comment on the contemplated changes to reassignment and physician self-referral rules relating to diagnostic services (the anti-markup provisions). We believe that CMS' decision to focus on the billing of diagnostic tests of one physician or group where the diagnostic test is performed by someone other than a full-time employee is appropriate. In addition, CMS' approach of paying the lesser of the Medicare fee schedule amount, actual charges, or the charges of the physician performing the diagnostic interpretative test is reasonable. We believe that the proposal to expand the anti-markup provisions from the

current technical component to include and cover the professional interpretative component not only simplifies the billing of such services but also strengthens the anti-markup prohibition. We agree that the physician performing the interpretation should be the only entity billing for this professional service. We recognize that some of these proposed measures may be needed in response to perceived Medicare abuses and to discourage business arrangements that carry significant risks of fraud and waste through kickbacks, fee-splitting and mark-ups, reassignments, generation of unnecessary pathology lab tests, inappropriate referrals, and other dubious practices.

We are, however, concerned that the proposed changes contemplated by CMS regarding anti-markup provisions related to anatomic pathology laboratory services may prevent dermatologists from practicing their specialty and risk harming patient care. It appears that much of CMS' rationale regarding diagnostic services has been focused disproportionately on issues related to size and location of laboratories, and the unfair presumption that physicians (such as dermatologists and dermatopathologists who are trained and able to biopsy, diagnose, and treat their patients) should not be allowed to order diagnostic tests they also perform as part of their full scope of service. **The Academy wishes to emphasize a key point: dermatologists who order a diagnostic test, should be able to perform and bill for such a test.** CMS should consider the adverse impact such constraints can have on our specialty by denying dermatologists and their patients access to accurate and timely interpretation of skin biopsies, and the attendant risk of compromising patient safety and quality of care.

The Academy strongly encourages CMS to consider the negative implications such revisions would have by preventing patients from access to care and restricting dermatologists—the physician specialists treating the majority of melanoma patients—from exercising their choice of dermatopathologists. All dermatologists have training and experience in dermatopathology. Indeed, dermatopathology is an integral part of a dermatologist's professional training. Dermatologists receive intensive training in dermatology, which includes
dermatopathology and dermatologic surgery. With this background and knowledge, dermatologists are singularly qualified to diagnose and treat the wide variety of dermatologic conditions as well as benign and malignant skin tumors. Dermatologists perform many specialized diagnostic procedures and often purchase the technical component (slide preparation) in order to be able to perform their own in-house diagnostic interpretation and pathology report.

The Academy is concerned that the proposed rule may be misinterpreted and misapplied so as to prevent a dermatologist from being able to read their own slides. As many dermatologists choose to interpret their own dermatopathology, the Academy supports the right of dermatologists to be able to continue to perform their own dermatopathology diagnostic interpretation, including having the ability to purchase the technical component, in accordance with current Medicare regulations, from an outside

lab vendor in order to provide their own in-house professional diagnosis and render cost-effective quality patient care. We wish to remind CMS that the expertise of dermatopathologists is relatively cost-effective because as the foremost experts in reading and interpreting skin biopsy specimens, dermatopathologists are able to detect and properly diagnose skin biopsies the first time around. Moreover, the consultative communication that goes on between dermatologists and their trusted dermatopathologists is essential; without communication or trained eyes, the skin's subtle signs may confuse and mislead. Misdiagnosis leads not only to deficient care by forcing patients to undergo unnecessary procedures, but also increases the cost of care and the risk of a liability lawsuit. Conversely, an early and correct diagnosis allows a problem to be treated before it becomes more severe—and thus more costly to treat.

We consider dermatopathologic interpretation of biopsies an integral part of a dermatologist's ability to serve their patients. Many dermatologists prefer to refer skin biopsy specimens to specialized dermatopathology labs directed and staffed by dermatologists and/or pathologists with expertise in dermatopathology and immunopathology. Pathologists employed with national reference labs often lack this high level of training and expertise to accurately interpret skin biopsies. Accurate interpretation of skin biopsies requires an ability to recognize and record the details of the specimen, and to synthesize these findings with the clinical data available. Failure to interpret skin biopsies can mislead the clinician and interfere with appropriate medical or surgical therapy, potentially harming the patient.

The Academy wishes to remind CMS that changes contemplated in the anti-markup provision final rule, designed to address of pathology lab services, need to be simple, straightforward, and uncomplicated so as to lighten the regulatory burden, minimize the margin of error, and contain costs. To that end, we wish to emphasize the following points:

- Dermatologists should have the opportunity and the right to interpret their own specimens and be reimbursed appropriately for the professional component as part of their professional scope of services.

- According to current CMS purchased diagnostic test regulations, if the tissue is prepared by an outside lab, either the lab should bill Medicare directly for the technical component, or the dermatologist can submit the bill to Medicare for the ***lesser of either*** the net lab charge, actual physician billing charge, or the Medicare fee schedule amount. We believe that such a scenario offers straightforward guidance to allow a physician to follow the basic premise ***when performing a medical service, the physician should be reimbursed for that service—nothing more, nothing less.***

- We recommend a back-to-basics approach wherein one could not mark up a "purchased diagnostic test". Whether it is the technical component or the professional component, if there is ***no mark up allowed***, there would be no problem. Indeed, such a clear and uncomplicated guideline would allow dermatologists to read their own slides and be reimbursed appropriately for this service and dermatopathologists, who have full-service labs, to be reimbursed fairly and appropriately for their services and not be in jeopardy of participating in fee-splitting and mark-up arrangements.

We believe that the best patient care is given when dermatopathologists are focused on managing their lab and being responsible for various regulations in their lab, rather than running around and dividing their attention among different "pod" lab practices for purposes of marking up assigned pathology services. We believe that by removing the financial incentives for markups and eliminating the opportunity of profit for increased self-referrals, CMS can effectively addresses its concerns raised in the anti-markup proposed rules. Medicare patients can be assured improved quality of care if their physicians have access to expert opinions from specialists trained in the evaluation of skin biopsy specimens. By working together, we believe we can help ensure patient safety and quality of care.

Proposed Elimination of Exemption for Computer-Generated Facsimiles

As office-based physicians, dermatologists recognize electronic prescribing (e-prescribing) is as much a patient safety issue as it is a workflow issue. Indeed, the most apparent benefits for dermatologists using e-prescribing include: speedy point-to-point ordering, transmission and tracking from prescribing physician to dispensing pharmacies; reduced medication errors or duplication; increased accuracy and transparency of the transaction; improved legibility; efficiency gains in practice workflow and reduced administrative steps; as well as enhanced ability to share and coordinate patient care information. The Academy is concerned with the proposed elimination of the exemption for computer-generated faxes from the e-prescribing standards by January 2009. By doing so, CMS may be overlooking the need for greater implementation flexibility and operational scalability for the prescribing office-based specialists, including dermatologists.

The Academy believes that e-prescribing can be a means to improving patient safety and increasing efficiency in the delivery of quality care. While the Academy encourages dermatologists who are keen on adopting new health information management technologies to do so, we are concerned that another unfunded e-prescribing mandate—particularly in the face of CMS' 2008 proposal to cut Medicare physician payments—will be counterproductive. We are concerned that many dermatology practices may lack the software that permits them to transmit computer-generated faxes

using the e-prescribing SCRIPT standard. Moreover, complying with this rule could require the purchase of costly new products and staff retraining. The Academy urges CMS to assess regularly the readiness level of both physician practices and pharmacies and extend the compliance date if too few organizations adopt this standard prior to the proposed implementation date of Jan. 1, 2009. While we support efforts to move the healthcare industry steadily toward full adoption of the e-prescribing standard, we request that such efforts take into account the realities of small and medium office-based practices. Therefore, we encourage CMS to increase the level of educational activities targeted to office-based physicians. To achieve this, CMS should augment its current level of educational outreach on health information technology, and particularly e-prescribing. Such outreach should target small and medium sized office-based practices, with special focus on steps required to implement and achieve return on investment from use of the SCRIPT standard, and coordinate with industry to ensure communication of a unified and consistent message.

Furthermore, the Academy calls on CMS to increase the level of health information technology vendor educational activities. As the industry found with the recent National Provider Identifier experience, physicians and their practices must often rely on entities, not covered by Medicare provisions, to come into compliance with those provisions. CMS should work more closely with health IT vendors to ensure that they understand the regulation and what the government expects of their covered-entity customers. CMS should offer vendors technical assistance to facilitate the development of appropriate products for all covered entities. The Academy suggests that CMS conduct regular assessments of industry progress. CMS should survey the industry on a regular basis after the final Medicare rule takes effect. These regular polls should include all provider types, pharmacies and health IT vendors. Ascertaining the number of health IT vendors that have updated their products and the number of medical groups and pharmacies that have adopted the standard will be critical to ensure that physicians do not revert to paper prescribing.

Finally, we urge CMS to extend the compliance date based on industry readiness: CMS should extend the compliance date should industry surveys not show an appropriate level of migration to the SCRIPT standard. It is critical that small and medium office-based practices have sufficient time to update their electronic prescribing systems and train clinical and administrative staff.

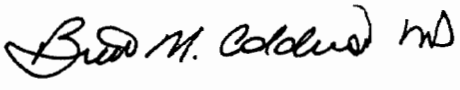
While we understand CMS' objective to foster greater practice automation through the migration toward the e-prescribing SCRIPT standard, based on the proposal to eliminate the exemption for computer-generated facsimiles, we strongly urge CMS to augment its educational activities, regularly assess the readiness level of the industry and extend the SCRIPT standard compliance date should the industry not be ready to adopt it a year after the effective date of the 2008 physician-fee-schedule final rule. The

Academy believes that it would be better to extend the compliance date than penalize practitioners. Forcing physicians to revert to paper prescriptions might jeopardize patient safety. While the Academy is confident that e-prescribing can help advance safe, quality-based, efficient and affordable patient care, further consideration must be given to overcoming the above structural, operational and fiscal barriers that prevent e-prescribing from becoming a widespread standard practice.

Conclusion

Let me conclude by reiterating the Academy's appreciation for this opportunity to comment on the various Medicare fee schedule changes proposed by CMS. We are eager to work with the agency to address these serious concerns in a manner that promotes access to dermatology services for Medicare patients while promoting fairness for the physicians delivering those services. I encourage you to contact Laura Saul Edwards (at ledwards@aad.org or 202.712.2602) and Norma Border (at nborder@aad.org of 847.240.1814) on our staff to discuss our concerns and the ways we can resolve them in he final rule for implementing the 2008 fee schedule. Thank you.

Sincerely,



Brett M. Coldiron, MD, FAAD
Chair, Health Care Finance Committee

BMC/jeb/nb/wb/lse

Attachment

cc: Diane R. Baker, MD, FAAD, President
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C. William Hanke, MD, FAAD, President-Elect
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Bruce A. Deitchman, MD, FAAD, AAD Alternate Representative to the AMA RUC
Dirk M. Elston, MD, FAAD, AAD Advisor to the AMA CPT Advisory Committee

James A. Zalla, MD, FAAD, AAD Representative to the AMA Correct Coding Initiative Committee
Ronald A. Henrichs, CAE, Executive Director & CEO
Karen Collishaw, Deputy Executive Director, AADA
Judit Magel, PhD, Senior Director, Practice Management, Science & Research
Laura Saul Edwards, Director, Federal Affairs
Norma Border, Senior Manager, Coding & Reimbursement
Jayna Bonfini, Assistant Director, Federal Affairs
William Brady, Manager, Practice Management

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

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

[Mohs Micrographic Surgery]

Comment: Some commenters stated that [illegible] graphic surgery, CPT [illegible] should be [illegible] multiple surgery [illegible] a series of [illegible] done on the same [illegible] operative [illegible] clearly separate [illegible] series of procedures. [illegible] the sense that these [illegible] are contemplated to [illegible] surgical procedures; they will be paid separately with no multiple surgery reductions.

[Multiple Surgery Policy for Multiple Trauma]

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

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

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

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

[Bilateral Surgery Code Applying to Ophthalmic Procedures]

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

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

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

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

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

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

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

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

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

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August 23, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201
Phone: 202-690-6726

Re: CMS 1385-P: 2008 Medicare Fee Schedule, Section II.E.2
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

On behalf of the members of the American Academy of Dermatology Association (AADA), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS) and the American Society for Mohs Surgery (ASMS), we are jointly submitting comment to you on the 2008 Medicare Fee Schedule: Proposed Rule regarding the explicit withdrawal of the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures. We appreciate this opportunity to offer comment on Section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

This proposed CMS action takes away the specific exemption accorded to the Mohs Micrographic surgery codes in the 1992 Medicare Physician Fee Schedule and maintained by CMS within all subsequent fee schedules since 1992 (see Federal Register, Vol. 56, No. 227, Nov 25, 1991, pg. 59602). We believe that this CMS action will unduly impact not only those Medicare beneficiaries who have or will be diagnosed with skin cancer but also those surgical dermatologists who provide these services. We also believe that the NPRM fails to articulate adequate justification for this action.

First, CMS states that "the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list." This appears to be both irrelevant and factually incorrect. That the removal of these codes from the exempt list is presented in an NPRM is evidence that CMS recognizes the payment policy formulation responsibility lies with the agency and not CPT. We also do not believe that the CPT Editorial Panel explicitly took this action as stated.

Second, the NPRM correctly states that 1) the AMA/Specialty Society Relative Value Update Committee (RUC) valued each code carefully; 2) the RUC assumed each code is a separate procedure, and 3) the RUC did not consider efficiencies when the procedures are performed on the same day. The NPRM then relies on these statements to justify changing the existing longstanding CMS policy. While these three factors are correct, they do not justify the NPRM's stated conclusion that these codes should not be exempt from the multiple procedure reduction rule. It is no surprise that the RUC did not consider efficiencies since CMS has long recognized that there are no efficiencies inherent in these procedures when performed together. Therefore, factors cited as the reason for removal from the exempt list are, in reality, the very same factors that CMS has previously considered and recognized to justify exemption. Simply stating the

factors does not provide any insight into the reasoning why a change is contemplated. The NPRM does not provide any explanation for this proposed change and certainly does not justify the reversal of a previously well-considered and long- standing CMS payment policy. CMS should defer from making this change and any proposal for change in the future should be based on sound rationale and factual data.

CMS agreed in the 1992 Medicare Fee Schedule: Final Rule that these *"are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be paid separately with no multiple surgery reductions."* This conclusion is still correct and applicable today.

We believe this proposal will negatively impact Medicare beneficiaries' access to timely and quality care and application of the Multiple Procedure Reduction Rule will not likely generate significant cost savings and may paradoxically increase the cost of providing care to these patients.

The American Academy of Dermatology (AAD), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS) and the American Society for Mohs Surgery (ASMS) support the RUC process and recognize the value it brings to the annual Medicare physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this, the RUC defied the predictions of critics who claimed that agreement would not be possible among the various stakeholders.

The RUC and CMS have also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple procedure reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do not strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process. We disagree with using the RUC for this purpose, but if CMS believes the RUC role should be expanded it should only be done by giving the RUC a public and well-articulated charge to take on this task.

In light of the concerns raised above, the American Academy of Dermatology (AAD), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS) and the American Society for Mohs Surgery (ASMS), respectfully request reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, 17311 and 17313, as appropriately exempt from the multiple procedure

reduction rule, as are the other add-on Mohs codes. We therefore request maintenance of the existing exemption from the MPRR.

We would appreciate the opportunity to meet with CMS to discuss this issue as soon as possible. Please feel free to contact Laura Saul Edwards at ledwards@aad.org or (202) 842-3555.

Respectfully,

Diane Baker, MD,
President, American Academy of Dermatology

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

Alastair Carruthers, FRCPC,
President, American Society for Dermatologic Surgery

Sharon Tiefenbrunn, MD,
President, American Society for Mohs Surgery

cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group
Amy Bassano, Director, Practitioner Services Division

Enclosure: Federal Register, Vol. 56, No. 227, Nov 25, 1991, page 59602

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

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N A T A

August 30, 2007

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

Dear Mr. Kuhn

These comments are submitted on behalf of the National Athletic Trainers' Association and the 30,000 licensed and certified athletic trainers we represent.

Our comments are directed at the THERAPY STANDARDS AND REQUIREMENTS and the request for comment on the PHYSICIAN SELF-REFERRAL PROVISIONS.

IN GENERAL

Traditionally, the licensure and authority to practice or provide healthcare has resided within the 50 states and the District of Columbia. The federal government does not set licensure standards for health professionals nor does the federal government license health care facilities. However, through the Conditions of Participation, the Federal government has established de facto licensure standards for most health care facilities. Failure to comply with the conditions (or achieve certification by a "deemed" entity) prevents the provider from participating in the Medicare and Medicaid programs and receiving funds from those programs.

By contrast, Medicare Part B does not have conditions of participation but rather defers to specific statutory authority to recognize various health professionals for the payment of services. Not all statutorily recognized health professionals are state licensed or certified in all states and

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when this occurs, CMS has typically established coverage standards in consultation with the relevant professional associations representing those health professionals in non-licensure states. The fact that Part A and Part B of Medicare have traditionally taken different approaches to determine when payment for services is warranted has also resulted in different standards with regard to use of health professionals.

THERAPY STANDARDS AND REQUIREMENTS

At the outset, we must question whether this proposal has gone through the usual rigorous and thorough vetting process associated with other changes in the Hospital Conditions of Participation (COP). **We also must question the fact that this major proposed revision to the Hospital COPs — a Medicare Part A issue—was incorporated in a Physician Fee Schedule proposed rule — a Medicare Part B proposed rule.** As there was no statutory deadline the agency was required to meet, no research or data presented indicating that patients were at risk nor was there any justification presented for this major change other than a desire to update the standards for physical therapists (PT) and physical therapy assistants (PTA), we question why a major proposed COP change was buried in the physician fee schedule proposed rule?

Executive Order 12866 of September 30, 1993, which was originally adopted by President Clinton and subsequently modified and continued by President Bush, states at the outset,

> "The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable."

The changes in the Hospital Conditions of Participation as they relate to physical medicine and rehabilitation standards fail to meet the objectives outlined in this Executive Order:

> 1. Adoption of the proposed Therapy standards will result in "unacceptable and unreasonable costs on society".
> 2. Adoption of the proposed Therapy standards will override the role of State government in licensing and determining the scope of practice of health professionals.
> 3. Adoption of the proposed Therapy standards would be a reversal of the long-standing approach in the COP to focus on outcomes and not process.

In outlining the philosophy behind the Executive Order 12866, the document states,

> "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people."

There is no compelling law mandating this change, these changes are not necessary to interpret the law and CMS has failed to identify any "compelling public need" for this change. In fact, the **proposed changes in the therapy standards can best be described as a "solution in search of a problem**."

Finally, EO 12866 stipulates that when considering how an agency should approach the regulation process, "agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach." It is clear that CMS did not consider the economic impact of this proposed change; **you did not consider the disruptive impact of this change** and provide no indication that in pursuing this change, public health will in any way be positively affected.

1. Adoption of the proposed Therapy standards will result in "unacceptable and unreasonable costs on society"

Rather than merely establishing a consistent definition for what is a physical therapist or physical therapist assistant, as CMS suggests, we believe the effect of this proposed change, if adopted, would be the inability of hospitals to continue to employ athletic trainers and other Physical Medicine and Rehabilitation (PMR) healthcare professionals to provide therapy services in their facilities.

Today, thousands of healthcare professionals who are not physical therapists or physical therapists assistants provide rehabilitation services in hospitals, nursing homes, outpatient departments and clinics. We are not aware of any studies which indicate that the services being provided by these health professionals are inappropriate in the context of the plan of care established for the patient; being provided by personnel unauthorized to deliver these services by the provider's medical staff or delivered by individuals unauthorized by state law or state regulatory mechanism to provide these services.

The loss of athletic trainers and other PMR health professionals will strain an already stretched health care delivery system. Hospitals, for example, are already reporting severe shortages of physical therapists (PT), and this will only exacerbate that problem. **Adoption of this proposed standard will be an economic boon for anyone with a valid PT credential as the demand for PTs will skyrocket while the supply of PTs will – at best - remain static.** In fact, there are some indications that the supply of PTs is being decreased with that profession's move to a clinical doctorate degree as an entry-level requirement for the field.

We would foresee significant increases in the salaries of PTs if this policy is adopted. With as many as 8,822 athletic trainers (AT) removed from the rehabilitation provider workforce, the health care system could pay as much as **$102,855,690** per year in higher wages. This figure does not account for the loss of lymphedema therapists, kinesiotherapists and low vision therapists and the higher cost in wages to replace these professionals. (Source: APTA.org/stats, NATA.org/employers)

For those providers unable to recruit or retain the PTs or PTAs necessary to meet patient demand, we will see facilities close or dramatically scale back service availability. Patients in need of physical medicine or rehabilitation (PMR) services will simply have to go without treatment, which means they will suffer needless pain for a treatable chronic condition. This happened as a result of a similar set of onerous rules put into effect with the therapy-incident to rule promulgated in the 2005 Physician Fee Schedule.

2. Adoption of the proposed Physical Therapy standards will override the role of State government in licensing and determining the scope of practice of health professionals

Current COPs for most rehabilitation providers allow staffing flexibility. For example, the Hospital Conditions of Participation stipulate that if Rehabilitation services are provided,

> "The organization of the service must be appropriate to the scope of the services offered.
> (1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.
> (2) Physical therapy, occupational therapy, or speech therapy, or audiology services, ***if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.***

The current standard defers to the collective judgment of the medical staff and recognizes the authority of the state to determine the appropriate scope of practice for various health professionals.

The proposed personnel standard for the Hospital COP would be changed to require that all therapy services must be provided by individuals meeting BOTH state licensure standards as well as additional education and certification requirements beyond state licensure. The proposed language reads as follows:

> (1) Except as specified in paragraph (c)(1)(ii) of this section, physical therapy, occupational therapy, or speech-language pathology services must be furnished—
>
> > (i) By qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists as defined in Sec. 484.4 of this chapter; or
> >
> > (ii) By qualified physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants who have been licensed, certified, registered, or otherwise recognized by the State in which practicing before January 1, 2008 and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.

We find it somewhat surprising that CMS would deem their judgment of who can appropriately provide rehabilitation services in a provider setting to be superior to the collective judgments of the state legislatures, provider medical staff, health departments

and regulatory agencies throughout the United States who make these determinations for individual states and individual providers.

3. Adoption of the proposed therapy standards would be a reversal of the long-standing approach in the COP to focus on outcomes and not process.

We find it unusual that at this point in time, CMS would propose to establish what we interpret as a mandatory staffing requirement – **a monopoly if you will** – under Medicare Part A. Unlike Part B, where specific staffing requirements exist as a condition of payment (generally mandated by statute), Part A providers have traditionally been given wider latitude in staffing decisions. Staff who are not recognized under Part B as independent providers of care are able to see and provide services to patients being treated by a provider.

For example, Medicare Part B only pays for assisting at surgery when provided by physicians, physician assistants or nurse practitioners. Medicare Part B will not pay for these services unless they are provided by one of these health professionals. Yet the Hospital Conditions of Participation permit the use of other health professionals—nurse first assistants, orthopaedic assistants and surgical technologists—to assist the surgeon in the performance of a surgical procedure, and this is not considered a violation of the Hospital Conditions of Participation. The hospital is given staffing latitude because none of these professionals are seeking independent reimbursement for their services, even though clinically they are doing exactly the same thing a physician, PA or NP would be doing in this capacity. In this case, Medicare trusts the judgment of the hospital and physician to only use qualified personnel to surgically operate on a patient, remove body parts and surgically suture the wound, but your proposed rules suggests we cannot trust that same hospital medical staff to ensure that only qualified personnel are providing therapeutic massage.

The traditional difference in approach for an institutional provider compared to an individual provider makes sense and has served patients and providers well over the years.

Even the change noted in the preamble with regard to therapy services provided "incident to" does not justify the changes you are proposing in this rule, and in fact, the enactment of that legislation and the agency's interpretation of that legislation undermines the case you made for this proposal. It is generally accepted that Congressional action to mandate a change is a clear indication of Congressional intent. But it is also recognized that the **failure** of Congress to make a change – when it had ample opportunity to do so – is also an indication of Congressional intent.

In proposing the current change, CMS cites, in part, the policy adopted by CMS in the 2005 Physician Fee Schedule final rule and its citation of Section 1862(a)(20) of the Social Security Act as the justification for that change. At the time that policy was under consideration by CMS, we repeatedly asked for data supporting the CMS position and were repeatedly told that it was not necessary for the agency to engage in such justification because CMS was merely following what Congress mandated in Section 1862(a)(20).

While we disagreed then and continue to disagree with CMS's 2005 interpretation (as opposed to the agency's interpretation of the intent of Section 1862 (a)(20) published in both 2001 and 2003), we can't help but note that when Congress enacted Section 1862(a)(20), it DID NOT apply that policy to 1861(p) of the Social Security Act nor did it apply the language of 1862(a)(20) to other providers of services. **Therefore, we believe that adoption of this proposal absent specific Congressional directive and any compelling health or safety concerns is unwarranted and unauthorized.**

What is a PT?

Developing a consistent definition of what is a physical therapist or physical therapist assistant is reasonable. The definition of a Physical Therapist in Part B of Medicare should be the same as the definition of a Physical Therapist in Part A.

We are concerned that your proposal goes well beyond it's stated purpose, *"...that when Medicare policies describe a physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants and speech-language pathologists, the qualifications for those professions would be the same in all settings, without exception."*

We also believe that you have made this initiative far more complicated than it need be to achieve your desired outcome.

If the desire is to create a uniform and consistent definition of a PT or PTA, why not simply say that a PT is someone who is licensed or authorized by the state to practice as a physical therapist? As you note, each state licenses physical therapists. It would be unlawful for someone to practice – even if authorized to do so under your COPs - as a PT without a valid PT license. To then add the exhaustive and complicated educational criteria is excessive and unnecessary. If a state does not recognize a particular educational program or credential, your recognition of that credential does not override state law. By imposing the specific education/certification criteria above and beyond state legal authority to practice, you are suggesting that states have allowed individuals who fail to meet certain educational or certification standards to practice. If that is the case, you are attempting to override state law and state regulatory authority when it comes to who can be defined as a physical therapist.

Inconsistent with Regulatory Approach in other areas

Current language that guides the personnel standard for Hospital Rehabilitation services is consistent with personnel or staffing standards in numerous other departments within the hospital and other providers. CMS's approach in this proposed rule is inconsistent with the past and current regulatory approach by the agency.

For example, the Radiology standards, which are intended to protect the patient from over exposure to deadly radiation, stipulate that, "Only staff designated as qualified by the medical staff may use the Radiologic equipment and administer procedures."

The Emergency Medicine Standards stipulate that the services, "must be organized under the direction of a qualified member of the medical staff;" and further, the standards stipulate that "emergency services must be supervised by a qualified member of the medical staff."

Finally, the Pharmaceutical Services Standards stipulate that, "All compounding, packaging and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with state and federal laws." Note that the standards speak to the pharmacist as the supervisor but do not address the standards for the individuals being supervised.

What we hope you will note here is that in each of these areas, specific personnel standards are either non-existent or you defer to the judgment of the hospital's medical staff and state law. In each of these areas, CMS rightly defers to the professional judgment of the medical staff and the authority of the state to determine who is most appropriate to provide various types of care. Why, when it comes to the delivery of physical medicine and rehabilitation services does CMS deem it necessary to remove the authority and judgment of the medical staff and the state legislature and superimpose its judgment on decisions best left in the hands of state and local officials?

What is it about PMR services that make them so dangerous or so unique that the prevailing wisdom of medical staffs, state legislatures and regulatory boards, long-standing medical facility conventions and even Executive Order 12866 must be overridden?

What is it you are trying to accomplish?

In the descriptive section of the proposed rule (page 38191), you indicate four reasons for proposing these new standards:

- The current regulations at § 484.4 contain outdated terminology relating to several of the relevant professional organizations

First, we would note that despite these assertions, CMS provides no information to support these contentions. What terminology is outdated and even if the terminology is outdated, has this caused any problems? What organizations are CMS referring to in the first bullet point? Did CMS solicit input from some organizations and not others in identifying problems? What opportunities were other organizations representing other PMR health professionals working in rehabilitation departments of providers given to identify their concerns? Is CMS even aware of the fact that there are many different health professionals working in rehabilitation departments whose livelihoods will be affected by these new standards? **I can assure you that neither NATA nor any of its experts were consulted in the process leading up to this proposed rule. As a legitimate PMR provider, how is this acceptable or wise practice for CMS staff?**

- The standards that now exist in the fields of physical therapy and occupational therapy have changed since a substantial portion of these qualification requirements were developed.

What changes have occurred? Even if changes have occurred, how has this affected the workforce or the providers? Are providers hiring individuals not licensed by the states? Are

states not being vigilant in their application of licensure standards? Are organizations attempting to achieve through the COP that which they cannot achieve in the individual states?

- Some of the current qualification requirements do not address individuals who have been trained outside of the United States, or refer to outdated requirements.

Again, if CMS merely deferred to state law as the determiner of who is qualified, this is not an issue. Either these foreign trained physical therapists are legally authorized to practice in the state or they are not. Adopting a COP standard does not overturn state law and allow someone to practice in a provider who would otherwise be prevented from practicing in that state.

- These revisions would have the benefit of establishing consistent standards across provider/supplier lines.

Most of the standards across providers are already consistent. In provider category after provider category, CMS defers to the medical staff and state law. This approach is consistent within the particular providers as well. It is only in the home health area that CMS had previously established the proscriptive standards. But instead of changing one to be consistent with the other nine settings, you are changing nine to be consistent with one. This makes no sense.

We cannot also avoid pointing out that in putting forth these standards, **the CMS staff responsible for developing this policy failed to consider whether the standards were even applicable in some settings. It is almost as if someone did an electronic word search and everywhere it found the term "provider," sought to either modify or create a standard.**

Take for example your proposal to establish a NEW standard for therapy provided in a Rural Health Clinic (RHC). **Had CMS staff, prior to proposing this new policy, consulted with the CMS staff responsible for oversight of the RHC program, you would have learned that therapy services provided by a PT or PTA are NOT covered services in the RHC**. Therefore attempting to establish a personnel standard for a provider who is unable to provide this service in this setting is absurd. In order for a RHC to be paid by Medicare or Medicaid, the service MUST be provided by a physician, physician assistant, nurse practitioner or certified Nurse Midwife. These are the ONLY health professionals recognized in the RHC environment for the delivery of physical medicine and rehabilitation services.

We contacted the staff responsible for RHC program oversight to discuss this conflict and learned that they were unaware of this proposed change. How is it that CMS can make such a major proposal but not consult with the staff responsible for oversight of that particular area of the Medicare program or consult with the national trade associations representing this provider type?

The problem with what CMS is proposing is that it goes well beyond establishing a consistent definition of PT or PTA and instead, seriously limits the ability of hospitals and other providers to hire appropriate staff for the delivery of physical medicine and rehabilitation services. Under the CMS proposal, only specific personnel can provide that service. As noted above, the terms therapy and rehabilitation are much broader than physical therapy or occupational therapy.

NATA must object again to CMS's continued attempts to rename—or assist in rebranding—all of PMR as physical therapy.

NATA Analysis of CMS Intent

In attempting to determine what CMS was hoping to accomplish with the new standard, we must admit to some confusion. There are two possible explanations for what has occurred:

1. **CMS, in collaboration with a professional organization, is attempting to establish a monopoly for PTs and PTAs for the delivery of physical medicine and rehabilitation services provided in various provider settings.**

Is this the intent behind this proposal? Is it CMS's goal to prevent any health professional other than a physical therapist from providing physical medicine and rehabilitation services? If this is the case, under what statutory authority has CMS pursued this objective? Is there no role for Athletic Trainers to work with Medicare or Medicaid patients in the rehabilitation department of the hospital or other provider? The AT who is qualified by state law and state regulatory mechanism to rehabilitate adult patients, senior recreational athletes and high school athletes from ACL surgery is just as qualified to rehabilitation a Medicare or Medicaid patient when that patient visits the hospital for his/her rehabilitation. Is CMS aware that there are thousands of athletic trainers employed by hospitals who contract with local high schools and colleges and amateur athletic organizations to provide athletic training coverage for high school and collegiate and amateur sporting events? These ATs provide follow-up care to patients and athletes when they come into the hospital's rehabilitation department for physical medicine and rehabilitation—regardless of age.

Is there no role for the non-PT lymphedema therapist to provide lymphatic drainage massage to breast cancer and other cancer survivors who come to the hospital rehabilitation department for services? Is there no role for a kineseotherapist to continue working with wounded veterans to build the strength and endurance necessary to learn how to walk because his legs have been lost because an improvised explosive device (IED) exploding underneath his truck? Given these unanswered questions and the significant loss of access to qualified capable therapists due to the similar "therapy-incident to" policy changes made by CMS in 2005, we believe that CMS has not fully considered the impact of these proposed rules.

We hope that we are wrong and that CMS has not unwittingly become the agent for a health professional association whose stated intent is the creation of a monopoly on the delivery of physical medicine and rehabilitation services. This would be bad public policy and an outrageous use of an agency's rulemaking authority to promote the interests of a single health professional association, to the detriment of patients.

Another possible explanation of CMS's actions would be—

2. CMS is attempting to establish a uniform definition of a physical therapist and a physical therapist assistant and has inadvertently gone too far. Should this be the case, we are concerned that in your zeal to create a single definition of a PT or PTA, **you have**

inadvertently undermined the ability of state surveyors to assess the qualifications of other providers of rehabilitation services.

As noted above, current personnel standards defer to state law and medical staff approval with regard to rehabilitation services. Thus, under current COP personnel standards, if a surveyor were to inspect a rehabilitation department that employed athletic trainers to deliver rehabilitation services, the surveyor could ascertain whether the AT was authorized by the state to work in this environment and provide these services and second, ascertain whether the AT was providing these services with medical staff approval. Under the proposed standards, presuming that an AT could still work in the rehabilitation department, how would a surveyor ensure that the AT was acting appropriately in that setting? Technically, we believe you have removed a viable survey tool from your state surveyors.

Cost of this Proposal

CMS provides no clinical or financial justification for this proposed change, nor has the agency provided any cost information on what the expected impact of this change will be on hospitals and other providers.

NATA estimates that as many as 8,822 athletic trainers in the U.S.—who are legally authorized by their state license, facility medical staffs and bachelor's or master's degrees to provide services—may no longer be able to provide services to patients of all ages if this proposed rule goes into effect. In salaries alone, the negative economic consequences on the athletic training profession could reach $382,354,000 annually.

The cost in terms of access for patients could be similarly devastating. We estimate that up to 4.16 million patients each year will lose access to PMR services. This includes Medicare, Medicaid and commercially insured individuals.

We estimate that thousands of Athletic Trainers, Lymphedema Therapists, Kineseotherapists, Low Vision Therapists and others will no longer be able to provide services in these hospitals and other rehabilitation facilities at a time when there is a clearly identified shortage of physical therapists, occupational therapists, PT assistants and OT assistants. This will only exacerbate the already identified shortage of rehabilitation providers.

The effect of exacerbating the shortage will be that Medicaid and Medicaid beneficiaries will experience reduced access to physical medicine and rehabilitation services; costs for providing these services will go up as various providers raise salaries and bonuses to attract or retain the limited number of providers available to provide these services; and the quality of care will decrease as PTs or PTAs working in providers are under increasing pressure to see more and more patients spending less and less time with each individual patient.

Conclusion

Historically providers (hospitals, nursing homes, specialty hospitals, clinics, public health agencies) have been given broad latitude in the hiring of state licensed or certified personnel to

deliver therapy/rehabilitation services in their facilities. This is consistent with the approach CMS has been taking for a number of years relative to personnel standards—to get away from proscriptive standards and instead, focus on outcomes.

Unlike physicians and practitioners (including PTs and OTs) who are paid on a fee schedule basis, providers are typically paid on either a Prospective Payment System (PPS) basis or a capped, cost-basis. This difference in payment methodology is important because unlike a fee-for-service methodology where personnel and payment are directly linked, in either the PPS or Cost-based models, the provider assumes financial risk because payment is capped. Because providers assume financial risk in these payment models, allowing the provider the flexibility to design a staffing model – consistent with state law – that assures the delivery of quality services in a cost-effective manner is critically important.

Furthermore, unlike physician offices or PTs in private practice offices, providers are subject to survey and certification which dictates that outside surveyors will periodically visit and inspect facilities and review medical records to ensure that patient services are being appropriately delivered by qualified personnel. These inspections can either be done directly by the government through state survey agencies, or through a non-governmental authority that has been granted "deemed" status for survey and certification purposes.

Recommendation 1 (THERAPY STANDARDS AND REQUIREMENTS)

We believe it is imperative that CMS state publicly in the final rule that it is permissible for providers to employ and utilize ANY state licensed or authorized health professional for the delivery of physical medicine and rehabilitation services and that use of such personnel would not violate the conditions of participation for that particular provider.

We also believe it is imperative that you restore the ability of the provider's medical staff, in conjunction with state law or state regulatory mechanism, to determine who is appropriate and qualified to provide physical medicine and rehabilitation services.

Recommendation 2 (THERAPY STANDARDS AND REQUIREMENTS)

Withdraw the proposed changes to the Therapy Standards and Requirements

Recommendation 3 (THERAPY STANDARDS AND REQUIREMENTS)

Convene a working group with representation of the range of physical medicine and rehabilitation providers and facilities (hospitals, CORF, outpatient therapy clinics, physicians and other health care professional groups) to discuss with CMS: workload, staffing, personnel qualifications and scope of services delivered and attempt to achieve a rational policy via consensus.

Recommendation 4 (THERAPY STANDARDS AND REQUIREMENTS)

The Office of Management and Budget should review these current proposed rules to assess economic impact on the Medicare system, patient access and quality.

PHYSICIAN SELF-REFERRAL PROVISIONS

3. In-Office Ancillary Services Exception

> (1) Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services).

In putting forward this inquiry, CMS cites previous communications from physical therapists who apparently object to physicians employing physical therapists to provide therapy services in the physicians office. Specifically, you state,

> "In response to Phase II, we received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices."

However, you also note that the rationale behind the in-office ancillary services exception adopted by Congress was,

> "...to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office."

We are unaware of anything that suggest that the rationale behind the exception cited above have changed.

Physicians and patients – as a matter of convenience, efficiency and overall quality of care, may wish to use to the same location for both the diagnosis AND treatment of a physical medicine problem.

If a patient goes to a physician's office for the diagnosis of a medical problem that falls within the category of physical medicine, it is reasonable to allow the physician who diagnoses the problem, to have a PT employed by that physician provide the prescribed treatment. Whether the physician is a Family Physician with a sports medicine subspecialty or an orhtopaedic surgeon repairing a torn ACL, allowing the patient to "one stop shop" is reasonable, appropriate and improves the overall quality of care received by that patient.

President Bush has been very emphatic in his desire to move the U.S. healthcare delivery system to a consumer directed system of care providing greater and greater authority to patients in medical decision making, where their dollars are spent, how they are spent, etc. Any move to

restrict where patients can obtain services runs completely counter to the stated position of this Administration.

In response to a question regarding the importance of Health Savings Accounts and patient choice posed during a White House sponsored call with Julie Goon, President Bush's Special Assistant to the President for Economic Policy (Health Care), Ms. Goon had this to say:

> "And HSAs give you more control and choice; you can choose how and where to spend from your account. HSAs help put you in charge of your health care."

Restricting where patients can obtain services is a reversal of the Bush Administration's approach and makes the government the determiner of where services are going to be available. The primary tests that the Medicare program should apply are the following:

1. Was the service medically necessary?
2. Was the practitioner who performed the service legally authorized to perform the service (and recognized by Medicare for the performance of that service)?
3. Is the service covered by the Medicare program?

If all of these tests are met, whether the service is provided in the physician's office by an individual employed by the physician, or referred to another practitioner should be irrelevant. Any abuses – real or perceived – can be easily addressed by applying the three tests above. To suggest that merely because a service is provided through an ancillary arrangement, a service is either unnecessary or inappropriate means that the Medicare's claims review process is a failure. Rather than restricting patient access and inserting the government into the physician-patient relationship, Medicare would be better served investing in a better claims review process to identify and disallow medically unnecessary services!

We find it ironic that CMS is ignoring its own information when it comes to PMR services. According to MedPAC and CMS's own data, the physician's office is the most cost-effective place to receive PMR therapy services. The average per beneficiary cost for therapy provided in the physician's office is significantly lower compared to a physical therapy in private practice. This is true in the aggregate, as well as looking at various specific medical conditions.

According to MedPAC, the average, per beneficiary costs for physical medicine and rehabilitation services, by setting are:

Physician $405.00
Average $581.00
PT in Private Practice $653.00

Why limit the ability of physicians to provide these services in the office where the average per beneficiary cost is $405 per beneficiary and instead, have them receive these services in another, more expensive setting? We would note that such a policy would not only increase Medicare's costs, but also beneficiary cost as the typical beneficiary would see their co-pay rise from $81.00 to $130.00.

Even if one argues that the physicians are only referring the more complicated cases to the PT, isn't that what should happen? Typically the reason a physician will provide a service – such as therapy – in the physician's office is as a convenience to the patient and the ability of the physician to closely monitor the patient's response to the treatment. By providing the service in the office, the physician can make the necessary adjustments on an immediate basis rather than waiting for the patient to return or get a separate report from the provider to whom the patient was referred.

Conflict of Interest

It is not surprising that many of the individuals or organizations expressing concerns about the in-office ancillary services exception are also individuals or organizations that have a vested financial interest in the outcome of this discussion. This appears to be a common theme for CMS staff associated with therapy rule changes; the staff uses industry experts who have an inherent conflict of interest to conduct reviews and write reports favorable to their own profession. **The therapists, who in this case oppose the ability of physicians to provide PMR services in the physician's office, are the same ones who complain that they are not getting enough referrals to support their own private businesses.**

Is the quality substandard? CMS provides no citation supporting a lack-of-quality conclusion. Are the PTs providing the service or the physicians providing the service unqualified? CMS provides no citations to support that conclusion. Are the services medically necessary? CMS provides no citations to suggest they are anything but medically necessary.

In putting forward this proposal for discussion, CMS cites no credible, independent study indicating that there is a problem that needs to be addressed. CMS implies that there might be some abuse but offers no evidence to support that contention.

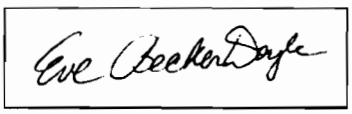
On the whole, we can only conclude that as with other issues involving the delivery of PMR therapy services, CMS has only listened to one or two organizations that have a vested financial interest in increasing the income of their members and are essentially asking the government to increase their members' business by preventing a physician from having a service provided in the physician's office.

Modifying the ancillary services exception to the physician self-referral regulations is anti-consumer, anti-choice and antithetical to everything the Bush Administration has been advocating for the last six years in terms of patient choice.

We strongly recommend that CMS spend more time working to develop a claims review process for determining when or if therapy services provided by any PMR provider—whether an athletic trainer, physical therapist or physician—are medically necessary and less time worrying about the physical location of where those services are being provided or the relationship between the physician and the therapy provider. There are monumental problems with CMS's reimbursement system. It should focus on fixing the business of reimbursement instead of

attempting to micromanage medical staffs and their capable, qualified, appropriate ancillary and other providers.

Sincerely,



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File No. 028543-0011

LATHAM & WATKINS LLP

August 31, 2007

VIA HAND DELIVERY

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1385-P: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008"—COMMENTS ON "*RESOURCE-BASED PE RVUS*," "*IDTF ISSUES*" AND "*PHYSICIAN SELF-REFERRAL PROVISIONS*"

To Whom It May Concern:

On behalf of our client, Alliance Imaging, Inc. ("Alliance" or the "Company"), we submit these comments on certain proposed revisions to policies under the Medicare physician fee schedule ("MPFS") for 2008.[1] Specifically, the Centers for Medicare and Medicaid Services ("CMS") has proposed to amend its reassignment regulations to apply the anti-markup rule to both the technical component and professional component of diagnostic tests and to modify the contractual arrangement exception to the reassignment rule. In addition, CMS is soliciting comments on a spectrum of proposed revisions to the agency's regulations implementing the Physician Self-Referral Law ("Stark Regulations").[2] Finally, the agency has proposed several changes and additions to its performance standards for independent diagnostic testing facilities ("IDTFs"). Alliance is concerned about and supports a number of aspects of the agency's proposals and appreciates the opportunity to offer its comments and recommendations.

Alliance is the leading national provider of diagnostic imaging services, based on the number of diagnostic imaging systems deployed. The Company's services include magnetic resonance imaging ("MRI"), computed tomography ("CT"), positron emission tomography ("PET") and positron emission tomography/computed tomography ("PET/CT"). The Company contracts with hospitals and other healthcare providers to furnish imaging and therapeutic services to their patients. These services normally include the use of the Company's imaging systems, technologists to operate the systems, equipment maintenance and upgrades and

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1 *See* 72 Fed. Reg. 38122 (July 12, 2007) (proposed independent diagnostic testing facility provisions to be codified at 42 C.F.R. pt. 410, proposed reassignment and physician self-referral provisions to be codified at 42 C.F.R. pts. 411 and 414).

2 *See generally* 42 C.F.R. § 411.350, *et seq.* (2007) (implementing 42 U.S.C. § 1395nn (2007)).

management of day-to-day shared-service and fixed-site diagnostic imaging operations. Alliance also provides services to its own patients as an IDTF. Alliance has approximately 500 diagnostic imaging systems, including 318 MRI systems and 75 PET or PET/CT in 43 states as of June 30, 2007.

Alliance offers the following comments and recommendations for CMS's consideration:

RESOURCE-BASED PE RVUS

(1) **Retain the current equipment usage assumption and equipment interest rate calculation with respect to resource-based practice expense ("PE") relative value units ("RVUs").** Alliance strongly supports CMS's position not to adjust the equipment usage assumption above the current level of fifty percent without sufficient empirical evidence to justify an alternative proposal on this issue. Additionally, Alliance supports the agency's efforts to obtain approaches that classify equipment into mutually exclusive categories, each with a specific usage rate assumption. In addition, Alliance also strongly supports the analysis undertaken by CMS to retain the eleven percent interest rate used in the current calculation of equipment costs.

PHYSICIAN SELF-REFERRAL PROVISIONS

(2) **Modify and clarify the proposed reassignment and anti-markup provisions to account for the practical impact on the imaging industry.** First, CMS's proposed revisions to the anti-markup rule would restrict the ability of physician groups to engage in legitimate arrangements with part-time or leased employees and would require physicians to absorb the costs of hiring full-time employees. To the extent that an individual provides services to a physician group on an exclusive basis, whether or not that individual is a full-time employee, part-time employee or leased employee, Alliance requests that the agency provide an exception for these arrangements in any revisions made to the anti-markup rule. Second, Alliance believes that the agency may be mixing its purchased diagnostic test policies with the contractual arrangements exception to the reassignment rule, which could result in confusion for the imaging industry. As such, Alliance requests that CMS taper its revisions accordingly.

(3) **Narrow the in-office ancillary services exception under the Stark Regulations to include only those ancillary services that are directly related to underlying services.** Alliance applauds CMS for soliciting comments as to how it can better shape the in-office ancillary services exception under the Stark Regulations to avoid fraudulent and abusive relationships. Alliance recommends that CMS add language to the Stark Regulations that would permit entities to utilize the exception only when the ancillary designated health services at issue are directly related to the primary services being offered. Alliance believes that such an approach is consistent with the intent behind this exception. Furthermore, the agency should apply the same quality and safety standards to all providers, not

just IDTFs. To the extent that these measures cannot curb abusive arrangements, Alliance suggests that the agency consider specifically excluding those services from the exception that are the source of abusive arrangements in the industry.

(4) **Implement the proposal to restrict the use of "per click" arrangements.** Alliance believes that CMS can prevent a significant area of abuse by restricting the availability of unit-of-service based payments to a physician-lessor for services rendered by a lessee to patients referred by the lessor to the lessee, as proposed. As such, the Company supports the agency's recommendation to amend its Stark Regulations to restrict the use of "per click" arrangements in this manner.

IDTF STANDARDS AND OTHER REQUIREMENTS

(5) **Modify the proposed limitations on retroactive billing for IDTFs.** CMS's prohibition on retroactive billing could result in a significant period of non-payment for IDTFs that penalizes suppliers. In addition, as proposed, the new rule delays the start of a supplier's ability to bill the program due solely to the presence of minor or *de minimis* errors in an application. Alliance requests that CMS revise its proposed rule to allow an IDTF to begin billing Medicare for claims with dates of service on or after the day on which the IDTF submits a "substantially correct" enrollment application or the date the IDTF first furnishes services at its location, whichever is later.

(6) **Amend the proposed restriction on IDTFs' ability to share space, equipment and staff.** Alliance applauds CMS for initiating reforms that would prevent overutilization and abusive relationships among providers. Alliance recommends, however, that the proposed restriction on sharing space, equipment and staff should not be applied to mobile IDTFs, as this would add both physical and financial burdens that mobile units simply cannot meet. In addition, Alliance recommends that the agency revise the proposed restriction to account for certain practical implications concerning the imaging industry. For instance, under the agency's proposed rule, certain common and legitimate sharing practices between multiple IDTFs, between IDTFs and hospitals and between IDTFs and radiologists might be prohibited, resulting in unfair financial burdens on these entities. While Alliance recognizes that some sharing arrangements present a legitimate concern and that the agency is attempting to curb these abusive relationships, Alliance requests that CMS modify its proposed rule to avoid banning arrangements that do not raise these issues.

(7) **Revise the proposed beneficiary complaint requirements for IDTFs to include only complaints relating to the quality of patient care.** IDTFs, like most healthcare providers, receive numerous comments that range from statements about a claustrophobic experience in an MRI machine to complaints about a long waiting period. Such comments, though important, do not focus on the quality of care being provided but are rather generic comments that any

healthcare provider would encounter. Alliance requests that CMS clarify that IDTFs are required to monitor only those beneficiary complaints that relate to the quality of care a patient receives. This would focus an IDTF's resources on monitoring and correcting serious problems and would prevent expending limited IDTF resources on monitoring less serious patient comments.

(8) **Implement the proposed revision to extend the time for reporting changes of information on an IDTF enrollment application.** Extending the deadline for reporting changes of information from 30 days to 90 days accounts for the practical realities of the imaging business and provides a more moderate standard for IDTFs to follow. Therefore, Alliance supports CMS's proposal to extend the deadline for reporting changes.

Below are more detailed explanations of each of the Company's comments.

RESOURCE-BASED PE RVUS

I. CMS SHOULD RETAIN THE CURRENT EQUIPMENT USAGE ASSUMPTION AND EQUIPMENT INTEREST RATE CALCULATION WITH RESPECT TO RESOURCE-BASED PE RVUS.

Alliance strongly supports the position taken by CMS in the proposed rule to not adjust the equipment usage assumption above the current level of fifty percent without sufficient empirical evidence to justify an alternative proposal on this issue.[3] Alliance agrees that if the equipment usage percentage is set too high, the result would be insufficient allowance at the service level for the practice costs associated with equipment. Additionally, Alliance supports the efforts of CMS to obtain approaches that differentially classify equipment into mutually exclusive categories with category specific usage rate assumptions and CMS's commitment to work with the physician community to examine equipment usage rate assumptions that ensure appropriate payments and encourage appropriate utilization of equipment.[4]

Further, Alliance also strongly supports the analysis undertaken by CMS to retain the interest rate used in the calculation of equipment costs at eleven percent.[5] We believe the data obtained by CMS from the U.S. Small Business Association provides an accurate representation and assumption of interest rate data for equipment purchase.

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3 *See* 72 Fed. Reg. at 38132.

4 *See id.*

5 *See id.*

PHYSICIAN SELF-REFERRAL PROVISIONS

II. CMS SHOULD LIMIT CHANGES TO THE PURCHASED DIAGNOSTIC TEST RULE AND THE REASSIGNMENT RULE.

In any final revisions to the purchased diagnostic test rule, Alliance recommends that CMS acknowledge that physicians regularly use part-time and leased employees to perform diagnostic tests. In addition, Alliance is concerned that the attempted inclusion of principles from the purchased diagnostic test rule into the reassignment rule's exception for contractual arrangements may unintentionally confuse the imaging industry.

A. Proposals

In part, CMS proposes that if a physician or physician group bills for the technical component ("TC") of a diagnostic test using employees who are not "employed" full-time by them, the anti-markup rule would apply.[6] In other words, CMS is implying that an absence of full-time employment automatically means that there would be a purchased diagnostic test that is subject to the anti-markup rule.[7]

Current Medicare rules provide for a number of exceptions to the general rule that payments are made only to those physicians or suppliers providing the specific service for which a claim is submitted.[8] Two such exceptions are the subject of CMS's proposed 2008 MPFS:

- First, the purchased diagnostic test rule provides that if a physician or physician group purchases a diagnostic test from an outside supplier (for instance, an IDTF), the physician or group can bill Medicare the TC of the test, so long as the physician or group interprets the test (the professional component ("PC")) as well.[9] Payment for the TC generally is limited to the lesser of the physician fee schedule amount for the test and the outside supplier's charge.[10] This longstanding policy is known as the anti-markup rule.

- Second, an exception to the general prohibition on reassignment permits an outside supplier to reassign to a physician or physician group the right to bill and receive payment for the TC and PC of a diagnostic test pursuant to a contractual arrangement between the physician or group and a physician that is not part of the group practice.[11] Entities relying on the contractual arrangement exception to the

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6 *See id.* at 38229 (proposed 42 C.F.R. § 424.80(d)(3)).

7 *See id.*

8 *See* 42 U.S.C. § 1395 u(b)(6); *see also* 42 C.F.R. § 424.80(a).

9 *See* Medicare Claims Processing Manual (CMS Pub. 100-04), chapt. 13, § 20.2.4 to 20.2.4.2 and chapt. 1, § 30.2.9.

10 *See* 42 C.F.R. § 414.50.

11 *See id.* § 424.80.

reassignment rule are obligated to abide by rules concerning physician billing for purchased diagnostic tests, which includes the anti-markup rule.[12]

B. Comments

First, Alliance acknowledges CMS's concern in proposing to limit the ability to bill for the full TC without mark-up provisions being triggered to full-time employees.[13] CMS appears to be concerned that, unless an individual is a full-time, W-2 employee, a physician might not maintain an adequate level of involvement or supervision in how tests are performed. To ensure adequate physician involvement and supervision, therefore, CMS proposes that if a physician or group bills for the TC that is performed by anyone other than a full-time employee, the anti-markup rule would apply.

Extending the application of the anti-markup rule to the TC of tests reassigned to the billing physician/group by all suppliers except for full-time employees may serve to prohibit legitimate arrangements between physicians and technicians who may not be full-time employees. Physician groups, like all businesses, engage staff to provide services in their offices depending upon demand and financial ability to retain staff. Physicians may staff their offices with a mix of full-time W-2 employees, part-time employees or employees leased from third parties. These are commonplace arrangements that are provided for the convenience of patient care in the physician's office or clinic and permit imaging services to be performed in a physician's own facilities that he or she would not otherwise be able to perform.

The requisite level of physician supervision, however, is not generally determined by employment status and is not an important distinction that should be incorporated into the anti-markup rule.[14] A physician maintains supervision and retains oversight, control and direction over tests performed by individuals exclusively engaged by his or her practice to provide services, regardless of whether the individual has been engaged on a part-time basis, has been leased from a third-party or is considered a full-time, W-2 employee.

In the case of IDTF suppliers' relationships with physicians and groups, if the physician group were required to employ only full-time technicians, groups would be hesitant to enter into relationships that permit the provision of convenient, necessary diagnostic services for their patients in their offices. This limitation would result in a decrease in the availability of imaging services on a convenient basis for Medicare beneficiaries, especially in rural areas. There would be no benefit to the program, since others, *e.g.*, an IDTF, would be offering the services at the full rate under the Medicare physician fee schedule.

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12 *See id.* Specifically, Medicare regulations regarding the reassignment rule note that "[n]othing in this section alters a party's obligations under . . . the rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter)." *Id.*

13 We assume that "full-time employees" means W-2 employees of a physician group or clinic.

14 *See generally* 42 C.F.R. § 410.32.

Therefore, Alliance recommends that the agency extend its revisions to apply to part-time employees and leased employees to the extent that they provide services exclusively for a billing physician or group.

Second, CMS's proposed changes to the purchased diagnostic test rule and the reassignment rule may be considered confusing by the imaging industry. CMS has adopted longstanding policies regarding purchased diagnostic tests, found at 42 C.F.R. § 414.50, and appears to be mixing these policies with restrictions regarding reassignment pursuant to contractual arrangements, found at 42 C.F.R. § 424.80, which already requires parties to comply with "obligations under the rules regarding physician billing for purchased diagnostic tests."[15] Further adding anti-markup language to the rules regarding reassignment could provide complicated and unclear parameters regarding reassignment.

Based on these reasons, we would propose the following changes:

> § 424.80(d)(3) *Reassignment of the technical or professional component of diagnostic test services.* If a physician or medical group bills for the ~~technical or~~ professional component of a diagnostic test . . . following a reassignment from a physician or other supplier *and purchases the technical component of the diagnostic test from an outside supplier pursuant to 42 C.F.R. § 414.50* ~~who performed the technical or professional component and~~ who was not a*n* ~~full-time~~ employee of the billing physician or medical group *or an individual providing services to the billing physician or group practice on a leased basis from another entity,* at the time the service was performed, each of the following conditions must be met . . . .[16]

These minimal changes should serve to render the proposed regulation clearer in how they apply to the variety of diagnostic imaging arrangements available in the industry.

III. CMS SHOULD NARROW THE IN-OFFICE ANCILLARY SERVICES EXCEPTION UNDER THE STARK REGULATIONS TO INCLUDE ONLY THOSE ANCILLARY SERVICES THAT ARE DIRECTLY RELATED TO A PHYSICIAN'S PRACTICE.

A. Proposal

In addition to CMS's proposed changes to the reassignment rule, the agency has also proposed and solicited comments on revisions to the Stark Regulations. With respect to the in-

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[15] *See* 42 C.F.R. § 424.80(a).

[16] *See* 72 Fed. Reg. at 38229 (proposed 42 C.F.R. § 424.80(d)(3)). Throughout this letter, the Company makes several suggested changes to regulatory language. In each suggestion, proposed language is in italics and underlined and proposed deleted language is scored.

office ancillary services exception found in the Stark Regulations, CMS is soliciting comments as to (1) whether certain services should not qualify for the exception (for instance, therapy services that are not provided on an incident-to basis, and services that are not needed at the time of the office visit in order to assist the physician in a diagnosis or plan of treatment); (2) whether changes are necessary to the definitions of "same building" and "centralized building"; (3) whether non-specialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the non-specialists; and (4) whether CMS should impose any other restrictions on the ownership or investment in services that would curtail program or patient abuse.[17]

B. Comments

Alliance supports the agency's decision to tighten the in-office ancillary services exception. Many abusive referral arrangements can result from the provision of medical services that are not truly ancillary to a physician's practice but that are protected under this exception. Offering services that tend to be not as closely connected to the physician practice represents a shift away from the fundamental principles of the in-office ancillary services exception found in Phase I of the Stark Regulations. Specifically, CMS cites in Phase I, "the Congress intended to protect some in-office ancillary services provided [that] they were *truly ancillary* to the medical services being provided by the physician or group; otherwise, the Congress would not have created the exception."[18] CMS further elaborates in the proposed 2008 MPFS that Congress most likely included an in-office ancillary services exception to the Stark Law to permit the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office in the first place.[19]

Therefore, we support the addition of language that would narrow the in-office ancillary services exemption to allow physicians to provide services that are directly related or "truly ancillary" to their practice. Specifically, any such language should restrict permissible ancillary services to those services necessary for the diagnosis and/or treatment of the medical condition that brought the patient to the physician's office.

Moreover, the high cost of operating certain imaging equipment can motivate providers to use the equipment, even on patients who do not have the appropriate clinical situation that requires the diagnostic or therapeutic service. Therefore, the need to cover equipment costs can result in inappropriate use of the equipment where a physician who owns the equipment can refer his or her patients to his or her own office. As currently drafted, the in-office ancillary services exception shields these arrangements, which can result in overutilization and higher costs to Medicare.

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17 *See id.* at 38181-82.

18 *See* 66 Fed. Reg. 856, 881 (Jan. 4, 2001) (emphasis added).

19 *See* 72 Fed. Reg. at 38181.

Furthermore, Alliance is concerned that diagnostic imaging services performed under the in-office ancillary services exception may not be of the same quality as those performed in the IDTF or radiology office setting. Tests performed in the physician office under the in-office exception may be supervised or performed by non-radiologists or by technicians with fewer qualifications, and may involve the use of older or lower-strength equipment. Also, this equipment may not receive proper and regular maintenance and may be subject to unskilled operation. Depending on the quality of the equipment used, tests performed in the physician office under the in-office exception can result in low quality images that could mean missed or delayed diagnoses. Therefore, Alliance recommends that CMS apply the same quality and safety standards for the same procedures, regardless of the site of services. Alliance also recommends that those performance and quality standards that apply to IDTFs should apply to all provider types. We believe that stricter safety and quality standards could ensure better patient care and could serve to curb some of the overutilization and increased charges to the Medicare program.

To the extent that these suggestions are ineffective at curbing abusive relationships in the imaging industry, Alliance urges the agency to consider excluding from the exception imaging and therapy modalities that are the source of such abusive arrangements.

IV. CMS SHOULD IMPLEMENT ITS PROPOSAL TO LIMIT THE USE OF PER CLICK ARRANGEMENTS.

In addition to soliciting comments on the in-office ancillary services exception, CMS also proposes that space and equipment leases may not include unit-of-service-based payments (commonly known as "per click" arrangements) to a physician-lessor for services rendered by a lessee to patients who are referred by the physician-lessor to the lessee. According to CMS, such arrangements are inherently susceptible to abuse, because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee.[20] CMS also solicits comments on whether per click payments should be permitted to a lessor by a physician-lessee, to the extent that such payments reflect services rendered to patients sent to the physician-lessee by the lessor.[21]

Alliance applauds CMS for its efforts to curb potentially abusive arrangements and agrees with CMS that these types of relationships are generally susceptible to abuse. Therefore, the Company concurs that they should not be permitted under Stark.

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20 *See* 72 Fed. Reg. at 38183.

21 *See id.*

IDTF ISSUES

V. CMS SHOULD ALLOW AN IDTF TO BILL FOR CLAIMS DATED ON OR AFTER THE DATE ON WHICH IT HAS SUBMITTED A SUBSTANTIALLY CORRECT ENROLLMENT APPLICATION.

A. Proposal

As part of the proposed 2008 MPFS, CMS would limit an IDTF's ability to bill Medicare for services rendered before a Medicare enrollment application is filed or approved.[22] Currently, once a Medicare contractor has approved an IDTF's enrollment application, Medicare pays for all services rendered prior to the date of approval, provided that the supplier has met all of the requisite standards on the dates of service.[23] In the proposed 2008 MPFS, however, CMS forecloses IDTFs from billing Medicare for services furnished prior to enrollment.

Specifically, CMS proposes to add 42 C.F.R. § 410.33(i), which would establish an initial enrollment date for IDTFs as the later of (1) the date of filing of a Medicare enrollment application that was subsequently approved by the contractor or (2) the date an IDTF first started rendering services at its new practice location. Medicare will not pay for services rendered prior to this date. The agency also proposes to define "date of filing" as the date that the Medicare contractor receives a signed provider enrollment application that the Medicare contractor is able to process for approval.[24] In other words, if the contractor rejects or denies an enrollment application, the new date of filing would be when an IDTF submits a new enrollment application that the contractor is able to process for approval.[25]

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22 *See* 72 Fed. Reg. at 38170 (proposed 42 C.F.R. § 410.33(i)).

23 *See* Medicare Program Integrity Manual (Pub. No. 100-08), Chapt. 10, § 4.19.8.

24 *See* 72 Fed. Reg. at 38170.

25 *See generally id.* We note that the language of the proposed regulation does not match the language described in the preamble of the proposed 2008 MPFS. Specifically, the preamble states:

> [W]e are proposing to add § 410.33(i) to state that Medicare will establish an initial enrollment date for an IDTF that would be the later of (1) The date of filing of a Medicare enrollment application that was subsequently approved by FFS contractor; or (2) the date an IDTF first started rendering services at its new practice location. We also propose to define the "date of filing" as the date that the Medicare FFS contractor receives a signed provider enrollment application that the Medicare FFS is able to process for approval."

72 Fed. Reg. at 38170. The proposed rule, however, states:

> (i) *Effective date of billing privileges.* The effective date of billing privileges for a newly enrolled IDTF is the later of the following: (1) The filing date of the Medicare enrollment application that was subsequently approved by a fee-for-service contractor; (2) The date the IDTF first furnished services at its new practice location; or (3) The filing date of the Medicare enrollment application or the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that it is able to process for approval.

B. Comments

Alliance respectfully requests that CMS modify its proposed restriction on retroactive billing for several reasons. First, the agency's proposed could result in a significant period of non-payment for IDTFs that penalizes suppliers unfairly. Enrollment applications generally are subject to a Medicare contractor's application processing time, which can last many months. Under current policy, however, IDTFs can bill for services rendered while waiting for their applications to be processed. Under the proposed policy, however, an IDTF could be required to wait to bill for claims until this processing period is complete. In other words, an IDTF potentially could be servicing beneficiaries for months without being paid.

Additionally, the agency's proposed definition of the "date of filing" could cause even further delays because the definition does not account for trivial mistakes in an application. As described in the proposed 2008 MPFS, if the contractor rejects or denies an enrollment application, the new date of filing would be when an IDTF submits a new enrollment application that the contractor is able to process for approval. If a supplier submits an application with a minor, technical error—transposed numbers, typographical mistakes, etc.—the application process (and, consequently, the delay in an IDTF's ability to bill for services) could take many additional months. This would be true even if the IDTF had been in substantial compliance with all of the IDTF performance standards for many months.

Furthermore, changing the agency's current policy could severely restrict an IDTF's ability to operate, especially in the case of IDTFs that must acquire expensive diagnostic imaging equipment. Requiring a lengthy delay before an IDTF can begin receiving Medicare payment might result in the facility foregoing altogether equipment and personnel necessary to furnish services to patients. If IDTFs are not paid for services provided to beneficiaries, an IDTF's incentive under the policy would be to deny services to Medicare beneficiaries or to refuse to accept Medicare during the enrollment approval process. Ultimately, this could mean a period of several months during which Medicare beneficiaries may be limited in their choice of supplier of diagnostic procedures.

To avoid delays in enrollment and billing caused by insignificant errors holding up an application (even if they do not impact whether the IDTF is fit to bill Medicare), Alliance suggests that CMS amend its proposed regulation to read as follows:

> (i) *Effective date of billing privileges.* The effective date of billing privileged for a newly enrolled IDTF is the later of the following:
>
> (1) The filing date of the Medicare enrollment application that was *substantially correct* ~~subsequently approved by a fee-for-service contractor~~; *or*

We have proposed a correction to the error in our comments.

72 Fed. Reg. at 38222 (proposed 42 C.F.R. § 410.33(i)).

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

~~(3)~~ The filing date of the Medicare application *is* ~~or~~ the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that it is able to process for approval.[26]

Establishing a "substantially correct" standard focuses a contractor's attention on issues pertinent to an IDTF's fitness to provide services to beneficiaries or to bill Medicare. Such a standard would also permit IDTFs to correct minor errors without slowing down the approval process, thereby preventing delays in billing rights that could affect beneficiaries' access to quality care. We would also expect, however, that the agency will instruct its contractors that an IDTF is considered to have submitted a "substantially correct" application when the contractor has sufficient information to assess whether the IDTF is fit to provide services to beneficiaries and to bill the program, regardless of any minor errors (*e.g.*, misspellings, typographical mistakes, transposed numbers, or other common slips) that may be included.

VI. CMS SHOULD NOT APPLY ITS PROPOSED RESTRICTION ON THE SHARING OF SPACE, EQUIPMENT AND STAFF TO MOBILE IDTFS AND SHOULD ADJUST ITS PROPOSAL TO ACCOUNT FOR THE PRACTICAL IMPACT ON THE IMAGING INDUSTRY.

A. Proposal

CMS is proposing a new performance standard at 42 C.F.R. § 410.33(g)(15) that would prohibit an IDTF from sharing "space, equipment, or staff or subleas[ing] its operations to another individual or organization." The agency notes its concern that allowing IDTFs to commingle office space (including waiting rooms), staff (including supervising physicians, non-physician personnel, or receptionists) or equipment through subleasing agreements may allow an IDTF to circumvent Medicare enrollment and billing requirements. The agency also believes that these types of arrangements may implicate the physician self-referral prohibition and the anti-kickback prohibition.[27] As part of its proposal, CMS also requests commenters to indicate whether the restriction on sharing space, equipment and staff should apply to mobile IDTFs.

B. Comments

Do not apply the proposed restriction on sharing space, equipment and staff to mobile IDTFs.

Alliance respectfully requests that the agency not apply the prohibition on sharing space, equipment or staff to mobile IDTF units. First, because of their limited size, mobile IDTFs simply cannot comply with a prohibition on sharing space and equipment. The nature of a

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26 *See id.* at 38222 (proposed 42 C.F.R. § 410.33(i)).

27 *See id.* at 38171.

mobile IDTF's practice requires the sharing of certain key areas. While mobile IDTFs keep appropriate equipment on site and maintain separate scanning rooms and patient examination areas, it is a common practice for mobile IDTFs to rely on a staging area for hand-washing and patient privacy accommodations on the premises of the client where tests are being performed. Mobile IDTFs also depend upon the client for parking areas and reception or waiting areas. The limited space available on a mobile unit's trailer renders such facilities an impossibility without sharing between the client and the IDTF.

Second, certain common arrangements between IDTFs and hospitals could be significantly impacted by applying the proposed new standard to mobile units. For instance, hospitals frequently contract with IDTFs for access to diagnostic imaging services for inpatients and emergency room patients. These arrangements arise when a hospital radiology department cannot handle patient demand in a timely manner, cannot use its own diagnostic equipment due to mechanical failure or maintenance or cannot justify the purchase of costly imaging equipment due to insufficient capital or patient demand. In such situations, an IDTF will arrange to share space at the hospital by parking there and allowing the hospital radiology department to utilize its facilities and bill for services provided to hospital patients.

Another commonplace situation is for mobile IDTFs to move to various locations (mostly small- to medium-sized hospitals, often in rural locations) on a scheduled basis each week. Depending on the specific contractual relationship, a mobile IDTF may simply rent space at a location and bill Medicare and other payors directly on its own behalf, or the mobile IDTF may provide outsourced, technical component services to a local healthcare provider who submits a claim to Medicare and other payers for the imaging services provided. Since the mobile unit may provide imaging services on its own account at several locations, it will be required to enroll as a separate IDTF for each such location. Multiple IDTFs could be deemed to be technically "sharing" the same mobile imaging unit. Additionally, when that same mobile unit provides services to a hospital, the unit might be seen as "sharing" its mobile equipment with that hospital.

Mobile IDTF units may also utilize the same staff at multiple locations. Mobile IDTFs, like any business, will choose to use staff as necessary based on demand for services and financial ability. This means that staff may be engaged at multiple locations or to cover multiple working shifts as necessary. By prohibiting this ability to share staff, a mobile IDTF would be required to hire or engage multiple individuals at each location serviced and could result in a difficult financial burden.

If mobile IDTFs are prohibited from sharing space, equipment and staff with other suppliers, they could be completely cut out of the Medicare market. Mobile IDTFs physically cannot accommodate separate parking, reception, changing and restroom areas, and attempted compliance with such a prohibition could make it cost prohibitive for mobile IDTF units to operate, at least with respect to Medicare beneficiaries. Mobile IDTFs also cannot afford to hire new staff for each separate location that they service. The result will be a significant decrease in a Medicare beneficiary's access to quality care, especially in rural areas where mobile IDTFs provide a significant amount of diagnostic imaging options. Therefore, Alliance requests that mobile IDTFs be rendered exempt from the new performance standard proposed at 42 C.F.R. § 410.33(g)(15).

Revise the proposed restriction on sharing space, equipment and staff to account for the practical impact on the imaging industry.

Alliance recognizes the agency's concern that certain abusive sharing arrangements may lead to overutilization, and we applaud the agency for initiating revisions to the IDTF performance standards that would eliminate these relationships. To the extent that CMS implements its proposed restriction on sharing, however, Alliance respectfully requests that the agency make the four clarifications described below.

First, Alliance requests that CMS not adopt the prohibition on staff sharing. While Alliance recognizes that there are some relationships that require scrutiny by the government, prohibiting all instances of staff sharing does not necessarily combat the problems of overutilization or poor quality care. Instead, the prohibition unintentionally implicates and bans a variety of appropriate business practices. For instance, it is a regular occurrence for commonly-owned IDTFs operating at multiple locations to share staff. Alliance itself has hundreds of employees, many of whom work at multiple IDTF locations and move from site to site, covering work shifts as needed. A technician staffed by Alliance at one location may be sick or otherwise unable to work, and a technician staffed by Alliance at another location would be unable to fill in for the sick technician as needed under the proposed rule, because the two locations would be considered to be "sharing staff"—a prohibited relationship.

In addition, the prohibition on sharing staff would create a full-time employment requirement or, in the very least, would limit individuals to working part-time at only one location. By not allowing multiple IDTFs to share staff, a physician, technician or other personnel (*e.g.*, a receptionist), would be required to work at one IDTF either full-time or part-time. It is unclear why IDTF personnel would be subject to such a requirement. The level of quality of services provided to Medicare beneficiaries does not vary with the employment status of personnel. Nor does prohibiting staff sharing ensure a higher degree of competence.

Furthermore, prohibiting legitimate staff sharing creates an inflexible and inequitable model for IDTF personnel. A single IDTF may not be able to provide its personnel with sufficient hours or pay. Accordingly, a physician, technician or receptionist may want to work in more than one setting. By prohibiting staff sharing (and essentially requiring that staff either be hired full-time or only work part-time at one IDTF), CMS is, by consequence, restricting a staff person's paycheck.

Second, Alliance requests that the proposed sharing restriction exclude space, staff and equipment shared between IDTFs and hospitals or radiologists and radiology groups. IDTFs enter arrangements with hospitals to provide radiology services where the hospital's radiology department cannot handle the number of patients. In addition, hospitals in rural areas may have insufficient resources to obtain imaging equipment and often enter arrangements with IDTFs for imaging services as a result. In either case, an IDTF located at a hospital, either as a mobile unit or as a fixed unit, is prohibited from billing for services rendered to hospital patients. The hospital has no incentive to overutilize an IDTF's resources under these situations and, to the extent that these arrangements comply with guidance issued by the Office of Inspector general,

there is no potential for abuse or for overutilization. Therefore, any shared space, equipment or staff used by both the hospital and the IDTF should not trigger the prohibition on sharing.

Similarly, arrangements between IDTFs and non-referring radiologists or radiology groups are not likely to result in abuse or overutilization. Radiologists do not refer patients to IDTFs; rather, radiologists and IDTFs depend upon patient referrals from other physicians. Radiologists often maintain office space in an IDTF and may provide radiologist services to hospitals or other IDTFs. These arrangements are commonplace in the industry. Radiologists may also use an IDTF's space, equipment and staff to perform interventional procedures such as pain management needle procedures, arthrograms and biopsies. These procedures are performed pursuant to the referring physician's order, and the radiologist does not become the patient's treating physician. In short, they are not in a position to self-refer.

Third, the prohibition should exclude situations in which space is shared in an incidental or de minimis manner that would not result in the types of abuse that CMS is attempting to curb. For example, IDTFs that lease space in a medical office building or on a hospital campus frequently use the same common areas such as waiting rooms, bathroom facilities or hallways. Under the proposed 2008 MPFS, IDTFs would be required to terminate these leases or to request dramatic physical changes. This would be a significant burden that could put these IDTFs out of business while having little effect in terms of curbing abuse or overutilization.

Based on each of these recommendations, Alliance requests that CMS revise proposed 42 C.F.R. § 410.33(g)(15) as follows:

> (15) Does not share space *or*~~,~~ equipment ~~or staff~~ or sublease its operations to another individual or organization*, except that this restriction does not include (a) space or equipment shared between an IDTF and a hospital, (b) space or equipment shared between an IDTF and a radiologist or radiology group or (c) the sharing of de minimis space, such as waiting rooms, hallways, and restrooms. The restriction contained in this standard does not apply to mobile IDTFs.*[28]

VII. CMS SHOULD REVISE ITS PROPOSED BENEFICIARY COMPLAINT REQUIREMENTS.

A. Proposal

The agency is also proposing to revise the IDTF performance standard at 42 C.F.R. § 410.33(g)(8) to require the documentation and monitoring of beneficiary complaints. CMS notes that it believes that the revision requiring such a documentation process is consistent with the established practice for other Part B suppliers found at 42 C.F.R. § 424.57(c)(19) (*i.e.*,

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[28] *See id.* at 38222 (proposed 42 C.F.R. § 410.33(g)(15)).

suppliers of durable medical equipment, prosthetics, orthosis and supplies). According to the agency, to meet the revised standard, an IDTF would be responsible for maintaining the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

- The name, address, telephone number, and health insurance claim number of the beneficiary.
- A summary of the complaint, the date it was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.
- If an investigation was not conducted, the name of the person making the decision and the reason for the decision. For mobile IDTFs, this documentation would be stored at their home office.[29]

B. Comments

Although Alliance supports the agency's initiative to document and monitor beneficiary complaints, we would recommend that CMS revise its proposal to account only for those patient comments that arise to the magnitude of complaints relating to the quality of care received and not all oral or written comments received by an IDTF. IDTFs, like all providers of medical services, receive numerous comments from their customers ranging from a reaction to contrast media to the feeling of claustrophobia during a diagnostic scan. These comments are sometimes received in writing and sometimes received orally during or after a scanning session. As currently drafted, CMS's proposed complaint-monitoring process does not provide IDTFs with the flexibility to distinguish between patient comments (*i.e.*, "I feel claustrophobic in the MRI machine") and patient complaints (*i.e.*, "I felt I was treated poorly during my testing"). It would be overly burdensome to require IDTFs to implement a documentation and monitoring process for all such patient comments.

Therefore, we request that CMS limit its proposed new standard in such a way that would allow IDTFs to distinguish between comments received that arise to the magnitude of a complaint that must be investigated and monitored and comments that do not require monitoring. Under our suggestion, proposed 42 C.F.R. § 410.33(g)(8) should read as follows:

> (8) Answer, document, and maintain documentation of all beneficiaries' questions and responses to their complaints *concerning the quality of patient care* at the physical site of the IDTF. This includes, but is not limited to, the following:
>
> (i) The name, address, telephone number, and health insurance claim number of the beneficiary.

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29 *See id.* at 38170.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision. For mobile IDTFs, this documentation would be stored at their home office.

For purposes of this section, the term "complaint" does not include patient comments, whether received orally or in writing, that an IDTF determines do not address issues relating to quality of care.[30]

In addition, CMS should provide clear instructions to its contractors that complaints concerning the quality of patient care include only those comments regarding services furnished to the patient and not comments (a) focused on events beyond the control of the provider, such as a patient's claustrophobia or reaction to contrast media or (b) concerning customer service, such as a long waiting period. We believe that revising this standard as described above and instructing contractors accordingly will ensure that only bona fide complaints are addressed. In addition, we believe that this would avoid requiring IDTFs to devote resources to monitoring patients' oral comments that do not necessarily relate to the quality of services being furnished by an IDTF but rather focus on common issues associated with all customer service providers.

VIII. CMS SHOULD IMPLEMENT ITS PROPOSED REVISION TO THE IDTF STANDARD THAT WOULD EXTEND THE TIME FOR REPORTING CHANGES OF INFORMATION.

Alliance applauds CMS for taking into account the practical realities of the imaging business in proposing to revise the deadline for reporting changes to information reported on an IDTF's enrollment application. Specifically, the proposed 2008 MPFS would extend the time in which an IDTF has to report certain changes to information on its enrollment application from 30 calendar days to 90 calendar days, although major changes to information (ownership, location, supervision, etc.) would still be reported within 30 days.[31] This is a moderate position that provides IDTFs with more flexibility to report changes. Alliance urges the agency to adopt the change.

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30 *See id.* at 38222 (proposed 42 C.F.R. § 410.33(g)(8)).

31 *See id.* at 38222 (proposed 42 C.F.R. § 410.33(g)(2)).

Thank you for considering Alliance's comments regarding the agency's proposed revisions to the policies under the MPFS. Should you have any questions or comments, we can be reached at (202) 637-2200.

Sincerely,

Stuart S. Kurlander
W. Andrew H. Gantt III
Esther R. Scherb
Of LATHAM & WATKINS LLP

Cc: Alliance Imaging, Inc.
Matthew E. Wetzel, Latham & Watkins LLP

HBMA
Healthcare
BILLING & MANAGEMENT
Association

August 29, 2007

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

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008.

Dear Ms. Norwalk:

The Healthcare Billing and Management Association (HBMA) is the premier trade association representing the third party medical billing industry. HBMA has over 650 Member companies of which more than 40 are dedicated to billing for Ambulance providers. Collectively HBMA Members represent all physician specialties along with a variety of allied health care professionals, submitting over 350 million claims annually. HBMA incorporated as a not-for-profit membership organization in 1993 and is preparing to celebrate 15 continuous years of service to our members and the industry.

In summary, we believe that the new signature requirements for Emergency Medical Services (EMS) providers contained in the proposed rule Physician Fee Schedule Rule for CY 2008 will add significant burden to ambulance staff and billing companies. This proposed rule could severely hamper the ability to bill Medicare for necessary ambulance transport services in many cases.

We understand that the proposed rule was inspired by the intention to relieve the administrative burden for EMS providers. We strongly agree with the American Ambulance Association that the "relief" being proposed by CMS would have the unintended effect of increasing the administrative and compliance burden on ambulance services, hospitals and their billers, and would result in shifting the payment burden to the patient if the proposed signature requirements at the time of transport are implemented. Accordingly, we urge CMS to abandon this approach and instead eliminate entirely the beneficiary signature requirement for emergency ambulance services.

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Currently, if a Medicare patient is physically or mentally incapable of signing and no family member or friend is available at the time of transport to sign, ambulance staff can note the patient's inability to sign on the transport documentation. The proposed Medicare revision would require field staff to obtain a signature from the facility documenting the patient's name, date and time of transport, and name and location of the receiving facility. Ambulance billers would be unable to submit Medicare claims for payment without this documentation from hospital staff at the time of the arrival. And in many cases, hospital staff will refuse to sign documents or engage in other "paper work" in advance of treating the patient for their emergent condition in order to avoid violating EMTALA regulations. And once the patient is transported to the hospital, the Ambulance provider cannot wait around until the patient's treatment in the hospital has been completed to receive the paperwork.

HBMA supports the American Ambulance Association efforts to stop this proposed change in Medicare requirements and urges CMS to reconsider this additional signature requirement. Adequate documentation of each transport already exists in the ambulance company and the facility's records, without this added requirement of a facility representative signature at the time of patient arrival. From a program integrity perspective, it would appear that the corroboration of the facility and ambulance provider records should suffice for audit and verification purposes, etc.

In light of the foregoing, we urge CMS to consider the recommendations as outlined in the attached letter by the American Ambulance Association.

Thank you for your consideration of these comments.

Sincerely,

Sherri L. Dumford

Sherri L. Dumford, CHBME
President
Healthcare Billing and Management Association

AstraZeneca

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August 31, 2007

By Overnight Mail

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

Re: CMS-1385-P – ASP Issues, CAP Issues, TRHCA – Section 101(b): PQRI, and Drug Compendia

Dear Mr. Kuhn:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca")) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Service ("CMS") proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Part B Payment Policies (the "Proposed Rule"). AstraZeneca is one of the world's leading pharmaceutical companies, with a strong commitment to discovering, developing, and delivering innovative pharmaceutical solutions for debilitating diseases and improving patient lives. Through its leadership in the cardiovascular, oncology, neuroscience, gastrointestinal and respiratory areas, AstraZeneca is committed to the discovery of drugs that will allow Medicare beneficiaries to lead longer, healthier and more productive lives.

In that regard, we respectfully submit the following recommendations concerning the Proposed Rule. Our specific comments recommend:

- Clarification concerning the treatment of bundled arrangements for purposes of calculating ASP.
- Discontinuing the use of least costly alternative ("LCA") policies in the ASP context.
- Not changing current CMS policy that prohibits CAP vendors from repackaging CAP drugs.
- Changing CAP policy to allow physicians to leave the CAP outside the annual enrollment period.
- Allowing for industry input on the establishment of PQRI Quality Measures.

- Clarification of drug compendia listing requirements and approval of at least one other compendium by year-end.

I. <u>ASP Issues:</u> AstraZeneca requests that CMS further clarify the treatment of bundled arrangements for purposes of calculating ASP and discontinue the use of LCA policies.

Our ASP-related comments primarily concern CMS's discussion of bundled arrangements. CMS proposes to define the term bundled arrangement and to require that, for purposes of calculating ASP, a manufacturer must allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement. CMS states that it seeks to make the ASP bundling methodology consistent with that applied to Medicaid AMP calculations, while addressing existing program differences. CMS solicits comments on its proposed allocation methodology, making the ASP bundling methodology consistent with the treatment of AMP in the Medicaid context, its impact on the estimation of lagged price concessions, and any recommended alternative approaches for the treatment of bundled price concessions that are appropriate in the ASP context.

AstraZeneca supports CMS's goal of providing consistent guidance across various programs (i.e., Medicaid rebate, ASP calculation) and applying such guidance only on a prospective basis. In light of the recent guidance in the AMP rule, we request that CMS further refine its guidance when it issues the final rule to clarify certain issues concerning bundled arrangements and ASP. First, CMS should clarify that, in the ordinary course, bundled arrangements must involve multiple products. For example, a contract involving different strengths and formulations of a single product may provide for discounts on all strengths and formulations and further require formulary placement for specified strengths and/or formulations. Absent express contingency requirements that all strengths and/or formulations must have formulary placement as a condition to earning the discounts, however, the contract should not create a bundled arrangement. Similarly a contract that simply relates to a product family, without differentiation among strengths, formulation, or package sizes, should not be a bundled arrangement. Second, CMS should clarify that a bundled arrangement is not created simply by having multiple products on a contract, but rather only where there is a contingency across multiple products that must be met as a condition to earning discounts on the products. Third, CMS should clarify that the scope of a bundled arrangement is limited to those products and discounts that are subject to the contingency. If a contract involves discounts contingent on meeting certain cross-product requirements, only the discounts and products to which the requirements apply should be included in a bundled arrangement. The bundled arrangement should exclude additional non-contingent discounts and products.

Separate and apart from the requested clarifications to the treatment of bundled price concessions, AstraZeneca requests that CMS instruct Medicare carriers to discontinue the use of least costly alternative ("LCA") policies in the ASP context. The ASP calculation methodology derives from the MMA whereas there is no statutory authority for LCA policies, which directly conflict with the principles underlying ASP.

Further, discontinuing the use of LCA policies is consistent with CMS's goal, as stated in its May Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics (http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/), of "working further to ensure that more accurate and, as appropriate, separate payment is made for single source drugs and biologicals under Section 1847A [of the Social Security Act]."

II. <u>CAP Issues:</u> AstraZeneca requests that CMS not permit CAP vendors to repackage CAP drugs and, separately, change CAP policy to allow physicians to leave the CAP outside the annual enrollment period.

Among other issues concerning the CAP, CMS seeks input concerning its policy on the use of prefilled syringes to determine whether it would be feasible to make the option of using prefilled syringes supplied by an approved CAP vendor available to all physicians who participate in the CAP. This approach would be in lieu of the current requirement that physicians go outside the CAP in order to obtain CAP drugs in prefilled syringes.

AstraZeneca has strong concerns about allowing approved CAP vendors to repackage CAP drugs. CMS's policy rationale for prohibiting this practice remains sound; the CAP is not intended to require CAP vendors to perform pharmacy admixture services when furnishing CAP drugs, particularly because such services require specialized staffing, training and equipment that a CAP vendor may not possess. We caution against CMS making broad policy changes that could compromise the integrity of CAP drugs and jeopardize patient care. When product labeling provides for a single dose vial, CMS should not allow CAP vendors to repackage the product or allow for its use as a multi-dose vial.

We also request that CMS outline a process whereby physicians may leave the CAP outside the annual enrollment period. We believe that allowing for increased flexibility in CAP participation will encourage more physicians to consider participating in CAP and increase that program's success.

III. <u>TRHCA – Section 101(b): PQRI:</u> AstraZeneca requests that CMS allow for industry input on the establishment of PQRI Quality Measures.

We applaud CMS for its continued use of PQRI Quality Measures and believe that having physicians report on the measures set forth in the Proposed Rule is an important step in gathering information about patient care. In setting future quality measures, AstraZeneca believes that industry can play an important role in refining and providing information that complements the findings of the National Quality Forum and the AQA Alliance. We request that CMS consider ways to incorporate industry perspectives in establishing PQRI Quality Measures. For example, pharmaceutical compliance and persistency is one area in which industry can provide substantive information that is beneficial in furthering the establishment of PQRI Quality Measures.

IV. <u>Drug Compendia:</u> AstraZeneca requests that CMS clarify drug compendia listing requirements and approve at least one other compendium by year-end.

CMS proposes to create a public notice and comment process related to requests for changes to the list of compendia used to determine medically accepted indications for drugs and biologicals used in anti-cancer treatments. The Proposed Rule describes a process for posting proposed changes on the CMS web site, the requirements for a complete request, the framework for public comments, standards for inclusion of compendia, the timeline for CMS decisions, and requirements pertaining to updated editions of approved compendia.

We commend CMS for addressing this important issue in the Proposed Rule. Cancer care is an area of intense clinical research, and there is a rapidly-developing body of knowledge regarding effective oncology treatment options. Congress and CMS have recognized that many emerging cancer treatment options involve compendia-listed uses of FDA-approved drugs and biologicals. It is imperative for Medicare coverage policy to continue to be responsive to these clinical developments in order to ensure that Medicare beneficiaries with cancer have access to the safest and most effective treatment options. We support the process outlined in the Proposed Rule, including, in particular, CMS's proposal to permit public comments on compendia recommendations. We urge CMS to adopt a mechanism to expedite review of a compendium's status when there is a name change or ownership change to promote seamless coverage to the extent possible. We also request that CMS identify what current sources are acceptable and approve at least one other compendium by year-end so that Medicare beneficiary access to the most current cancer treatments is not compromised.

* * *

We appreciate your consideration of our comments, and would be pleased to answer any questions you may have.

Sincerely,

Sandra Leonard, MPH
Director, Government Reimbursement
AstraZeneca Pharmaceuticals LP

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Office of the Vice President
Fellowship Activities
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August 30, 2007

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

Re: **CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008**

Dear Mr. Kuhn:

The American College of Obstetricians and Gynecologists (ACOG), representing more than 52,000 physicians and partners dedicated to improving women's health, appreciates the opportunity to comment on the "Medicare Program; Proposed Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Changes to Payment Under Part B" published in the July 12, 2007 Federal Register. Our primary concern in reviewing any proposal for new reimbursement policies is the potential impact these policies may have on access to and quality of health care for women.

Resource-Based PE RVUs

ACOG is pleased that CMS is seeking ways to classify equipment according to category-specific usage rate assumptions. MedPAC's recommendation to increase the equipment utilization assumption, cited in the Rule, is based on a limited study of CT and MRI equipment only, which should not be viewed as representative of all equipment or all imaging equipment. The RUC's request to refine this percentage cites the same limited data. We do not believe a higher usage assumption is justified for ultrasound or x-ray equipment.

ACOG has conducted a survey to determine utilization rates for ultrasound and x-ray imaging equipment among obstetricians and gynecologists. The mean time of use for ultrasound equipment among the 54 responses, with 91 machines, was 23.79 hours per week. The mean time for use of x-ray equipment was 21.47 hours, with 14 responses and 19 machines. These results largely validate the current 50% assumption rate. Increasing the usage assumption for this equipment to unsubstantiated levels would arbitrarily reduce payments. We plan to conduct a similar survey in the near future to determine usage rates for other types of medical equipment.

Equipment is often used significantly more or fewer than 25 hours per week, the usage currently assumed by CMS. A recent Lewin Group survey found that, on average, DXA machines are used for patient care fewer than 15 hours per week. CMS should accept ACOG's survey data and consider commissioning additional surveys to gather similar information. ACOG is willing to assist in this process. Please contact James Scroggs (202-863-2447 or jscroggs@acog.org) if additional information is desired.

77080: CMS's new methodology for calculating practice expenses would reduce PE RVUs for CPT code 77080 [Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton] from 2.42 to 0.87. At this level of practice expense reimbursement, physicians will not be able to afford to provide DXA scans, and women will lose access to this important diagnostic test. CMS should re-evaluate the value of this service to ensure that women retain access to needed care and physicians are adequately reimbursed.

A4562: Medicare payment for pessaries, HCPC code A4562, is consistently below the cost incurred by the practice providing such devices. CMS should increase these payments to ensure that providers are adequately reimbursed for the cost of pessaries. Reimbursement should cover the cost of the pessary plus shipping and reasonable practice expense for storage and handling.

Please contact ACOG staff person Kim Chisolm at 202-863-2456 if you need additional documentation or information regarding pessaries.

Physician Self-Referral Provisions

We agree with CMS that the exception for obstetric liability insurance subsidies is unnecessarily restrictive, and is unlikely to have the desired effect of increasing access to obstetrical care in a Health Professional Shortage Area (HPSA). While most of the requirements for the exception seem reasonable, it is unlikely that an obstetrician will be able or willing to annually certify that some specified percent of the physician's patients treated under the liability insurance subsidy reside in a HPSA or medically underserved area or are part of a medically underserved population. Even determining the exact location of a HPSA is not a simple task, since they are listed by census tract, the boundaries of which are difficult to determine.

Instead, physicians should initially certify that the practice is in or near a HPSA, and that more than half of patients are expected to reside in a HPSA or medically underserved area or be part of a medically underserved population. We urge maintaining the subsidy for an extended period, even if physicians are successfully recruited and the nearby census tract loses its HPSA status. Otherwise, immediate loss of the subsidy could put physician practices and patient care in a Catch-22. Obstetricians must be able to count on the subsidy to continue for much longer than a year. It might be acceptable to ask the physician to verify that a majority of obstetric patients reside in a HPSA or medically underserved area or are part of a medically underserved population after an extended period of ten years. Annual certification is an unreasonable administrative burden.

Sustainable Growth Rate

The Medicare Fee Schedule and Resource Based Relative Value System are used not only by CMS, but also as benchmarks by many insurers. Declining reimbursement in the face of rising costs, especially the cost of professional liability insurance, is already forcing some physicians to stop accepting new Medicare and Medicaid patients, and may soon have serious adverse effects on women's access to care. We urge CMS, working with Congress, to take the cost of physician-administered drugs out of the physician payment calculation, to do everything in its power to prevent the projected 9.9% cut to physician payment and to find a long-term solution that will accurately reflect increases in medical practice costs.

Coding – Additional Codes from 5-Year Review

We agree with the RUC's recommendation to bundle CPT code 93325 [Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)] into Doppler echo code 93307 [Echocardiography, transthoracic, real-time with image documentation (2D) with or without

M-mode recording; complete]. However, it is not appropriate to bundle 93325 into CPT codes 76825, 76826, 76827, or 76828, all of which are echo exams of the fetal heart. Fetal echo exams are usually performed alone without Doppler color mapping. In cases when the color flow velocity mapping is needed, determining the direction of blood flow in a fetus is considerably more complex than in an adult since there are a multitude of anomalies that must be considered, and physicians spend significantly more time and effort to perform the study.

TRHCA - Section 101(b): PQRI

ACOG is concerned that CMS is expanding the 2008 Physicians Quality Reporting Initiative (PQRI) without any review of the program that began on July 1, 2007. The impact on patient care, physician participation rates, and implementation costs are unknown. We urge the agency to review the 2007 program before extending or expanding the program.

CMS' requirement that measures for the 2008 program be developed "through the use of a consensus-based process" is too broad. Direct specialty physician involvement in the development, testing and implementation of quality measures is the only way to ensure that specialty measures are appropriate and clinically-relevant. While the proposed rule recognizes the American Medical Association's Physician Consortium for Performance Improvement (AMA-PCPI) as a source for the development of quality measures eligible for inclusion in PQRI 2008, we urge CMS to designate the AMA-PCPI as the only entity appropriate for the development of physician-level quality measures. The AMA-PCPI process is consensus-based and physician-led. These characteristics ensure physician buy-in on measures, which is essential for an effective quality reporting program. There is the risk of developing conflicting or inconsistent measures if there are multiple development organizations.

TRHCA - Section 101(d): PAQI

CMS should apply the $1.35 billion available in the Physician Assistance and Quality Improvement Fund to reduce the 9.9% payment cut scheduled to take effect Jan. 1, 2008, consistent with the intent of Congress and the recommendation of the Medicare Payment Advisory Commission. Using funds for this purpose would have a positive impact on all physicians, rather than funding an untested quality reporting program that has not been shown to have any positive effect on patient care or health outcomes.

ACOG appreciates CMS's continued willingness to work cooperatively with the physician community to assure implementation of sound policies for governing Medicare payment policy. We are eager to work with CMS to resolve the issues identified in these comments.

Sincerely,

Albert L. Strunk, JD, MD, FACOG
Vice-President, Fellowship Activities

NATIONAL OSTEOPOROSIS FOUNDATION

Standing Tall For You®

August 31, 2007

Herb Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
445-G
200 Independence Avenue, SW
Washington, DC 20201

Attention:

Re: CMS-1385-P
Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Acting Administrator Kuhn:

Introduction

On behalf of the National Osteoporosis Foundation (NOF), thank you for the opportunity to comment on the Center for Medicare and Medicaid Services Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008. This letter and its comments address Code 77080 (previously 76075) – Dual energy x-ray absorptiometry (DXA) a bone density study at one or more sites of the axial skeleton (e.g. hips, pelvis, spine).

NOF is the nation's leading voluntary health organization solely dedicated to osteoporosis and bone health. Its mission is to prevent osteoporosis, promote lifelong bone health and help improve the lives of those affected by osteoporosis and related fractures and find a cure. NOF achieves its mission through programs of awareness, advocacy, public and health professional education and research. NOF is a leading authority for anyone seeking up-to-date, medically-sound information and educational material on the causes, prevention, detection and treatment of osteoporosis.

Osteoporosis

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased

susceptibility to fractures, specially of the hip, spine and wrist, although any bone can be affected.

Osteoporosis is the most common bone disease in humans. In the United States, it is a public health threat for 44 million Americans, 55 percent of the people 50 years of age and older. Ten million Americans are estimated to already have the disease and almost 34 million more are estimated to have low bone mass, placing them at increased risk for osteoporosis. Of the ten million Americans with osteoporosis, eight million are women and two million are men. The former Surgeon General states in his report on bone health and osteoporosis, unless the US makes a concerted effort, "in 2020 one in two Americans over the age of 50 will have, or be at high risk of developing, osteoporosis.[i]

Osteoporosis often is called a "silent disease" because bone loss occurs without symptoms. People may not know that they have osteoporosis until their bones become so weak that a sudden strain, bump or fall causes a fracture or a vertebra to collapse. Collapsed vertebrae may initially be felt or seen in the form of severe back pain, loss of height, or spinal deformities such as stooped posture.

Risk factors, such as low body weight or use of steroid drugs, increase the likelihood of specific people developing osteoporosis and fractures. Individuals either at risk for or with osteoporosis may be prescribed a bone mineral density test (BMD). These tests not only identify osteoporosis and predict a person's risk for fractures, but they also monitor an individual's response to an osteoporosis treatment.[ii] Central dual x-ray absorptiometry (DXA), which may measure the hip and/or spine, is the preferred measurement for definitive diagnosis and monitoring of the effects of therapy.[iii]

Osteoporosis is not an inevitable consequence of aging but a disease that is largely preventable. Individuals at risk for osteoporosis often do not think they are at risk and thus, do not engage in beneficial behaviors. A risk factor assessment, coupled with BMD testing, as appropriate, can determine overall risk for the disease and subsequently, for fracture, so that prevention and/or therapeutic measures may be taken. Likewise, if therapies are prescribed, there is a need to monitor whether they are working appropriately for an individual patient.

Current Policies

According to CMS data, fewer than 20 percent of those eligible to be tested for osteoporosis actually are tested.[iv] This extremely small number belies the fact that NOF has worked with the federal government, other policy bodies and professional and lay groups to expand awareness and

education about better bone health, prevention of osteoporosis, and increased and improved diagnosis and treatment for the disease.

During the last decade, federal initiatives have provided recommendations for bone density testing and achieved Medicare coverage of these tests and treatments for osteoporosis. The "Welcome to Medicare" exam includes an osteoporosis evaluation as part of its key preventive services. In 2006, CMS acknowledged that central DXA testing is the standard for diagnosis and by which progress in osteoporosis treatment should be measured. Enacted as part of the Tax Relief and Healthcare Act, Medicare's expanded Physician Voluntary Reporting Program (Physician Quality Measures), now includes four measures relating to osteoporosis. All of these measures depend on evidence produced by DXA tests.

Comments on Overall Impact

Regarding Medicare's continued reduction in physician reimbursement for central DXA testing outside of a hospital setting, NOF's major concern is that this year's proposal will reduce patient access to quality health care. NOF believes that it will reduce the number of people being tested for a "silent disease" whose severe consequences, for the most part, can be prevented. In addition to the pain and suffering this policy may cause for individuals, it also may exact an economic toll on the government, despite the government's goal to lower its health care costs.

The Health Plan Employer Data and Information Set (HEDIS) fracture measure tracks the percentage of women age 67 and older who were diagnosed with a fracture and who received either a BMD test or prescription drug treatment within six months of the date of fracture. The number of women who were tested or treated for osteoporosis has risen just one percent a year each year for the last three recorded years – from 18 to 19 to 20 percent.[v] And this is for individuals who already have sustained a fracture, which puts them at even greater risk for additional fractures! Therefore NOF believes that despite improved public policies, further reduction in physician reimbursement for osteoporosis testing will only erode any progress to increase the number of individuals tested, diagnosed and treated for the disease.

Access to Quality Care

The proliferation of DXA systems in physicians' offices has made it easier for a patient to be tested in conjunction with a visit to their physician. Approximately 70 percent of osteoporosis testing currently is performed outside of the hospital setting.[vi] After the 2007 reduction in physician reimbursement, a physician survey was conducted which indicated that 37 percent would stop performing DXA by the end of the year; 73 percent

would curtail professional development activities; and based on the 2010 Medicare Physician Fee Schedule, 93 percent would stop performing DXA studies.[vii] Some facilities, both urban and rural, have begun to close and others have begun to cancel purchases of new machines.

With fewer facilities, the need to travel greater distances to potentially unfamiliar, clinical hospital settings with unfamiliar staff and possibly a higher deductible, the likelihood of patients getting tested is reduced. Older, frail patients, especially in rural areas, may find this travel to be particularly difficult. The need for a subsequent physician visit to review results of the test also may add logistical and financial burdens for patients. As the complexity of care increases, including additional medical visits and record transfers, the barriers point to people potentially not following through with recommended DXA testing, impeding their diagnosis and treatment.

This runs counter to the expert opinions expressed by well respected policy forums, such as the Physician Consortium for Performance Improvement and the National Committee for Quality Assurance, whose work resulted in the osteoporosis measures included in the Physician Quality Reporting Initiative, and it runs counter to programs and policies advanced and supported by the NOF.

In finalizing the Medicare rule governing bone density testing, CMS states that "the single best predictor of fracture risk, with the most widely accepted method for measuring BMD being the dual energy x-ray absorptiometry (DXA) for a bone density study of the axial skeleton (for example, hips and spine)."[viii]

In addition, quality of care for those with or at risk for osteoporosis depends on the ability of the person who gives the DXA exam, the machines on which it is given, and the knowledge of the professional who interprets the test. Results of a recent survey (previously cited) demonstrate that continuing professional education and the purchase of new equipment will be curtailed, potentially resulting in diminished quality of care as a result of reduced reimbursement.

However, fracture rates may increase along with global health care costs. A study published this year concludes that by 2025, "annual fractures and costs are projected to rise by almost 50%..." with the most rapid growth - greater than 87 percent, estimated for individuals ages 64-74.[ix] "Among women over age 45, the government pays for most of the cost of osteoporotic fractures: Medicaid covers almost a fourth of the expense and Medicare pays nearly half."[x] According to a study published in 2005, the use of central DXA testing (in this instance, of the hip) for osteoporosis in

older adults was associated with 36 percent fewer incident hip fractures over six years compared with usual medical care.[xi]

The Lewin Group recently was commissioned to conduct a Congressional Budget Office-style scoring analysis of five-year costs to Medicare if the Deficit Reduction Act and other reductions to reimbursement were reversed through legislation. According to their analysis, although direct DXA payments would increase by $648 million, after accounting for savings associated with avoided fractures and the cost of treating at-risk individuals, the savings would be $1.14 billion over five years.[xii]

Conclusion

In conclusion, NOF is very concerned about how further reduction in Medicare reimbursement for Code 77080 (previously 76075), central DXA testing, will affect access to and quality of care for individuals with and at risk for osteoporosis. For years, NOF and federal policymakers have encouraged prevention of osteoporosis, and when this is not possible, they have encouraged early diagnosis and treatment to alleviate the severity of the disease and reduce the risk for fracture. Unfortunately, the current rate at which this is occurring is still very low comparable to other disease testing, and there is general agreement among interested healthcare professionals and policymakers that not enough is being done to prevent, diagnose and treat osteoporosis.

Now federal policymakers are concerned about over-utilization of a relatively inexpensive test that has the ability to prevent highly costly hip fractures, costly not only in terms of economic dollars, but also costly in terms of their physical and emotional toll. And, large portions of the bill for these fractures are paid for by government agencies, such as Medicare and Medicaid. Surely, there is a disconnect.

NOF urges you to reevaluate the most recently proposed reduction in reimbursement for Code 77080, taking into consideration the arguments put forth in this document as well as others presented by various medical specialty societies. By reviewing the entire scope of concerns surrounding this reimbursement reduction, we urge you, above all, to consider the patient, who often gets lost in the fray of technical arguments. If patients have limited access and lesser quality of healthcare, we all have lost sight of our objectives. After all, the ultimate goal we all strive for is to simplify access to improved healthcare so that patients can live longer and have more productive and fulfilling lives.

As NOF moves forward, and hopefully, the federal government continues to encourage those individuals at risk for or with osteoporosis to seek appropriate healthcare (as it has through its "A Healthier US Starts Here"

Prevention Bus Tour), we look to agencies such as the Centers for Medicare and Medicaid Services to lead the way toward more enlightened and scientifically-based public health policies.

Thank you again for the opportunity to comment, and if we can be provide additional information, please do not hesitate to contact Roberta Biegel, senior director of public policy and government relations at 202-721-6364 or roberta@nof.org.

Sincerely,

Thomas Einhorn

Thomas A. Einhorn, MD
Co-chair, Advocacy Committee

Conrad Johnston

C. Conrad Johnston, Jr., MD
Co-chair, Advocacy Committee

Citations:

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[i] U.S Department of Health and Human Services. *Bone Health and Osteoporosis: A Report of the Surgeon General.* Rockville, MD: U.S. Department of Health and Human Services, Office of the Surgeon General, 2004: 4

[ii] U.S. Department of Health and Human Services: 198

[iii] National Osteoporosis Foundation. *Physician's Guide to Prevention and Treatment of Osteoporosis.* Washington, DC, 2004: 14

[iv] 2004 Centers for Medicare and Medicaid Services Claims Data

[v] National Committee for Quality Assurance. *The State of Health Care Quality* (Years 2004, 2005, 2006)

[vi] Based on 2002 Medicare data

[vii] Administered by the International Society for Clinical Densitomety. *A Multi-Clinical Society Survey of Physician's Responses to the Scheduled DXA Reimbursement Cuts To Be Phased In Over the Next Four Years*

[viii] U.S. Department of Health and Human Services. Centers for Medicare and Medicaid Services. *42 CFR Parts 405, 410, et al. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule,* Federal Register August 22, 2006: 49059

[ix] Burge, R, et al. *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025.* Journal of Bone and Mineral Research 2007 Vol. 22, No. 3: 465-475

[x] U.S. Department of Health and Human Resources: 94

[xi] Harris, TB, et al. *Association between screening for osteoporosis and the incidence of hip fracture.* Annuals of Internal Medicine 2005 Vol. 142, No. 3: 173-181

[xii] The Lewin Group. *Assessing the Total Cost of Providing DXA in the Office-Based Setting and Scoring a Reimbursement Alternative. (*August 28, 2007 presented to CMS)

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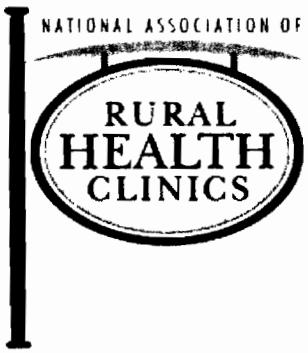

August 30, 2007

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

Dear Mr. Kuhn

These comments are submitted on behalf of the National Association of Rural Health Clinics and the more than 3,000 RHCs we represent.

Our comments are directed at the THERAPY STANDARDS AND REQUIREMENTS

CMS has proposed the inclusion of new standards for therapy professionals providing services in federally certified Rural Health Clinics.

These new standards are inappropriate and unnecessary as physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants and speech language hearing pathologists are not recognized providers in the RHC setting. Consequently, the establishment of standards for these providers makes no sense.

In order for a Medicare service to be covered in the RHC setting, there must be a face-to-face encounter with a physician, physician assistant, nurse practitioner or certified nurse midwife. If the service is a mental health service, the RHC can utilize a PhD Psychologist or Masters trained Clinical Social Worker. Why does CMS feel the need to establish a personnel standard for PTs, PTAs, OTs, OTAs or SLPs when they are not one of the name health professionals?

We find it particularly disconcerting that CMS has put forward this particular proposal at a time when the RHC community has been waiting for nearly a decade for CMS to publish new standards that are necessary for RHCs to provide higher quality care. How is it that you are able to put forward this particular proposal, which we did not ask for nor need, when you have been unable to publish proposed rules that are relevant to the RHC community?

On behalf of the NARHC and the patients we serve, we strongly recommend that you withdraw this proposal.

Sincerely,

Bill Finerfrock
Executive Director
National Association of Rural Health Clinics
202-543-0348
info@narhc.org

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PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

George Paz
Chairman, CEO
Express Scripts, Inc.

Mark Merritt
President & CEO

August 31, 2007

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

Re: File Code: CMS-1385-P

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

Dear Acting Administrator:

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the Notice of Proposed Rulemaking (NPRM) regarding proposed revisions to payment policies under the physician fee schedule, and other Part B payment policies for CY 2008.

PCMA supports eliminating the exemption of computer-generated faxes from the e-prescribing standards under Medicare. However, we do not believe this will drastically increase widespread physician adoption. The best path to widespread adoption of e-prescribing in Medicare is through a combination of incentives and a requirement for physicians to use e-prescribing technology. If Congress were to enact such a law, a recent Gorman Health Group study estimated that roughly 80 percent of prescriptions in Medicare would be prescribed electronically by 2017.

Our specific comments focus on the following:

- Elimination of the computer-generated fax exception should not impact electronically faxed prescriptions outside of Medicare e-prescribing;
- CMS should continue to work with the Drug Enforcement Agency (DEA) to allow for e-prescribing of controlled substances; and
- The effective date of eliminating the exemption should be consistent with the date that the Secretary implements the final e-prescribing standards.

Elimination of the Exemption Should Not Impact Fax Technology Outside of E-Prescribing

There are certain circumstances outside the true definition of "e-prescribing" in which faxing prescriptions is necessary, including controlled substances, mail order pharmacy, and circumstances in which there may be temporary system failures, among others.

PCMA Recommendation: Electronic faxing technology continues to serve an important purpose in medication prescribing and should, therefore continue to be allowed outside the scope of e-prescribing standards under Medicare.

CMS Should Continue to Work with the DEA to Allow for E-Prescribing of Controlled Substances

Under the Controlled Substances Act, DEA regulations prohibit e-prescribing of controlled substances, requiring a manual signature from a registered practitioner. As a result, prescribers often manually sign prescriptions for controlled substances and, in turn, fax the script to the dispenser. It is critical that a workable path be established to allow for e-prescribing of controlled substances to ensure these medicines can also be factored into the patient safety and savings benefits associated with e-prescribing.

PCMA Recommendation: PCMA fully supports CMS's continued work with the DEA and Department of Justice to develop standards that would allow for the e-prescribing of controlled substances.

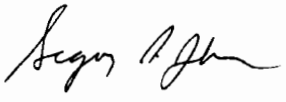
Elimination of the Exemption Should be Consistent with the Effective Date of the Proposed E-Prescribing Standards

The Medicare Modernization Act requires the Secretary to issue final, uniform standards for e-prescribing to be implemented no later than April 1, 2008. The MMA also provides for flexibility for those standards to take effect within one year after that date. To ensure all standards are consistently adopted in the same timeframe, it follows that any changes, such as those proposed in this rule, take effect when all the other standards are final.

PCMA Recommendation: The effective date of the elimination of the computer-generated fax exemption should be consistent with the implementation of the Secretary's final, uniform standards for e-prescribing.

On behalf of PCMA, I appreciate the opportunity to comment on proposed rule CMS-1385-P. PCMA looks forward to working with CMS to ensure widespread adoption of electronic prescribing.

Sincerely,



Greg Johnson
Senior Director, Federal Affairs

B. J. Ness Consulting Group, LLC

DATE: August 21, 2007

TO: Centers for Medicare & Medicaid Services

FROM: Bernie Ness, President, B. J. Ness Consulting Group, LLC

SUBJECT: Comments to File Code CMS-1385-P
"PHYSICIAN SELF-REFERRAL PROVISIONS"

I am responding to your solicitation of comments on this subject. I wish to begin with a broad scope discussion of relative and significant comments and proceed to more specific comments. My comments are based on my 33 years experience in the lab industry, the last 13 years as a consultant to pathology groups nationwide. For the following reasons, I am writing to ask CMS not to adopt the requirement that a pathologist be employed full-time by a physician practice in order to bill the Medicare program for professional pathology services.

Broader Scope Comments

After years of witnessing the evolution of rules and regulations regarding pathology and laboratories, it is apparent to me that treating parties unequally has led to many of the contortions in the rules today. In addition, it appears CMS suffers from some incorrect impressions. The specific items are:

- Rules prohibiting markup should apply equally to all parties. Otherwise, we get exemptions in the current rules that make little sense. Some examples:
    - A hospital-based pathologist who provides pathology services for tissues derived from a private practice physician's office and charges Medicare full global fees, although the pathologist purchased the technical services associated with those tissues from the hospital at highly discounted fees with no disclosure.
    - A pathologist provides pathology services for tissues from Medicare patients and charges Medicare full global fees, although the pathologist purchased the technical services associated with those tissues from another pathology laboratory at highly discounted fees with no disclosure.

- The idea that pathologists do not order tests is one of the oldest myths in the laboratory industry. Some specific examples:
    - While the Pap smear/test is on the laboratory fee schedule, the review by a pathologist of abnormal Pap smear/test slides is on the physician's fee schedule. The criteria for which Pap slides are to be reviewed is set by a pathologist. The same pathologist bills the reviewed slides to Medicare. The percentage of reviews varies greatly among pathologists with no published protocols.

5035 Cartagena Drive, Suite B100, Toledo, OH 43623 800.280.3785 bjness@BEX.net

- When a clinician sends tissue from a Medicare patient to a pathologist for diagnosis, rarely does the clinician know that a pathologist can directly order one or more special or IHC stains on that tissue and charge those stains to Medicare at global fees. Those fees are then paid directly to the pathologist or the laboratory for which he/she is employed. The stains in question are CPT 88312, 88313 and 88342, among others. Furthermore, the percentage of tissue slides that are ordered by a pathologist to be stained varies dramatically across pathology practices and across the country, even when adjusted for types of tissue being diagnosed. Recent studies reported in *Laboratory Economics Special Report* (July 2007) indicate that from 2000-2005 all special stains increased dramatically (8% per year) as well as IHC stains (16.8% per year). Pathologists account for over 95% of this dramatic increase in cost to the Medicare program. There are no published standards for staining and the amount varies from 5% to 35% of all cases diagnosed by a pathology group.

- The reference to "profits" being made at the expense of the Medicare program is just not realistic and does not serve any meaningful purpose. Some examples:

  - CMS has to recognize that without a profit, ***no one*** will perform services needed by Medicare or any other program. CMS is in a unique position with a published fee schedule whereby pathology and laboratory services are paid. Who collects those fees and makes that profit, whether an individual pathologist or a commercial laboratory or a specialty practice, should not be a focus of CMS (other than assuring timeliness and quality of services to Medicare patients) because someone (pathologists included) will make a profit or the service will not be provided.

  - CMS should assure that Medicare patients actually do receive the services for which payment was made. CMS should avoid determining whether a pathologist, a specialty physician laboratory, a commercial laboratory or a hospital outreach program or some other party is receiving the payment and, hence, the profits. If a pathologist's professional service is billed to Medicare, whether the bill comes directly from the pathologist, or the commercial laboratory that employs the pathologist, or the specialty practice that contracts for pathologist services, CMS should be neutral in terms of payment. Not one cent more gets paid to any of these parties, yet all of them provide the pathology services necessary for the Medicare patient. This is a "cost neutral" situation for M/Care.

- Reference to "abuse" in the form of overutilization is similar to the profits issue in terms of incessancy and is a diversionary tactic. Examples:

  - CMS should review the current standards of care and hold providers to those standards. A good example of this is the number of cores that are to be performed on a patient undergoing prostate biopsy. The National Comprehensive Cancer Coalition (NCCN) has developed standards for a patient with early prostate cancer as well as many other forms of cancer. (http://www.nccn.org/professionals/physician_gls/PDF/prostate_detection.

pdf). For a long time this number was only 2 cores. In the mid 1990's the standard was upgraded to 6 cores. With additional research, the number was upgraded to 10 cores and the recommendation was recently further upgraded to 12 cores. The research has shown a dramatic increase in prostate cancer detection with increased core sampling. Any comparisons in urology over the last decade must take into account the dramatic change in the published protocols. As a prostate cancer survivor, I am grateful that my urologist sampled me at the then current standard of 6 cores. My blood PSA was only slightly elevated but I had prostate cancer in both lobes of my prostate gland. My cancer would have been missed with only 2 cores taken.

- As a sales and marketing consultant to the pathology community for over 12 years, I was routinely ordered by pathologists to solicit urology, GI and dermatology practices. These groups generate 80% of all biopsies in the US. I find it ironic and hypocritical that pathologists are claiming overutilization of services from specialty groups with internal pathology. These same pathologists accepted those same 12 core biopsy patients work without a whisper of discontent. I do not know of a single instance in 12 years where the pathologist called the urologist to complain of overutilization of services. In fact, many times a pathologist would call the urologist and suggest that they switch from 6 cores to 12 cores or ask them to submit the cores in individual containers to increase their billings to Medicare.

- CMS should actively pursue those practitioners (including pathologists) who do not follow the accepted and published standards of care. By doing so, overutilization will become a non-issue and, importantly, Medicare patients will receive the highest standard of care and the quality they deserve and that Medicare pays for daily. The routine overutilization of special stains and IHC stains would be a good place to start.

- Biopsy procurement is much more invasive than phlebotomy for blood work. Plus, there is always some clinical indication for a biopsy (abnormal blood results, abnormal X-rays, etc). No specialist is going to risk a multi-million dollar med/mal lawsuit to take medically unnecessary biopsies for an extra hundred dollars. The studies on lab utilization by MD's were all done relative to lab blood work not tissue biopsies many years ago.

The above issues should give pause to those at CMS considering the next steps. Further complications to an already overly complicated set of existing rules are not needed here.

Narrower Scope Comments

To respond to your request for comments on specific issues, I offer these examples:

- *Should certain services not be exempted?*

  - All pathology services, including anatomic and clinical, should remain exempted whether provided directly by a solo pathologist, a pathologist in

a group practice or employed or contracted to a commercial laboratory or employed by a specialty practice in-office pathology laboratory. The focus of CMS should be quality of services to Medicare patients, not the vehicle taken by the provision of the pathologist's professional service.

- The organized pathology community prefers to split clinical from anatomic pathology and allow only clinical pathology in specialty practice in-office pathology laboratories. The rationale provided is that anatomic pathology results are not needed immediately for patient treatment. This may explain the substandard service for pathology results by local pathologists. Pathologists do not seem concerned that a PSA test may be performed in specialty physician laboratories. There is no concerted organized pathology effort to stop it. A clue for this stance is that Medicare does not pay professional component fees for clinical pathology services, such as PSA. However, this is not the case with anatomic pathology testing.

- CMS needs to recognize that the structure of practices has changed over the years into significantly larger-sized groups than ever existed before except in pathology. Urologists and gastroenterologists have led the way, driven by higher cost and lower reimbursement pressures, partly caused by lower Medicare fees. These physicians are seeking ancillary services, such as full clinical and anatomic laboratories, to accompany their much larger investments in new physical facilities encompassing sophisticated urology procedure suites and endoscopy centers, respectively. Pathologists have done relatively little or nothing to upgrade their practice facilities or services in the same period of time.

- *Should changes impact the definition of same/centralized building?*

  - When the building issue was raised in 2006, so were many eyebrows in bewilderment. CMS should be out of the definition of laboratory size or staffing levels. Whether the space should be 350 sq. ft. or 10 sq. ft. larger or smaller and whether there should be 0.35 or 0.75 FTEs is a moot point and not a place for CMS to exert itself. These labs are all CLIA certified and inspected yearly. The real issue is whether owners of the laboratory have continual oversight of their laboratory. This means, is it in their "neighborhood"? A laboratory in Florida owned by a practice in Kansas is not in the neighborhood. A laboratory in Kansas City (KS) owned by a practice in Kansas City (MO) is in the neighborhood. The neighborhood oversight issue is one that does make sense.

  - In a similar vein, requiring a full-time employed pathologist at a specialty practice in-office or other such laboratory is a burden that serves no one except organized pathology. Only the very largest of group practices (20+ MD's) can afford a full time pathologist. This is discriminatory against practices that want the medical benefits for their Medicare patients. This becomes an issue when the laboratory needs only 0.75 of a pathologist to operate efficiently, or if they need 1.3 pathologists. Requiring full-time

pathologists in these examples adds to the inefficiently and increased costs in the US healthcare system. This will cause major problems for pathologists who service smaller laboratories or free standing surgery centers with fractional FTE efforts. It's no different than the arbitrary square footage issue for pod/condo laboratories.

Other Comments

- CMS also needs to recognize that specialty practices and other pathology laboratories must retain a pathologist to diagnose the Medicare patient's tissue. There is no shortage of very competent and well-trained pathologists willing and able to do the work. They do that work at less than the full Medicare professional component fee because they are bright enough to recognize that the professional fee includes a practice expense which they do not incur when working in a laboratory where no investment or expenses have come from their own pockets. Organized pathology prefers that CMS rein in these so called "renegade" pathologists. It is the typical Teamster reaction; "if it's a truck, a Teamster, at union rates, should be driving it". CMS should not be in an enforcer role for organized pathology. It has been shown time and again that a free market economy does best for all parties to increase quality, increase services and reduce costs.

- No one should be surprised about pathologists performing professional work for less than Medicare's professional component fee. This happens whenever a pathologist takes employment with a commercial laboratory or a pathology practice. These entities bill the professional fee and pay the pathologist a salary and benefit package that are less than the total professional fees generated by the pathologist. The same occurs when a pathologist is contracted by a specialty practice to provide pathology services in their in-office laboratory. The owners of these laboratories must earn a return on their investment by billing and collecting more dollars than they are spending. The CMS PC fee includes a practice expense component. The vast majority of hospital-pathologists have little or no practice expense as the hospital provides these services free. They usually provide their own microscopes and that is all. It would appear that taking the full practice expense under false pretenses is fraud and abuse. If CMS ever investigated this practice expense issue they would be able to recoup millions of dollars in overpayments for non-existent practice expenses. In the specialty practice pathology environment, the specialty practice is providing all the practice expenses (rent, utilities, software, transcription, dictation, microscope, billing and collections, etc) and is deducting that amount from the PC fees accordingly the way it should be done.

- CMS appears to be pained when a pathologist does not receive full professional component fees. Although a pathologist may work part-time at a discounted fee for a specialty practice in-office laboratory or other such laboratory, an important question may be how many of these pathologists charge Medicare a discounted professional fee when they do work at a hospital for a Medicare patient. The answer is none or very close to none. CMS should not lose sight of this point and focus on properly setting professional fees, not on whether a solo pathologist,

commercial laboratory, specialty practice or any other such entity receives those fees. The market will efficiently take care of fee distribution. CMS' concern should be to assure that proper quality pathology professional services are delivered to Medicare patients in a timely fashion.

I appreciate the opportunity to contribute my comments to CMS' understanding of many issues facing pathology and laboratories in our changing healthcare environment. In summary, I respectfully request that CMS not adopt the "full time employee" requirement in order for a physician practice to bill and collect from the Medicare program for the professional services rendered by its pathologist.

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SPORTS MEDICINE, INC.

August 1, 2007

Via Regular Mail and E Mail

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1385-P
P.O. Box 8018
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: CMS-1385-P - Proposed Revisions to the Physician Fee Schedule for CY 2008;
Support for Non-Facility PE RVUs for Arthroscopy Procedures
(CPT Codes 29870, 29805, 29839, 29840, 29860)

Dear Ms. Norwalk:

Arthrotek, Inc., now Biomet Sports Medicine, appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Proposed Revisions to the Physician Fee Schedule for Calendar Year 2008, 72 Fed. Reg. 38122 (July 12, 2007).

Biomet Sports Medicine is one of the world's leading manufacturers of arthroscopy products. As such, we, our physician customers, and their patients, are keenly interested in Part B payment policy that impacts arthroscopy procedures. We applaud CMS for its thoughtful work in this area and the important discussion included in the 2008 Proposed Rule regarding establishment of non-facility practice expense relative value units (PE RVUs) for arthroscopy procedures. We offer the following comments for the agency's consideration.

I. Office/Non-Facility PE RVUs for Arthroscopy Procedures

CMS' regular attention to the office/non-facility PE RVUs is an important component of the agency's ongoing effort to develop and maintain an accurate Medicare payment system that ensures patient access to reasonable and necessary procedures in the appropriate practice setting. As the agency finalizes its 2008 policies, **we respectfully request that CMS add non-facility PE RVUs to arthroscopy procedures described by CPT codes 29805, 29830, 29840, 29870, and 29900.**

A. Resource-Based Practice Expense RVUs

Under the Resource-Based Relative Value System, CMS is required to develop resource-based PE RVUs for each physician service. Two distinct PE RVUs

are established for those procedures that are performed in both a non-facility (office) and a facility (hospital outpatient department) setting in order to account for the fact that facilities receive separate payment from Medicare for the cost of providing the service. Because the PEs for services provided in a facility are included in the payment to facility, and not in the payment to the physician, the PE RVUs are generally lower for services provided in the facility setting. In contrast, the "office" or non-facility PE RVUs must reflect all of the direct and indirect PEs of providing a particular service in order to appropriately compensate the physician for the costs he incurs.

B. PE Methodology and RUC Inputs

For 2007, CMS implemented a new "bottom-up" methodology for calculating PE RVUs. Under the "bottom-up" approach, CMS determines the direct PE by adding the costs of the resources (i.e., clinical staff, equipment, and supplies) that are typically required to provide each service. After calculating the direct inputs, factoring in the indirect allocations, and applying various budget neutrality adjustments, CMS assigns relative value units for the practice expense costs. Although CMS has and continues to rely on the Relative Value Update Committee or RUC to provide non-facility PE inputs, CMS need not wait for the RUC to act. CMS is required to establish PE RVUs for all physician services, and frequently, the agency solicits price/cost information from manufacturers, physicians, and specialty societies to update its PE supply and equipment data base.

C. Arthroscopy Procedures Have Been Safely and Effectively Furnished in the Office Setting for Over a Decade

Physicians across the country have been safely and effectively furnishing arthroscopy procedures in their offices for decades, and their experiences are well documented in US peer-reviewed journals. Moreover, the clinical literature shows that office based arthroscopy has a safety profile that compares favorably with arthroscopy performed in the hospital outpatient setting.[1] There are numerous peer-reviewed articles, dating back to the early 1990s, that document the fact that office operative arthroscopy of the knee is feasible, cost-effective, safe, and preferred by the patient.[2]

1. Physicians Requested Non-Facility PE RVUs

Several surgeons, including Dr. Michael Kolczun II, of the Cleveland Clinic and Frank Bonnarens, M.D, of Orthopaedic Associates, have met with CMS. These

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[1] See, e.g., Szachnowski, P., Complications of Office Based Arthroscopy of the Knee. J Rheumatol. 1995 Sep; 22(9): 1722-5. (Finding that office based arthroscopy in patients with rheumatic diseases has a safety profile that compares favorably with arthroscopy performed in an ambulatory surgical center or operating room setting.)

[2] Small NC, et. al., Office Operative Arthroscopy of the Knee: Technical Considerations and a Preliminary Analysis of the First 100 Patients. Arthroscopy. 1994 Oct; 10(5):534-9.

surgeons, and others, have persistently advocated for the establishment of non-facility PE RVUs because the office setting is and has been an appropriate setting for

arthroscopy procedures.[3]

2. Specialty Society Support for Non-Facility PE RVUs

We understand that the American Association of Orthopaedic Surgeons (AAOS) asked CMS to assign non-facility PE RVUs to these codes in 1998. More recent informal comments from AAOS representatives indicate that AAOS staff support non-facility PE RVUs for arthroscopy procedures, but they are unclear as to the next steps for adding the PE RVUs.

While the preamble indicates that there may be one orthopedic specialty society that is reluctant to provide non-facility PE input information, we believe that CMS should move forward and establish non-facility PE RVUs based on the overwhelming evidence of safety, effectiveness, and performance of office-based arthroscopy procedures.

II. Specific Direct PE Inputs for Arthroscopy Procedures

Office-based practice expense inputs for diagnostic arthroscopy are summarized below. They include typical pre-operative tasks by the nursing staff as well as supplies unique to arthroscopy procedures. To facilitate the appropriate assignment of non-facility PE RVUs, we conducted a mini-survey of several offices to identify the supplies typically used. This data is incorporated in the table below, which also, where appropriate, uses price information from CMS's Practice Expense data file.

PE Inputs	Item	Time minutes	Price($)
Staff Time			
Pre-operative Care, review labs, informed consent, take vitals, assisting patient with preparation for procedure	*20 mins – RN@ $0.51* *20 mins LPN @ $0.37*		***$ 10.20*** ***$7.40***
Set-up Room and Equipment for Procedure	LPN	*30 mins*	***$11.10***
Arthroscopy Procedure	LPN	*45 mins*	***$16.65***
Post-operative care, dressing, vital checks, etc	RN LPN	*15 mins* *20 mins*	***$7.65*** ***$7.40***
Follow-up instructions	RN	*10 mins*	***$5.10***
Room turn over/clean up	LPN	*20 mins*	***$7.40***
Subtotal staff $72.90			
Equipment			
InnerVue Usage**		*60*	***$33.61***

[3] See, Zelle BA, Arthroscopic Restoration, Orthopedic Technology Review, Vol. 7, March 2005, describing the office as an appropriate practice setting for arthroscopy. Foot and Ankle Arthroscopy, Book Chapter, Office Foot and Ankle Arthroscopy, 2006.

PE Inputs	Item	Time minutes	Price($)
Table, power ***		83	***$1.80***
Subtotal $35.41			
Supplies			
Saline infusion	1 liter		*$2.09*
Disposable arthroscope	1		*$895.00*
Disposable scope cannula, obturator, trocar, plug	1 ea		*$150.00*
1% Lidocaine w/epi	30cc	0.06 per ml	*$1.80*
Procedure Kit	1		*$55.00*
IV infusion set	1		$1.11
IV extension tubing	2	$0.53 ea	$1.06
Ancef (antibiotic)	1 gram		*$5.00*
Stop cock - three-way	1		$1.18
Conscious sedation pack	1		$17.31
Canister, suction	1		$3.91
Tubing, suction, non-latex (6 ft) with Yankaurer tip	1		$2.96
Steri Strip Closures (6 pk.)	1		$1.12
Dura Prep Skin Cleanser	1		$7.95
20 ml. Syringe- OSHA compliant	1	$0.43	$0.43
22 gauge needle for syringe	1		$0.18
#11 scalpel	1		$0.69
Needles	3	$0.09 ea	$0.27
Syringe	3	$0.18 ea	$0.54
Bandage, elastic (post-procedure wrap)	1		$1.54
Gown, surgical	2 @4.67		$9.34
Gloves, sterile	2 @$0.84		$1.68
Gauze pads – 4x4	2 @$0.79 ea		$1.58
Bandage, ace/elastic wrap (pre-procedure wrap for foot, hand, leg, arm, etc)	1 roll		$1.54
Subtotal supplies $898.28			
Non-Facility Practice Expense			**$1,271.59**
** Based on 3 year life expectancy of InnerVue unit	$47,595.00		
Based on 2 hour day use	$ 33.61	per hour	
	$ 0.56	per minute	
*** Based on a 10 year life of table @ $6,153.63	$ 0.02	per minute	

III. Recommendations: Establish PE Inputs for Arthroscopy Procedures

Office-based arthroscopy procedures have a long history of safety and efficacy. Notwithstanding these well-documented clinical benefits, the arthroscopy procedures

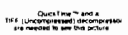
described by CPT codes 29805, 29830, 29840, 29870, and 29900 have not been assigned non-facility PE RVUs. As a result, patient access to these procedures is placed in jeopardy because doctors are not adequately reimbursed for the significant practice expenses associated with providing arthroscopies in the office setting.[4]

The payment inequity faced by doctors seeking to provide arthroscopy procedures in the office setting can be easily corrected if CMS establishes non-facility PE RVUs that take into account the costs of the devices and supplies used to provide in-office arthroscopy services falling under CPT codes 29870, 29805, 29830, 29840, and 29900. Appropriate payment under the Medicare physician fee schedule will allow doctors to more expeditiously manage their patients' conditions and will preserve patient access to in-office arthroscopy procedures.

For this reason, Biomet Sports Medicine respectfully requests that CMS add non-facility practice expense relative value units (PE RVUs) to cover physician office expenses for CPT codes 29805, 29830, 29840, 29870, 29900 arthroscopy procedures.

Thank you for your attention to this critical issue.

Sincerely,



David A. Nolan Jr., President

Attachments: Biomet Sports Price List

cc: Pam West (via email)
Rick Ensor (via email)
Gail Daubert (via email)

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[4] We estimate the costs for supplies and devices used for arthroscopy procedures at approximately $1,270 in "concrete" non-facility practice expense costs, as described above.

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922112	InnerVue™ Xenon Bulb Assembly (must send unit in for repair)	1,375.00
922113	InnerVue™ Printer Paper/Ink Set	45.00
922120	InnerVue™ Handpiece	6,710.00

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ORIGINAL

Boston Scientific

Parashar B. Patel
Vice President
Health Economics & Reimbursement

One Boston Scientific Place
Natick, MA 01760

August 31, 2007

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

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

Dear Mr. Kuhn:

Boston Scientific Corporation (Boston Scientific) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Revisions to Payment Policies Under the Physician Fee Schedule (CMS-1385-P, Federal Register, Vol. 72, No. 133, July 12, 2007).

As the world's largest company dedicated to developing, manufacturing, and marketing of less-invasive and innovative therapies, Boston Scientific supplies medical devices used by physicians in the following medical specialty areas:

- Cardiac Rhythm Management;
- Cardiovascular;
- Endosurgery; and
- Neuromodulation

We are particularly dedicated to patient safety and quality in the delivery of health care. These goals are paramount, and should guide policymakers as they develop payment policies that impact Medicare patients. Toward that end, we are focusing our comments exclusively on the safety concerns we have with Medicare's proposal to create non-facility (in-office) practice expense RVUs for transcatheter intravascular stenting (CPT codes 37205 and 37206).

I. Establishment of Non-Facility Practice Expense RVUs for CPT codes 37205 & 37206

Do not provide differential physician payment for CPT Codes 37205 and 37206 when not performed in facilities.[1]

For CY 2008, CMS is proposing to provide differential in-office payment for CPT codes 37205 (Transcatheter placement of an intravascular stent(s), [except coronary, carotid, and vertebral vessel], percutaneous; initial vessel) and 37206 (Transcatheter placement of an intravascular stent(s), [except coronary, carotid, and vertebral vessel], percutaneous; each additional vessel). Currently, Medicare physician billing shows that about 98% of these procedures are performed in hospital settings.

As manufacturers of medical devices, Boston Scientific is naturally interested in expanding access to services that use our products. However, our first and foremost concern is the safe and effective delivery of health care services. In that regard, we believe CMS must tread carefully – much as it did when it addressed these procedures in ambulatory surgical centers (ASCs). Therefore, for the following four reasons, we urge CMS to not allow a differential payment for procedures 37205 and 37206.

1) These procedures involve major blood vessels;
2) Even when performed in hospitals, transcatheter intravascular stenting can trigger serious complications, which while rare, would require emergent hospital care;
3) CMS' proposal to establish non-facility (in-office) RVUs for intravascular stenting procedures is wholly inconsistent with its safety-based policy regarding the same procedures in ambulatory surgery centers (ASCs); and
4) There are no consistent safety and quality measures, nor are there safety standards in place for physician office-based procedures, which become critically important as the complexity and risk of procedures performed in that setting increases.

Peripheral Stenting Procedures Involve Major Blood Vessels [2]

We recognize CMS has no specific policy on procedures which can be safely performed in a physician's office. However, it does have some safety standards for ASCs. For example, CMS does not pay for procedures in ASCs that usually require an overnight stay and pose safety concerns. This policy should be extended to the physician office. Major blood vessels that may be treated under codes 37205 and 37206 include:

- The superficial femoral artery and the femoral popliteal artery (maintaining blood supply above and below the knee);
- The iliac vessels (main source of blood supply to the legs);
- The renal arteries (main source of blood supply to the kidneys); and
- Veins of the abdomen and pelvis, the lower limbs, and the hepatic portal system (critical to the circulation of blood from the extremities and liver to the heart).

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[1] Current Procedural Terminology (CPT) © 2006 American Medical Association. All rights reserved.

[2] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.

Intravascular Stenting May Trigger Complications Necessitating Emergent Hospital Care
In our review of the literature on peripheral vascular procedures, we obtained key insights to the importance of consistent safety standards across treatment settings. While transcatheter intravascular stenting is generally safe, there can be complications associated with peripheral vascular procedures including infection, dissection, amputation and even death. These complications are often relatively easily managed in hospitals. If such complications arise in a physician office or ASC setting, the patient would require transportation to a hospital for further management while maintaining open femoral access. Maintaining an open femoral puncture during transport raises the risk of dissection or infection.

In a recent study of 112 interventions in 97 patients, nine (8%) outpatient procedures resulted in admission, including one patient with a major puncture site hematoma requiring blood transfusion and two patients with minor hematomas at the puncture site.[3] In another study of 197 interventional procedures, there were 68 complications (35%), including five patients (2.5%) who had significant problems requiring admission and active therapy.[4] Waugh and Sacharias described a significant complication rate of 3.6% among patients undergoing peripheral interventional procedures.[5]

Occlusion is also commonly found in, or may be a complication of, peripheral vascular interventions including transcatheter placement of intravascular stents. In one study of 181 lesions in 166 vessels, 55% of lesions were either occluded or stenosed and occluded.[6] In another study of 23 patients with critical limb ischemia, patients typically presented with combined stenoses and occlusions in 15 (60%) limbs, stenoses alone in four (16%), and occlusions alone in six (24%).[7]

Occlusion is often managed with inpatient lytic therapy. Because lytic therapy is administered on an inpatient basis typically via intra-arterial catheters, it would necessitate transfer with an open catheter site from an ASC or physician office to a hospital. Movement associated with transfer could result in dissection/perforation. Moreover, transfer involves movement of the patient in non-sterile environments, increasing the risk of infection. Recognizing this, CMS decided in its 2008 Ambulatory Surgery Center Payment Policy Final Rule that procedures frequently associated with the need for systemic lytic therapy should not be performed in ASCs.[8]

Therefore, intravascular stenting should not be performed in settings where:

1) Emergent hospital care is not immediately available; and
2) There are currently no consistent safety or quality standards and measures in place.

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[3] Akopian G and Katz SG. Peripheral angioplasty with same-day discharge in patients with intermittent claudication. *J Vasc Surg.* 2006;44:115-8.
[4] Young N, *et al.* Complications with outpatient angiography and interventional procedures. *Cardiovasc Intervent Radiol.* 2002; 25:123-126.
[5] Waugh JR, Sacharias N. Arteriographic complications in the DSA era. *Radiology.* 1992; 182:243-246.
[6] Krankenberg H, et al. Percutaneous Transluminal Angioplasty of Infrapopliteal Arteries in Patients with Intermittent Claudication: Acute and One-Year Results. *Catheter Cardiovasc Interv.* 2005; 64:12–17.
[7] Gray BH, *et al.* Complex Endovascular Treatment for Critical Limb Ischemia in Poor Surgical Candidates: A Pilot Study. *J Endovasc Ther.* 2002; 9:599-604.
[8] Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Parts 410 and 416 Medicare Program; Revised Payment System Policies for Services Furnished in Ambulatory Surgical Centers (ASCs) Beginning in CY 2008; Final Rule. Federal Register. Vol. 72, No. 148. Thursday, August 2, 2007. Page 42481.

In-Office Payment for Intravascular Stenting Inconsistent with ASC Safety Concerns
In its 2007 and 2008 ASC Payment Policy Final Rules (CMS-1506-FC and CMS-1517-F, respectively), CMS decided not to pay for intravascular stenting when performed in ASCs. In the 2007 ASC Payment Policy Final Rule, CMS stated:

> "Although the procedures are being performed about half of the time in hospital outpatient departments (HOPDs), the other half are being performed on an inpatient basis and they virtually are never done in a physician office. As we have stated in the past, there are many procedures that may be safely performed in a hospital outpatient department that may not be safely provided in an ASC, because only the hospital outpatient department has immediate access to the full spectrum of emergency and acute care facilities of the hospital. Our medical advisors reconsidered our proposal to add CPT codes 37205 and 37206 to the ASC list and determined that it would be in the best interests of Medicare beneficiaries to continue to deny payment for them in ASC facilities. Our medical advisors believe that the procedures would require more than 4 hours of recovery time and would most often require an overnight stay in the facility."[9]

CMS upheld this decision in its 2008 ASC Payment Policy Final Rule, stating:

> "We agree with the commenters that the procedures reported by CPT codes... 37205 (Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel); and 37206 (Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), each additional vessel) should be excluded from the ASC list of covered surgical procedures because they could pose a significant safety risk to beneficiaries in ASCs."[10]

If CMS determined these procedures are not safe to be performed in ASCs, we have similar or even greater concerns about these procedures being performed in physician offices.

No Physician Office Clinical Quality or Safety Reporting Standards or Methods for Attributing Adverse Events to the Originating Site of Care
Currently, CMS and the PERC arrive at the in-office direct cost inputs assigned to procedures based upon requests by professional societies and individual physicians as well as other characteristics of the procedures in question. However, safety and quality information associated with the performance of these procedures in the office are not currently considered because they are not consistently measured or collected. Boston Scientific believes that it is critical that CMS establish both safety and quality reporting standards for interventional procedures in the physician offices just as it doing for hospitals and planning to do for ASCs. Once these reporting standards are established and implemented, CMS will have a means of reviewing the safety and

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[9] Department of Health and Human Services, Centers for Medicare & Medicaid Services. 42 CFR Parts 410, 416 *et al.* Medicare Program—Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final Rule. *Federal Register*. Vol. 71, No. 226. Friday, November 24, 2006, Page 68168.
[10] Department of Health and Human Services, Centers for Medicare & Medicaid Services. 42 CFR Parts 410 and 416. Medicare Program; Revised Payment System Policies for Services Furnished in Ambulatory Surgical Centers (ASCs) Beginning in CY 2008; Final Rule. *Federal Register*. Vol. 72, No. 148. Thursday, August 2, 2007, Page 42488.

quality records associated with these services when provided in the office, even if only at an aggregate (rather than practice-specific) level. This information can inform future determinations regarding the advisability of the establishing payment for procedures provided in the office.

Currently, Medicare has no means to track complications associated with cases performed in physician offices or to link infections and complications stemming from procedures performed in the office to the original site of care. Until physician offices are subject to consistent and enforceable quality and safety reporting requirements that are appropriate to the treatment setting, Boston Scientific urges CMS to refrain from providing in-office payment for intravascular stenting procedures and other similar procedures.

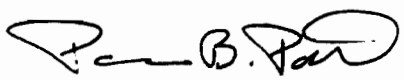
Given that peripheral stenting involves major blood vessels, raises significant potential safety concerns and conflicts with CMS's determination that these procedures are not appropriate for ASCs, in-office RVUs should not be established for these procedures.

Recommendation and CMS Requested Action:

- Do not implement proposal to create in-office practice expense RVUs for peripheral stenting procedures (CPT codes 37205 & 37206).

Thank you for the opportunity to comment on the proposed physician payment rule. We appreciate your consideration of our recommendation. Please contact me at (508) 652-7492 or parashar.patel@bsci.com or Scott Reid, Director of Health Policy and Payment, at (202) 637-8021 or reids@bsci.com if you have any questions.

Sincerely,



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August 31, 2007

HAND DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1385-P;
Comments on the PHYSICIAN SELF-REFERRAL PROVISIONS in the Proposed Calendar Year 2008 Physician Fee Schedule Rule

Ladies and Gentlemen:

Our firm is filing these comments to the proposed changes to the physician self-referral ("Stark") provisions included in the Proposed Revisions to Payment Policies Under the Physician Fee Schedule (the "Stark Portion of the Proposed Rule")[1] on behalf companies that form ventures with physicians to invest in medical equipment and use that equipment along with appropriately trained personnel to furnish medically related services to hospitals and ambulatory surgery centers and those service companies.

Our clients believe that in an effort to prevent the exploitation of Medicare beneficiaries and the Medicare system by a few bad actors, CMS would potentially prohibit virtually all physician ownership, including companies that have significantly improved Medicare beneficiary access to beneficial technologies while at the same time reducing costs to Medicare. This does not make sense, especially when CMS admits that its concerns are based upon anecdotal evidence related largely to diagnostic imaging equipment.

Phase III

Our clients note that it is especially difficult to file these comments when Stark Phase III only became available 4 days before the end of the comment period for the proposed

[1] 72 FED. REG. 38122 (July 12, 2007).

2008 Physician Fee Schedule rule. We strongly urge CMS to reopen the comment period for the Stark Portion of the Proposed Rule for an additional 30 days.

Per Click

CMS proposes to add a requirement to the Stark equipment rental exception that would prohibit an entity that furnishes designated health services ("DHS") from paying a "per click" fee to a physician lessor for any services rendered to patients referred by the physician lessor for those services. It appears that for the time being that per click payments still would be permitted under the indirect compensation arrangement exception.

However, CMS indicates in Phase III, that it is considering future changes to extend the concept of physicians "standing in the shoes" beyond physicians' medical practices. In addition, the Phase III preamble indicates that CMS has an evolving view of what is permitted under the indirect compensation arrangement exception, even under the current language.

If the CMS interpretation of the current indirect compensation arrangement exception changes or there are modifications to that exception, or if in further rulemaking physician investors are deemed to "stand in the shoes" of the companies in which they invest, the investors would need to make use of the equipment rental exception. The physician investor companies would not be able to charge hospitals and other DHS entities for their services on a "per click" basis. This change to the equipment lease exception would seriously and unnecessarily harm urologists and patients.

As CMS acknowledged in Phase I, Congress clearly intended to permit "per click" payments. The House Conference provides as follows:

> the conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.[2]

Interestingly, in Phase I, CMS cited to lithotripsy in its interpretation of Congressional intent as permitting per click arrangements. Now, CMS is ignoring Congressional intent in an effort to curb abuse of the Medicare system by abusive imaging and radiology services. CMS should narrowly tailor its regulations to prevent the known abuses, within the constraints of Congressional intent.

Further, our clients believe that CMS's reliance on 42 U.S.C. §1395nn(e)(1)(B)(vi) is misplaced. This is especially so when the rationale for the proposed contradictory requirements is based on admittedly anecdotal evidence.

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[2] House Conf. Rep. No. 103-213, at 814 (1993).

CMS is treading on thin ice in its reliance on its authority to protect against program or patient abuse. CMS' bases its conclusion that "per click" lease arrangements are "inherently susceptible to abuse" on diagnostic imaging services. Lithotripsy, laser services to treat BPH and other therapeutic urology arrangements where the referring physician performs the professional portion of the service are very different from diagnostic imaging. CMS has presented no evidence that arrangements for therapeutic equipment cause program or patient abuse. If there is abuse in diagnostic radiology, the prohibition should be limited to that abuse.

Further, the prohibition is largely based on less than even anecdotal evidence. CMS further justifies its prohibition on "per click" payments on unexplained and unsubstantiated concerns that "per click" payments for DHS *could* result in overutilization or other program abuse. Yet the prohibition would extend to all leasing arrangements and not just those for DHS. Thus, if the changes is made final and other changes are made to "stand in the shoes" and the indirect compensation arrangement exception, payments for lithotripsy, which is not a DHS, and for which there has never been any assertion of overutilization, could not be made on a per click basis. Urological and other therapeutic equipment that is not of itself DHS and only is so because it is arguably furnished as an inpatient or outpatient hospital service also would be adversely affected by this prohibition on "per click" arrangements.

Urologists also provide other therapeutic equipment, such as lasers for the treatment of benign prostatic hyperplasia ("BPH"), and cryotherapy for prostate cancer. We know of no assertion, let alone any study, that indicates overutilization of any of these services.

Our clients' experience is that a "per click" financial arrangement results in more accurate and fairer allocations of risk and compensation than flat rate lease arrangements. Referrals for therapeutic procedures ebb and flow by the week, by the month and by the year. Hospitals cannot determine what their needs will be. They are unwilling to commit to an amount that could turn out to be too high for the amount of services received and the physician venture is unwilling to commit to an amount that would be too low for the services rendered. Indeed, it is difficult to know how the hospital and the physician investment venture could arrive at a flat fee that would represent fair market value.

A flat fee arrangement also might not cover the less usual procedures that might need to be covered such as use of the C-arm and lithotripsy table for the urologist to provide other services such as repositioning a stone in preparation for a lithotripsy procedure, or use of the C-arm and table merely to locate the stone.

"Per click" payments protect hospitals against thin margins. Without the advantage of such arrangements, hospitals or physicians may be unable to reach agreement on volume, and refuse to enter into arrangements for new technologies, depriving the Medicare population of effective treatments, such as lithotripsy, which is the most non-invasive and efficacious treatment for stones too large to pass. Medicare beneficiaries make up fewer than 20% of our clients' lithotripsy cases. Because Medicare fees are lower than those for virtually every other health plan except Medicaid, Medicare revenue constitutes less than 15% of our

client's revenue. If CMS makes it too difficult for physician investor entities to furnish services to Medicare patients, these companies will cease to provide services to Medicare beneficiaries and move their technical services to locations that will not subject them to Stark scrutiny.

Current Stark requirements that rental charges be set in advance, consistent with fair market value, not determined in a manner that takes into account the volume or value of any referrals, and commercially reasonable even if no referrals were made between the parties appropriately guards against any potential abuse even with per click payments. It is almost impossible to comply with requirement not to take into account volume/value of referrals if a flat fee lease is required. The proposed ban on per click payments would promote inefficiencies and would deny Medicare beneficiaries access to effective therapeutic services.

"Set in Advance" and Percentage-Based Compensation

CMS further prohibit percentage-based compensation except for professional physician services. This is based on concern that percentage compensation arrangements are "potentially abusive." In the five and one half years that have passed since the original delay in the prohibition on percentage compensation, CMS has not published even one example of actual abuse. We would expect that it would do so if it had the examples to cite. Vague notions of potential abuse are not sufficient to prohibit a practice.

Except for Medicaid, Medicare is almost uniformly the lowest payor. Compensation usually varies widely among payors. It is sometimes difficult for a hospital to estimate what its reimbursement will be for a procedure where it participates with a wide range of third-party payors, making it difficult to determine a fair fee. If the hospital's estimates are off, the arrangement can cause it to lose money. Percentage compensation arrangements afford the hospital and the service provider the opportunity to share the risk. Neither the hospital nor the physician service company provider determines the third party payor reimbursement. Thus, our clients fail to see where the potential for abuse lies.

It is likely that the prohibition on percentage compensation arrangements will have unintended effects. For example, it would prohibit a hospital that leases office space in its medical office building from charging the physician tenants a pro rata percentage of real estate taxes.

Stand in the Shoes

Under the proposed rule, would amend 42 C.F.R. § 411.354(c) to provide that, a DHS entity would "stand in the shoes" of an entity that it owns or controls. Thus, the DHS entity "would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls." We cannot find proposed regulatory language to that effect, which makes it difficult to adequately comment.

Looking at the preamble language, deeming a DHS entity to stand in the shoes of an entity that it owns or controls is overly broad. Each of the relevant terms, "owns" and "controls" should be defined. We question whether a minimal ownership interest should cause a DHS entity to stand in the shoes of the entity in which it has an ownership interest. CMS should clarify whether there is a minimum percentage of ownership or control that will trigger this provision. We question, for example, whether a DHS entity's ownership of a 1-percent investment interest in an entity would or should constitute "owning the entity."

Causing a hospital to stand in the shoes of any entity that it owns or controls would have a particularly devastating effect on entities in which hospitals have an ownership interest and relationships with those entities. This may be an unintended consequence.

Our clients are concerned that CMS will further expand the "stand in the shoes" concept to physician investor companies. Many hospitals hold an ownership interest in ambulatory surgical centers ("ASCs"). ASCs are generally not DHS entities. ASCs, in turn, have contractual arrangements with entities in which physicians hold an ownership interest to provide services to the ASC that are not DHS, such as lithotripsy and other urological equipment such as lasers. Currently, those relationships are analyzed under the indirect compensation arrangement. If the hospital is deemed to stand in the shoes of an ASC in which the hospital holds an ownership interest, and if a physician is deemed to stand in the shoes of an entity in which the physician holds an ownership interest, the physician would have to meet a direct compensation arrangement exception. The result would be that "per click" and percentage compensation arrangements would not be permitted. In essence, if the proposed prohibitions on per click and percentage compensation arrangements are adopted, CMS would turn therapeutic services that are not DHS, such as lithotripsy and laser surgery into DHS. If CMS finalizes each of its proposed changes to the Stark requirements, physicians would no longer be permitted to enter into per click or percentage-based compensation arrangements with hospital owned or controlled ASCs. We believe that CMS lacks authority to, in effect, create additional categories of DHS. The consequence of this change would be that physicians withdraw from ASCs in which hospitals are invested and would establish separate ASCs to provide services for their patients. The result would be increased costs and increased inefficiencies in the healthcare system.

In addition, as noted above, our clients are concerned that in future rulemaking the "stand in the shoes" will be enlarged to include entities other than physician groups.

"Under Arrangements"

Proposed Changes by CMS

CMS would prohibit the provision of services "under arrangements" if the physician making a referral for the services also furnishes the services provided "under arrangements." To do so CMS would revise the definition of the term "entity" to include "the person or entity that has performed the DHS." A physician's referral for a service that is

furnished "under arrangements" would be deemed a referral to the DHS entity and the "under arrangements" provider.

We believe that the meaning of the phrase "person or entity that has performed the DHS" is unclear. The phrase could apply to the physician who performs the service, the location where the services are performed, the person or entity that owns the equipment with which a DHS is performed, or possibly some other person. We request that CMS clarify the meaning of this phrase. We will assume for purposes of this comment that "the person or entity that has performed the DHS" includes an entity that furnishes a service "under arrangements."

The primary services furnished by our clients is lithotripsy, which for Medicare beneficiaries is always furnished "under arrangements" to hospitals. Lithotripsy, however is not a DHS as a result of the decision in *American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002). Under the letter of the proposed regulation, lithotripsy provided "under arrangements" would not be affected by the proposed modification to the definition of "entity." Our clients do, provide other services "under arrangements" that would be adversely and needlessly affected by this change.

Again, CMS has reversed itself because it has received anecdotal reports of joint ventures among hospitals and physicians to provide hospital imaging services, clinical laboratory services, and therapy services, many of which were formerly provided by the hospitals directly and which could, in most cases, continue to be furnished directly by the hospitals. CMS concludes that there is no legitimate reason for these "arranged-for" services other than to allow referring physicians an opportunity to make money on referrals for separately payable services, and that this leads to overutilization.

This generalization is unfortunate and unfair. Imaging services are always DHS whether furnished by a hospital, an imaging center or otherwise. Congress made the determination that there were abuses in referrals for those services. It has not made a similar determination for other services and CMS can point to no evidence of utilization. Extending the prohibition to non-DHS services, without record proof of abuse similar to DHS services is unsupportable and unwarranted.

Unlike referrals for diagnostic imaging, when a physician makes a referral for the technical component of a service for which the physician furnishes the professional component, any perceived incentive to refer would be present in the professional fee. All professional medical services other than capitated services are paid on a per procedure basis.

In furnishing these therapeutic services under arrangements, a referring urologist also performs the professional portion of the referred procedure. The urologist receives a professional fee for the procedure, which is generally far greater than the incremental increase in his distribution as an investor in the venture that would result from any referral of a patient. The portion of the technical fee that he will earn in distributions from his investment in the joint venture is not likely to create an inducement to refer for the procedure. CUI recommends that

CMS continue to permit the provision of services "under arrangements" where an investor physician performs the professional portion of the procedure, and where there is no compelling evidence of overutilization and program abuse.

Urology and other joint ventures, which furnish treatment services for which the professional component is performed by the referring physician, provide beneficial services to patients, including Medicare beneficiaries and do not exhibit any of the features condemned by CMS. Urologists were among the first group of physicians to furnish services to hospitals "under arrangements" when they began to provide lithotripsy services. Urologists formed these ventures chiefly for two reasons. The first is that hospitals refused to invest in expensive technology because that would produce a double punch negative economic effect for the hospitals. The hospitals would have to make a major capital outlay for the lithotripter and the hospital would experience a decrease in use of its operating and inpatient rooms. A good quality lithotripter costs $500,000-$900,000 and requires a maintenance contract of approximately $45,000-65,000 per year. Yet a typical hospital may only do 6-9 cases per month. Urologists, who wanted to provide a new non-invasive treatment for their patients, were willing to invest in a company to purchase a lithotripter and hire a technologist. The second reason is that even when hospitals were willing to invest in lithotripters, they would frequently purchase the cheapest model available and use the part-time intermittent services of a radiology technician who only performed a minimal number of lithotripsy procedures. Patients have poorer results when lithotripsy is furnished with lower quality lithotripters and/or by inexperienced technicians. Good urologists are not willing to subject their patients to inferior equipment and poorly trained technicians.

In addition to lithotripsy, our clients typically own and provide to patients "under arrangement" with a hospital, urological services to patients requiring holmium or KTP lasers. Lasers used for urological procedures are not as expensive as lithotripters but they have a much shorter useful life. A good laser for treatment of benign prostate hyperplasia ("BPH") typically costs $120,000-$130,000. The useful life can generally be as short as 2 ½ years as manufacturers are constantly improving this technology, making the lasers more powerful and precise. Hospitals are generally not willing to purchase a piece of capital equipment that will become outmoded in such a short time period. Urologists who use the equipment to treat their patients are willing to invest to purchase newer equipment in order to treat their patients with up-to-date equipment.

Additionally, a single hospital often will have few urologists on staff and does not have a sufficient volume of patients requiring the use of a particular technology to justify a large capital expenditure to obtain the technology. Physicians are able and willing to invest in joint ventures with other physicians practicing at different hospitals to purchase the technology to achieve economies of scale. Through these joint ventures, a single hospital is able to use the equipment on a schedule that corresponds to its needs. Rationalizing use of expensive, new technology equipment among many community hospitals, as opposed to forcing each hospital to buy equipment for which it has insufficient volume to amortize the cost, is obviously a better programmatic choice. The obvious incentive to overutilize equipment exists where a hospital

needs an expensive piece of equipment but does not otherwise have sufficient volume to justify the cost. The joint venture undertakes the responsibility to rotate the equipment among various hospitals, providing access to valuable treatment for the hospitals' patients that may not otherwise have been available. The mobile equipment offered through physician joint ventures also reduces overall capital costs by reducing the quantity of equipment purchases (*i.e.* hospitals are able to share equipment through a physician joint venture).

Patients also receive better service when there is physician ownership. Physician investors who use the service require their companies to schedule extra treatments, even for one patient and demand upgraded equipment, even when it is uneconomic to do so in order to provide excellent services to their patients.

CMS especially noted that in certain cases a physician venture will replace a service previously offered by the hospital and stated that there could be no legitimate reason for this. We disagree. Urologists, gastroenterologists, and other physicians are willing to invest in state-of-the-art equipment to replace inferior or outdated equipment owned by the hospital when doing so provides better medicine for their patients. We believe that the ability to provide state-of-the-art equipment and highly skilled technologists is a legitimate reason for a physician venture to furnish a service previously furnished by the hospital. At various times, our clients have been approached by urologists, gastroenterologists and other physicians to form a venture to provide new equipment that will replace outmoded or unusable cystoscopy, endoscopy, and other equipment in a hospital.

MedPAC Recommendation

For support, CMS cites to the MedPAC March 2005 report in which MedPAC raised concerns regarding physician-owned entities that provide equipment and services to imaging centers and other DHS providers. MedPAC suggested that the Stark definition of "entity" should be expanded to include any entity that derives a substantial proportion of its revenue from a provider of DHS. CMS agrees with the MedPAC concerns but elected to change the definition of "entity" to include whoever furnishes the service instead of limiting the definition to who files the claim. But CMS solicits comments whether to implement the MedPAC recommendation to expand the definition of "entity" to include any entity that derives a substantial proportion of its revenue from a provider of DHS, whether the MedPAC recommendation should replace the CMS proposal, or whether there should be a combination. CMS is particularly interested in what should constitute a substantial proportion of revenue derived from providing DHS.

The March 2005 MedPAC report notes that the definition of "ownership" under Stark permits a physician-owned entity to lease imaging equipment to imaging centers on a "per click" basis which gives the physician-owned entity the same benefits of ownership of the imaging center. In the same report MedPAC points to a 1994 GAO report regarding overutilization. MedPAC notes that these lease arrangements combined with per click payments undermine the intent of the Stark statute. Based on the GAO study and other reports that address imaging services, MedPAC expands its concerns to all services furnished to DHS entities.

There are numerous flaws in the MedPAC report, and CMS should not adopt MedPAC's recommendations on these regulations. First, MedPAC cites no contemporary study or evidence justifying its recommendations. To the contrary, the most recent study is the 1994 GAO report that indicates that physicians with imaging equipment in their offices order more imaging than those who do not have such equipment. The studies did not control for health status of the patients or whether the imaging services were appropriate. Most important, neither that study, nor anything else cited by MedPAC supports its conclusion that all lease arrangements with per-click payments should be swept up in a new ban on permitted referrals. Certainly it does not stand for the proposition that per-click lease arrangements of Urologic equipment lead to over utilization or inappropriate treatment, yet its recommendations and CMS proposed rules, would treat such arrangements as if they were abusive.

MedPAC asserted that its recommendation would decrease federal program spending, would decrease beneficiary premiums and cost sharing, would have no adverse impact on beneficiary quality or access to care, and would not adversely affect the ability to provide quality care to Medicare beneficiaries. These conclusions are not based upon any studies. To the contrary, physician-owned ventures have brought Medicare beneficiaries state-of-the-art therapeutic equipment that hospitals are unwilling to purchase and promote access to services. CUI members state unequivocally that, but for their initiative in purchasing and providing new urological equipment to hospitals, their patients would not have had access to the treatments.

Because Stark II is a strict liability statute it is important to construe its provisions narrowly. The Stark II law makes careful distinctions, banning referrals only where there was demonstrable evidence of abuse. The Stark II law does not give CMS authority to create new designated health services, nor to extend referral bans to non-DHS services. CMS should reject MedPAC's recommendation.

Alternative Method of Compliance

CMS offers an alternative method of compliance with a Stark exception. We find it unfair to require a voluntary disclosure in order to make use of such an exception. CMS should create a very specific alternative method for compliance that does not require self disclosure.

Burden of Proof

CMS also proposes that if payment is denied for a DHS on the basis that the service was furnished pursuant to a prohibited referral, the entity submitting a claim for payment, and not the government, would bear the burden of proving that a prohibited referral did not occur. This ignores common views of fundamental fairness in our legal system.

CMS states that this rule is consistent with its policy with respect to claims denials. Our clients view it quite differently. Where there is a dispute over a claim, the entity

only need produce the medical record, which will indicate that a service was provided, and, in combination with accepted standards of care, will indicate that a provided service was medically necessary. And, each challenge is to a single claim.

When CMS mounts a challenge to referrals based on Stark, thousands of claims are at stake. If the physician's relationship with the DHS entity is deemed not to meet a Stark exception thousands of referrals could be at risk, with a potential $15,000 per violation penalty in addition to the denial of all of the claims, and possible exclusion.

Audit authority vested in CMS and the OIG gives them the right to require production of documents to determine whether objective Stark requirements are met (*e.g.*, whether there is a written contract). Many of the Stark exceptions, however, include requirements that are a matter of opinion. Valuation experts using traditional valuation methods often disagree on what is fair market value. Although ultimately it is a trier of fact who would decide whether the burden of proof has been met, Stark cases rarely go to trial because of the extreme penalties. CMS and the OIG would be able to force settlements where reasonable minds could disagree. Knowing this would be the case, DHS entities would likely seek the lowest possible valuation to avoid scrutiny. Many arrangements do not involve compensation significant enough for a fair market valuation. The DHS entity may unfairly lowball the physician in order to stay "under the radar."

For several Stark requirements, a DHS entity would be forced to prove a negative in order to meet its burden of proof. These include: (i) that compensation is not determined in any manner that takes into account the volume or value of referrals generated, (ii) that the compensation is not related to volume or value of referrals or other business between the parties, (iii) that the arrangement does not exceed that which is reasonable and necessary for the legitimate business purposes of the arrangement, (iv) that equipment or space is not shared by others, that the agreement would be commercially reasonable even if no referrals were made between the parties, that a productivity bonus does not reflect volume or value of referrals, (v) that the services do not involve counseling or promotion of a business arrangement or other activity that violates any state or federal law, and (vi) that no payment is made directly or indirectly as an inducement to reduce or limit medically necessary services.

In addition, pursuant to 42 C.F.R. § 411.353(e), payment may be made to an entity that submits a claim for a DHS even if there was a prohibited referral if the DHS entity "did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral..." It would be difficult, if not impossible, for the DHS entity to prove that it did not know of the identity of the referring physician or acted in reckless disregard of the identity of the referring physician.

Several exceptions require that the arrangement does not violate the anti-kickback statute or violate laws regarding billing or claims submission. Normally, the burden is on the government to prove an anti-kickback violation, which critically requires the government to prove a high level of unlawful intent. Placing the burden of proof on the DHS entity that the

service was not furnished pursuant to a prohibited referral and thus did not engage in criminal activity would reverse the government's burdens regarding the anti-kickback statute. This smacks in the face of fundamental fairness In addition, it would require the DHS entity to prove another negative, that its intent was not to induce referrals.

Moreover, although Stark is a civil statute, it is a strict liability statute. The government should not be able to shift the burden of proof where there is strict liability. Medicare contractors, or CMS, would become "judge and jury" over complex and highly debatable issues.

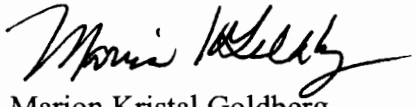
Additional Concerns

From a broad perspective, we note that physicians and entities have invested money, time, and effort in forming arrangements compliant with the Stark regulations as previously interpreted by CMS. If the CMS proposals are made final, some of these previously compliant arrangements (*e.g.* per click arrangements that were explicitly permitted in prior Stark preambles) will violate Stark prohibitions. The changing regulations will cause undue hardship to those who have invested in reliance on prior CMS interpretations. CMS should not finalize the Stark Portion of the Proposed Rule as we have commented in this letter. In the alternative, at a minimum, CMS should delay implementation for a period of five (5) years so that physicians who invested in good faith and in compliance with the law are not subjected to a "fire sale."

Further, we reiterate our request that CMS reopen the comment period for the Stark Portion of the Proposed Rule once Phase III of Stark is released so that the interested public has the opportunity to comment on the complete rule with all of its implications.

Please do not hesitate to contact me if you need further clarification of the our clients' concerns.

Sincerely,



Marion Kristal Goldberg

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COUNCIL FOR UROLOGICAL INTERESTS

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Joseph Jenkins, M.D.
Chairman and Executive Director

August 31, 2007

HAND DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1385-P; Comments on the PHYSICIAN SELF-REFERRAL PROVISIONS in the Proposed Calendar Year 2008 Physician Fee Schedule Rule

Ladies and Gentlemen:

The Council for Urological Interests ("CUI") appreciates the opportunity to comment on the proposed changes to the physician self-referral ("Stark") provisions included in the Proposed Revisions to Payment Policies Under the Physician Fee Schedule (the "Stark Portion of the Proposed Rule").[1] CUI is a voluntary membership organization whose members form joint ventures with urologists to furnish lithotripsy, urological laser and other services to hospitals and ambulatory surgery centers. CUI members were the principal members of the American Lithotripsy Society. The CUI members represent more than 4,900 investor urologists, approximately 50 % of all urologists practicing throughout the United States.

CUI agrees that it is important to prevent the exploitation of Medicare beneficiaries and the Medicare system. But, in an effort to combat abuse, CMS has cast its net far too wide. Each example of abuse that CMS identifies is a diagnostic service and most of these are of an imaging arrangement. The imaging arrangements appear to be an end run around Stark prohibitions on physician referrals to imaging centers. Yet, CMS proposals would prohibit virtually all physician ownership, including many that are not only not abusive, but have significantly improved Medicare beneficiary access to beneficial technologies while at the same time reducing costs to Medicare.

Moreover, each concern raised by CMS, by its own admission, is based upon anecdotal evidence. CMS does not, and CUI believes it cannot, point to even one study that validates its concerns. Nonetheless, CMS would cause the termination of arrangements that promote patient well being, bring new technology to patients, and promote economic efficiency in the delivery of healthcare services.

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[1] 72 FED. REG. 38122 (July 12, 2007).

It appears that CMS has reversed itself with regard to several exceptions from its position in Phases I and II. It is plainly unfair for CMS to reverse itself in this manner in such a short amount of time. Phase II was issued just three years ago in March 2004. There have been substantial investments in equipment and facilities based upon those regulations. Members of the healthcare community should be able to rely upon regulations and not expect them to be changed in the absence of an immediate and compelling need. No such showing has been made.

I. Phase III

As an initial matter, CUI protests the requirement to comment on the Stark Portion of the Proposed Rule when Stark Phase III only became available 4 days before the end of the comment period for the proposed 2008 Physician Fee Schedule rule. That was hardly enough time to digest the 516 pages of Phase III and rework our comments based upon the voluminous Phase III changes. By breaking up the changes into two parts that are not simultaneously available, CMS has not given interested persons a real opportunity to participate in the rulemaking process, as required by the Administrative Procedure Act. CUI recognizes that the timing may not be of CMS' making, but the result is the same. A comment period that affords half a comment is no comment period at all. On issues as important as these we wonder what is the rush. The underlying law is 13 years old. CUI urges CMS to re-open the comment period for the Stark Portion of the Proposed Rule for an additional thirty days.

II. "Under Arrangements"

A. Proposed Changes by CMS

CMS proposes to prohibit the provision of services "under arrangements" if the referring physician also furnishes the technical services provided "under arrangements." CMS would accomplish this by revising the definition of the term "entity" to include "the person or entity that has performed the DHS." Thus, CMS proposes that a physician's referral for a service that is furnished "under arrangements" would be deemed a referral to the DHS entity and the "under arrangements" provider.

As an initial matter we note that the meaning of the phrase "person or entity that has performed the DHS" is unclear. The phrase could apply to the physician who performs the service, the location where the services are performed, the person or entity that owns the equipment with which a DHS is performed, or possibly some other person. We request that CMS clarify the meaning of this phrase. We will assume for purposes of this comment that "the person or entity that has performed the DHS" includes an entity that furnishes a service "under arrangements."

The primary services furnished by CUI members is lithotripsy, which for Medicare beneficiaries is always furnished "under arrangements" to hospitals. However, pursuant to the decision in *American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002), lithotripsy is not a DHS. Thus, the provision of lithotripsy "under arrangements" would not be affected by the proposed modification to the definition of "entity." CUI members do, however, provide other services "under arrangements" that would be adversely and needlessly affected by this change.

The stated basis for CMS' complete reversal on "under arrangements" is that it has received anecdotal reports of joint ventures among hospitals and physicians to provide hospital imaging services, clinical laboratory services, and therapy services, many of which were formerly provided by the hospitals directly and which could, in most cases, continue to be furnished directly by the hospitals. CMS believes there is no legitimate reason for these "arranged-for" services other than to allow referring physicians an opportunity to make money on referrals for separately payable services, and that this leads to overutilization.

Unfortunately, CMS has painted all "under arrangements" services with a broad brush. The imaging and other services described by CMS are all "DHS" even if they were not furnished as outpatient hospital services, and, therefore, the legislative and administrative record presumably has some evidence of overutilization and/or program abuse. Extending its prohibitions to non-DHS services, without record proof of abuse, is unsupportable and unwarranted.

CUI expresses no opinion on radiology, laboratory and therapy arrangements, which we note are of themselves DHS whether or not performed in a hospital. Importantly, each is a service where the physician makes a referral but is not involved directly in the furnishing of the service. In stark contrast (pun intended), urological services furnished "under arrangements" are all ones where the referring physician furnishes the necessary professional service. Urology joint ventures, which furnish treatment services for which the professional component is performed by the referring physician, provide beneficial services to patients, including Medicare beneficiaries, and do not exhibit any of the features condemned by CMS. The incentive for over-utilization of diagnostic imaging services, is not present for therapeutic urological services.

For therapeutic urological procedures, the referring urologist performs the professional portion of the referred procedure for which he receives a professional fee. The portion of the technical fee that the urologist will earn in distributions from investment in the joint venture is a fraction of the professional fee and, therefore, is not likely to create an inducement to refer for the procedure. Any incentive to refer a patient, which is inherent in all professional services provided by a physician, is already present in the professional fee.

Urologists were among the first group of physicians to furnish services to hospitals "under arrangements" when they began to provide lithotripsy services. Urologists formed these ventures chiefly for two reasons. The first was that hospitals refused to invest in expensive technology because that would produce a double punch negative economic effect for the hospitals. The hospitals would have to make a major capital outlay for the lithotripter and the hospital would experience a decrease in use of its operating and inpatient rooms. A good quality lithotripter costs $500,000-$900,000 and requires a maintenance contract of approximately $45,000-65,000 per year. Yet a typical hospital may only do 6-9 cases per month. Urologists, who were more concerned about their patients' ability to access this breakthrough non-invasive treatment, were willing to invest in a company to purchase a lithotripter and hire a technologist.

The second reason was that even when hospitals were willing to invest in lithotripters, they would frequently purchase the cheapest model available and use the part-time intermittent services of a radiology technician who only performed a minimal number of lithotripsy procedures. Patients have poorer results when lithotripsy is furnished with lower quality lithotripters and/or by inexperienced technicians. Good urologists are not willing to subject their patients to inferior equipment and inexperienced technicians.

Beyond the hospitals' reticence, physician investor companies provide economies of scale. A single hospital often will have few urologists on staff and does not have a sufficient volume of patients requiring the use of a particular technology to justify a large capital expenditure to obtain the technology. Physicians are able and willing to invest in joint ventures with other physicians practicing at different hospitals to purchase the technology to achieve economies of scale. Through these joint ventures, a single hospital is able to use the equipment on a schedule that corresponds to its needs. Rationalizing use of expensive, new technology equipment among many community hospitals, as opposed to forcing each hospital to buy equipment for which it has insufficient volume to amortize the cost, is obviously a better programmatic choice. The obvious incentive to overutilize equipment exists where a hospital needs an expensive piece of equipment but does not otherwise have sufficient volume to justify the cost. The joint venture undertakes the responsibility to rotate the equipment among various hospitals, providing access to valuable treatment for the hospitals' patients that may not otherwise have been available. The mobile equipment offered through physician joint ventures also reduces overall capital costs by reducing the quantity of equipment purchases (*i.e.* hospitals are able to share equipment through a physician joint venture).

While there are commercial companies that provide lithotripsy and other equipment to hospitals, there is no indication that these companies provide better care or save the Medicare trust fund. Quite the contrary, in the early – to - mid 1990s, the Federal Trade Commission ("FTC") investigated physician investor lithotripsy ventures. At the end of a five year investigation, including review of comprehensive, raw quality assurance and utilization review data, the FTC concluded that the physician ventures were not monopolistic and were not

abusive. Indeed, the data indicated that patients of urologists who were investors in the companies had better outcomes than patients of physicians who were not investors.

In addition to lithotripsy, CUI members typically own and provide to patients "under arrangement" with a hospital, urological services to patients requiring holmium, KTP, or thulium lasers. The alternative to laser surgery for benign prostatic hyperplasia ("BPH"), is a far more invasive surgery. Lasers used for urological procedures are not as expensive as lithotripters but they have a much shorter useful life. The useful life is as short as 2 ½ years, as manufacturers are constantly improving this technology, making the lasers more powerful and precise. A good laser for treatment of BPH typically costs $120,000-$130,000. Hospitals are generally not willing to purchase a piece of capital equipment that will become outmoded in such a short time period. Despite the fact that laser ventures are only minimally profitable, urologists are willing to invest to purchase newer equipment in order to more effectively treat their patients. As an example, our members purchased a significant numbers of lasers for treatment of patients under arrangements at hospitals. Within two years, another manufacturer introduced a higher powered laser and shortly thereafter the original manufacturer began to market a higher powered laser. Both of these new lasers had significant advantages over the earlier one, including shorter treatment time and fewer post operative complications. Physician investors recognized the clinical benefits of the higher powered lasers. Even though they had significant money invested in the lower powered laser, still owed money on loans for those lower powered lasers, were advised that there was no resale market for the obsolete laser, and knew that the newer laser caused the venture to incur higher disposable (fiber) costs, the doctor owners pursued the purchase of the new laser for patient benefit. Equipment to perform other urological procedures such as cryosurgery, TUMT and TUNA present similar scenarios.

Underlying certain of the proposed changes in the Stark Portion of the Proposed Rule is a sense that CMS believes that surgeons in general, and urologists in particular, recommend a surgical procedure to receive a fee rather than because the patient needs the procedure, and choose a particular surgical procedure based on the professional fee that they receive. Such a cynical view is unwarranted and not supported by evidence. CUI understands that there are a few bad actors in the medical profession. But they are a distinct minority, notwithstanding they receive a lot of publicity. The vast majority of physicians act in the best interests of their patients, often to their own economic detriment.

Let a historical example of doctor joint venture activity serve as a reminder of CMS's overly cynical perspective. In the late 1990's, TUMT was introduced to the urology community as the "newest and best" minimally invasive treatment for patients suffering from enlarged prostates (BPH). Many CUI members formed joint ventures to purchase these capital intensive first generation units (which are very different from the units on the market today) to provide services on mobile routes to hospitals under arrangement. Despite the doctors' investment in this early technology, many came to believe that the older surgical approach was

better for most of their patients and therefore, did not use the TUMT partnership equipment despite their financial investment. The joint ventures failed and the doctors lost their investment. But their patients continued to receive the therapy that was in their best interest, regardless of whether the urologists had an ownership in a partnership or not.

When physicians are investors in the lithotripsy, laser, and other therapeutic urological ventures, they demand a higher level of service for their patients. It is the repeated experience of CUI members, that urologist investors will demand that their company fit in an extra service day, provide an emergency stop for an acutely ill patient, offer service to small facilities even if only one or two patients need treatment, treat on holidays, and fly in a technologist or piece of equipment to treat a patient. The investor urologists do not want their patients to be in pain and a significant reason for their investment is that they will be able to obtain a better, more immediate level of care. A commercial company cares only about its bottom line. Its executives do not have a continuing relationship with the patients or their families. The urologists will follow those very same patients for the rest of their career.

CMS has asserted that there is no legitimate reason for a physician venture to replace a service previously offered by the hospital. We disagree. Urologists have demonstrated a willingness to invest in state-of-the-art technology to replace inferior or outdated equipment owned by the hospital when doing so provides better medicine for their patients. We believe that the ability to provide state-of-the-art equipment, patient centric scheduling, broader geographic access, highly skilled technologists, and cost efficiencies are all legitimate reasons for a physician venture to bring a new service to the community.

B. **MedPAC Recommendation**

For support of its proposals, CMS cites to the MedPAC March 2005 report in which MedPAC raised concerns regarding physician-owned entities that provide equipment and services to imaging centers and other DHS providers. MedPAC suggested that the Stark definition of "entity" should be expanded to include any entity that derives a substantial proportion of its revenue from a provider of DHS. CMS agrees with the MedPAC concerns but instead elected to change the definition of "entity" to include whomever furnishes the service instead of limiting the definition to the person who files the claim. But CMS solicits comments whether to implement the MedPAC recommendation to expand the definition of "entity" to include any entity that derives a substantial proportion of its revenue from a provider of DHS, whether the MedPAC recommendation should replace the CMS proposal, or whether there should be a combination. CMS is particularly interested in what should constitute a substantial proportion of revenue derived from providing DHS.

The March 2005 MedPAC report notes that the definition of "ownership" under Stark permits a physician-owned entity to lease imaging equipment to imaging centers on a "per click"

basis. By so doing, the physician investors gain the same economic benefit as if they held an ownership in the imaging center. In the same report MedPAC points to a 1994 GAO report regarding overutilization. MedPAC notes that these lease arrangements combined with "per click" payments undermine the intent of the Stark statute. Based on the GAO study and other reports that address imaging services, MedPAC expands its concerns to all services furnished to DHS entities.

There are numerous problems with the MedPAC report, and CMS should not adopt MedPAC's recommendations on these regulations. First, MedPAC cites no contemporary study or evidence justifying its recommendations. To the contrary, the most recent study is the 1994 GAO report that indicates that physicians with imaging equipment in their offices order more imaging than those who do not have such equipment. MedPAC points out, however, that even those limited studies did not control for health status of the patients or whether the imaging services were appropriate. But, of course, that report preceded the effective date of Stark II, and, however flawed, formed the basis for Congress concluding that diagnostic imaging services should be a designated health service. Neither that study, nor anything else cited by MedPAC, supports its conclusion that all lease arrangements with per-click payments should be swept up in a new ban on permitted referrals. Certainly it does not stand for the proposition that per-click lease arrangements of Urologic equipment lead to overutilization or inappropriate treatment, yet its recommendations and CMS proposed rules, would treat such arrangements as if they were abusive.

MedPAC asserted that its recommendation would decrease federal program spending, would decrease beneficiary premiums and cost sharing, would have no adverse impact on beneficiary quality or access to care, and would not adversely affect the ability to provide quality care to Medicare beneficiaries. These conclusions are not based upon any studies. To the contrary, physician-owned ventures have brought Medicare beneficiaries state-of-the-art therapeutic equipment that hospitals are unwilling to purchase and promote access to services. CUI members state unequivocally that, but for their initiative in purchasing and providing new urological equipment to hospitals, their patients would not have had access to the treatments, and certainly not on an as needed basis.

Because Stark II is a strict liability statute it is important to construe its provisions narrowly. Congress did not accept Congressman Stark's original proposal to ban all physician referrals to entities in which they had a financial interest. Rather the Stark II law made careful delineations, banning referrals only where there was demonstrable evidence of abuse. The Stark II law does not give CMS authority to create new designated health services, nor to extend referral bans to non-DHS services.

CMS may not and should not accept MedPAC's undifferentiated, blunderbuss recommendation. Certainly CMS should acknowledge the broad scale offensive mounted by the hospital lobby to ban physician ownership, and avoid involving itself in a turf fight on the side of the hospitals.

III. **Per Click**

The Stark Portion of the Proposed Rule would revise the Stark equipment rental exception to prohibit "per click" lease payments to a physician lessor for services rendered to patients referred by the physician lessor. While CUI believes that under the proposed regulations and Phase III, the new "per click" prohibitions would not apply to arrangements between physician investor entities and DHS entities (such as hospitals), which are permitted by the indirect compensation arrangement exception, CUI is concerned that CMS may consider an extension of the prohibition.

Prohibiting "per click" payments contradicts Congressional intent. Congress has already made its intent clear on this issue. House Conference Report No. 103-213 states that

> the conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.[2]

Thus, Congress explicitly considered "per click" payments and determined that "per click" payment arrangements would be permitted. CMS recognized this in Phase I when it reviewed the legislative history and concluded that Congress intended to permit "per click" arrangements. CMS has not explained why its interpretation of the legislative history has since changed.[3] Based on the clearly expressed Congressional intent, CMS does not have the authority to prohibit "per click" space and equipment leases as proposed.[4]

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[2] House Conf. Rep. No. 103-213, at 814 (1993).

[3] It is instructive that, in the Phase I Stark rulemaking, CMS used an example of lithotripsy in its interpretation of Congressional intent as permitting "per click" arrangements. Now, CMS is ignoring Congressional intent in an effort to curb abuse of the Medicare system by abusive imaging and radiology services. CMS should narrowly tailor its regulations to prevent the known abuses, within the constraints of Congressional intent.

[4] See, *e.g.*, *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc. et al.*, 467 U.S. 837 (1984).

CMS bases its authority to add the "per click" prohibition on 42 U.S.C. §1395nn(e).[5] We believe that CMS is without authority to ignore clear Congressional intent and impose contradictory requirements based on admittedly anecdotal evidence.

Even if Congress had not expressly and unequivocally set forth its intent, we believe that CMS has exceeded its authority under 42 U.S.C. §1395nn(e) in this regard. As with other elements of the Stark Portion of the Proposed Rule, CMS' conclusion that "per click" lease arrangements are "inherently susceptible to abuse" is based on diagnostic imaging services. Therapeutic urology arrangements where the referring physician performs the professional portion of the service are very different from diagnostic imaging and are not inherently susceptible to abuse. CMS has no evidence that arrangements for therapeutic equipment in general, and urological equipment in particular, cause program or patient abuse. The unwarranted breadth of the proposed changes is magnified when looking at the specific concerns of CMS. Any restrictions on these arrangements should be narrowly tailored to address the specific areas of abuse noted.

Not only do we believe that CMS exceeded its authority in imposing this broad prohibition, the prohibition does not make sense. CMS justifies its prohibition on "per click" payments on unexplained concerns that "per click" payments for DHS *could* result in overutilization or other program abuse. The concerns are not substantiated by evidence of overutilization and the prohibition would extend to all leasing arrangements and not just those for DHS. Potentially, payments for lithotripsy, which is not a DHS, and for which there has never been any assertion of overutilization, could not be made on a "per click" basis. Other urological equipment that is not of itself DHS and only is so because it is arguably furnished as an inpatient or outpatient hospital service would be adversely affected by this prohibition on "per click" arrangements.

Urologists also provide other therapeutic equipment, such as lasers for the treatment of BPH, and cryotherapy for prostate cancer. We know of no assertion, let alone any study, that indicates overutilization of any of these services. As noted above, these are therapeutic services. The referring urologists receive a professional fee for each of these services. The professional fee is by far larger than the increase in a physician's distributions that would be attributable to the technical fee for any service he performs. We reiterate that we believe that it is the norm that urologists select the treatment method in the best interests of their patients. CMS has presented no evidence to the contrary. CMS should not contravene Congressional intent based on a theoretical possibility.

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[5] The last requirement in the equipment lease exception is: "The lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse." 42 U.S.C. §1395nn(e)(1)(B)(vi).

Moreover, a "per click" financial arrangement results in more accurate and fairer allocations of risk and compensation than flat rate lease arrangements. Patients do not get sick in equally spaced numbers. More or fewer services are required in any given week or month. Certain procedures may be more necessary in one season than another. Numbers differ from year to year. The hospital and the joint venture that provides services to the hospital are unable to determine in advance how often the services for acute maladies will be needed or which procedures will be required. Many of our members service small hospitals that may need a service for a small number of procedures, 1-3 in a month. In some months they may not need any service.

CUI members' consistent experience has been that hospitals are reluctant to commit to a flat compensation fee that may not be covered by the number of procedures for which they will be able to bill. If the hospitals underestimate the number of anticipated procedures in order not to commit to too high a lease or service rate, patients will be forced to wait for an appointment. Companies providing a service are unwilling to give hospitals an open-ended schedule because they may be forced to provide more services than for which they are paid. A flat fee arrangement could provide incentives for increased referrals, which is precisely what CMS is attempting to prevent.

Current Stark requirements that rental charges be set in advance, consistent with fair market value, not determined in a manner that takes into account the volume or value of any referrals, and commercially reasonable even if no referrals were made between the parties appropriately guard against any potential abuse even with "per click" payments. It is almost impossible to comply with requirement not to take into account volume/value of referrals if a flat fee lease is required. The proposed ban on "per click" payments would promote inefficiencies and would deny Medicare beneficiaries access to effective therapeutic services.

A flat fee arrangement also will not take into account other procedures that may be required. For example, immediately prior to initiating lithotripsy, the X-Ray C-arm may indicate that the stone has fallen from the kidney down into the ureter and the urologist may determine that the patient would have a better result if he pushes the stone up the ureter and back to the kidney. The technical payment in such a case would be for the use of the C-arm and lithotripsy table and a lithotripsy procedure. Other times the C-arm may indicate that the stone has moved so close to the opening of the bladder that a ureteroscopy and not a lithotripsy procedure is more appropriate. In such a case, the hospital may only be required to pay for the use of the C-arm and table to locate the stone. The patient would be moved to the operating room for the ureteroscopy.

Hospitals are understandably loathe to invest in expensive or innovative new technologies. Physicians are in the best position to assess the needs of their own practices and patients, and are willing to bear the risks of usage in order to provide the most beneficial

treatments to their patients. In order to protect their thin margins from low usage volume of a piece of leased equipment, hospitals may require "per click" arrangements. Without the advantage of such arrangements, hospitals and physicians may be unable to reach agreement on volume, and refuse to enter into arrangements for new technologies, depriving the Medicare population of effective treatments.[6]

IV. "Set in Advance" and Percentage-Based Compensation

CMS proposes to limit percentage-based compensation to professional physician services. Again, CMS bases this limitation on its concern that percentage compensation arrangements are "potentially abusive." Five and one half years have passed since the original delay in the prohibition on percentage compensation. Yet, CMS publishes not even one example of actual abuse. Surely it would have cited specific examples if it had them. Vague notions of potential abuse are not sufficient to prohibit a practice.

Percentage-based compensation is usually applied when there is variation in reimbursement from third-party payors. It is sometimes difficult for a hospital to estimate what its reimbursement will be for a procedure where it participates with a wide range of third-party payors. If the hospital's estimates are off, the arrangement can cause it to lose money. Service providers do not want to price their compensation too low. Percentage compensation arrangements afford the hospital and the service provider the opportunity to share the risk.

Moreover, the prohibition on percentage compensation arrangements will likely have wide-ranging and unintended effects. One that comes to mind is that the proposed regulatory language would prohibit a hospital that leases office space in its medical office building from charging the physician tenants a pro rata percentage of real estate taxes.

V. Stand in the Shoes

CMS proposes to amend 42 C.F.R. § 411.354(c) to provide that, "where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls." That said, we can find no proposed regulatory language. In addition to the procedural defect, it is difficult to comment without proposed language.

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[6] Lithotripsy is the least invasive, safest, and least expensive treatment for a kidney stone that is too large for the patient to pass naturally. It is a treatment procedure, not a diagnostic procedure such as an imaging service. In order to perform a lithotripsy procedure, a stone must be localized (identified) on the lithotripter's C arm, and according to protocols of every entity of which we are aware, the stone must be of a size too large to pass. The alternatives to lithotripsy are invasive surgical procedures. We know of no study that indicates lithotripsy is performed unnecessarily and we know of no such claim by CMS.

It appears that CMS has reversed itself with regard to indirect compensation arrangements. In Phases I and II, CMS took the position that if the contracting entities did not fit within the exact words of the parties for a direct compensation exception, the arrangement would need to meet the indirect compensation arrangement exception. It is plainly unfair for CMS to reverse itself in this manner in such a short amount of time. Phase II was issued just three years ago in March 2004. There have been substantial investments in equipment and facilities based upon those regulations. Members of the healthcare community should be able to rely upon regulations and not expect them to be changed in the absence of an immediate and compelling need. No such showing has been made.

Looking at the preamble language, deeming a DHS entity to stand in the shoes of an entity that it owns or controls is overly broad. Each of the relevant terms, "owns" and "controls" should be defined. We question whether a minimal ownership interest should cause a DHS entity to stand in the shoes of the entity in which it has an ownership interest. CMS should clarify whether there is a minimum percentage of ownership or control that will trigger this provision. We question, for example, whether a DHS entity's ownership of a 1-percent investment interest in an entity would or should constitute "owning the entity."

Causing a hospital to stand in the shoes of any entity that it owns or controls would have a particularly devastating effect on entities in which hospitals have an ownership interest and relationships with those entities. This may have been an unintended consequence. This would be of particular concern if CMS expands the breath of "stand in the shoes."

Many hospitals hold an ownership interest in ambulatory surgical centers ("ASCs"). ASCs are generally not DHS entities. ASCs, in turn, have contractual arrangements with entities in which physicians hold an ownership interest to provide services to the ASC that are not DHS, such as lithotripsy and other urological equipment such as lasers, TUMT, TUNA and cryotherapy equipment. Currently, those relationships are analyzed under the indirect compensation arrangement. If the hospital is deemed to stand in the shoes of an ASC in which the hospital holds an ownership interest, and if a physician is deemed to stand in the shoes of an entity in which the physician holds an ownership interest, the physician would have to meet a direct compensation arrangement exception. The result would be that "per click" and percentage compensation arrangements would not be permitted. In essence, if the proposed prohibitions on "per click" and percentage compensation arrangements are adopted, CMS would turn therapeutic services that are not DHS, such as lithotripsy, laser surgery, TUMT and TUNA into DHS. If CMS finalizes each of its proposed changes to the Stark requirements, physicians would no longer be permitted to enter into "per click" or percentage-based compensation arrangements with hospital owned or controlled ASCs. This would likely result in such physicians withdrawing from those ASCs and establishing separate ASCs to provide services for their patients. The result would be increased costs and increased inefficiencies in the healthcare system.

VI. Alternative Method of Compliance

CMS offers an alternative method of compliance with a Stark exception. Rather than an alternative method of compliance, it appears to us that the proposal would create an ability for CMS or the OIG to do what it says it cannot now do, grant immunity in connection with a self disclosure. It is really not an exception at all. We find it unfair to require a voluntary disclosure in order to make use of such an exception. CMS should create a true alternative method for compliance that meets all the other proposed requirements except for voluntary disclosure.

VII. Burden of Proof

CMS is proposing to "clarify" that in any appeal of a denial of payment for a designated health service ("DHS") that was made on the basis that the service was furnished pursuant to a prohibited referral, the entity submitting a claim for payment, and not the government, bears the burden of proving that a prohibited referral did not occur. CMS states that this rule is consistent with its policy with respect to claims denials.

We disagree that the general requirements regarding claims submission to prove that a service was provided and was medically necessary is the same or even consistent with a requirement that the DHS entity prove that the claim was submitted pursuant to a permitted referral. To prove that a service was provided, the entity only need produce the medical record, which will indicate that a service was provided, and, in combination with accepted standards of care, will indicate that a provided service was medically necessary. In addition, a denial of a claim usually applies to a single claim. Each challenge is to a single claim.

In contrast, when CMS challenges a referral as permissible, thousands of claims are at stake. If the physician's relationship with the DHS entity is deemed not to meet a Stark exception, thousands of referrals could be at risk, with a potential $15,000 per violation penalty in addition to the denial of all of the claims, and possible exclusion.

Under Medicare statutes and regulations, CMS and the OIG have the right to audit DHS entities and to require production of documents regarding claims. Through this authority, CMS can require a DHS entity to produce written contracts and other documentation required by a Stark exception, which will indicate to CMS whether Stark requirements are met. Accordingly, CMS has ample access to all of the information necessary for fair adjudication of any claim as to which compliance with Stark II is an issue. In contrast, a contention by CMS that the claimant does not meet an exception, or otherwise comply with Stark II, must, of necessity and fairness, be clearly articulated by CMS in order that a claimant respond effectively. For example, certain Stark requirements are a matter of opinion. Virtually all of the Stark exceptions require that compensation must be at fair market value. Valuation experts using traditional valuation methods often disagree on what is fair market value. Although ultimately it

is a trier of fact who would decide whether the burden of proof has been met, because of the draconian penalties associated with Stark violations, CMS would be able to force entities to settle where there is reasonable disagreement on fair market value. Knowing this would be the case, if the burden is on the DHS entity to prove fair market value, it is likely in contract negotiations a DHS entity would feel the need to take the lowest possible valuation to avoid a possible attack. Moreover, many compensation arrangements between a DHS entity, such as a hospital, and a physician are not of sufficient value to obtain a third-party valuation. The DHS entity may unfairly lowball the physician in order to stay "under the radar."

For several Stark requirements, to meet its burden of proof, a DHS entity would be forced to prove a negative. These include: (i) that compensation is not determined in any manner that takes into account the volume or value of referrals generated, (ii) that the compensation is not related to volume or value of referrals or other business between the parties, (iii) that the arrangement does not exceed that which is reasonable and necessary for the legitimate business purposes of the arrangement, (iv) that equipment or space is not shared by others, that the agreement would be commercially reasonable even if no referrals were made between the parties, that a productivity bonus does not reflect volume or value of referrals, (v) that the services do not involve counseling or promotion of a business arrangement or other activity that violates any state or federal law, and (vi) that no payment is made directly or indirectly as an inducement to reduce or limit medically necessary services.

In addition, pursuant to 42 C.F.R. § 411.353(e), payment may be made to an entity that submits a claim for a DHS even if there was a prohibited referral if the DHS entity "did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral..." It would be difficult, if not impossible, for the DHS entity to prove that it did not know of the identity of the referring physician or acted in reckless disregard of the identity of the referring physician.

Several exceptions require that the arrangement does not violate the anti-kickback statute or violate laws regarding billing or claims submission. Normally, the burden is on the government to prove an anti-kickback violation, which critically requires the government to prove a high level of unlawful intent. Placing the burden of proof on the DHS entity that the service was not furnished pursuant to a prohibited referral would reverse the government's burdens regarding the anti-kickback statute. That would be manifestly unfair and nearly impossible to achieve. In addition, it would require the DHS entity to prove another negative, that its intent was not to induce referrals.

Placing the burden of proof on the entity submitting the claim would place Medicare contractors, or CMS, in a position of being "judge and jury" over complex and highly debatable issues. The effect would be to force DHS entities into settlements because of the draconian Stark penalties.

Importantly, Stark is a strict liability statute. Where intent and inadvertence are irrelevant, there is additional reason that the government should not be able to shift the burden of proof to the DHS entity.

VIII. **Additional Concerns**

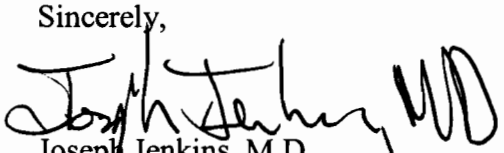
From a broad perspective, we note that physicians and entities have invested money, time, and effort in forming arrangements compliant with the Stark regulations as previously interpreted by CMS. If the CMS proposals are made final, some of these previously compliant arrangements (*e.g.* "per click" arrangements that were explicitly permitted in prior Stark preambles) will violate Stark prohibitions. The changing regulations will cause undue hardship to those who have invested in reliance on prior CMS interpretations. CMS should not finalize the Stark Portion of the Proposed Rule as we have commented in this letter. In the alternative, at a minimum, CMS should delay implementation for a period of five (5) years so that physicians who invested in good faith and in compliance with the law are not subjected to a "fire sale."

Further, we reiterate our request that CMS reopen the comment period for the Stark Portion of the Proposed Rule once Phase III of Stark is released so that the interested public has the opportunity to comment on the complete rule with all of its implications.

The proposed regulatory changes in the Stark Portion of the Proposed Rule would place unfair burdens on companies providing lithotripsy and other urological procedures. Medicare beneficiaries make up only 20% of the patients receiving lithotripsy services. If these changes are finalized, physician investor companies would terminate contracts with hospitals, enter into contracts solely with ambulatory surgery centers, and cease providing services to Medicare beneficiaries. Medicare beneficiaries would receive lower quality service and would encounter longer waiting times.

Please do not hesitate to contact me if you need further clarification of the Council for Urological Interests' concerns.

Sincerely,



Joseph Jenkins, M.D.
Chairman and Executive Director

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The Voice Of Interventional Pain Management since 1998

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August 28, 2007

Kerry N. Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

CMS-1385-P
2007 AUG 29 P 12:27

Re: CMS-1385-P

Dear Mr. Weems:

The American Society of Interventional Pain Physicians ("ASIPP") would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the Proposed Rule) published in the *Federal Register* on July 12, 2007. As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

ASIPP is a not-for-profit professional organization comprised of over 4,000 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 7,000 physicians practicing interventional pain management in the United States. Physician offices, along with hospital outpatient departments and ambulatory surgery centers, are important sites of service for the delivery of interventional pain services.

We appreciate that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for their services in 2007, interventional pain physicians are facing additional proposed cuts in payment as much as 7.8% to 19.8% in 2008 alone. This will have a devastating effect on physicians' ability to provide interventional pain services to Medicare beneficiaries. We are deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. We urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expenses methodology does not accurately take into account the practice expenses associated with providing interventional pain services. We recommend that CMS make a modification to its practice expenses methodology so that all physicians who provide interventional pain services and their practice expenses will be appropriately recognized in the methodology. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as

their secondary Medicare specialty designation, along with the physicians who list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. **CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.**

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

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05 (Non-Facility)	Interventional Pain Management Physicians -09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

We urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

We urge CMS to not delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While ASIPP believes that the Physician Practice Survey is critical to ensuring that physician services are more appropriately paid, we do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of

drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with stringent statutes and compliance regulations, along with wages and salaries for specially trained and licensed compounding pharmacists. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have complete discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 mg of Bupivicaine, and 4 mg of Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physicians experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) mandated CMS to pay providers 106% of the manufacturer's Average Sales Price (ASP) for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged; the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

ASIPP commends CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. We believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. We urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV. CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate (SGR) formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to survive these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase more than 20% over the same period. The

reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

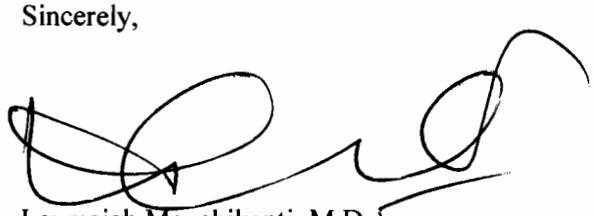
Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they can continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. We fear that unless CMS addresses the underpayment for interventional pain services today that there is a risk that Medicare beneficiaries will be unfairly harmed if they do not have access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services.

Sincerely,



Laxmaiah Manchikanti, M.D.
Chief Executive Officer, ASIPP

mgwell 667

AMERICAN COLLEGE OF GASTROENTEROLOGY

6400 Goldsboro Road, Suite 450, Bethesda, Maryland 20817-5846; P: 301-263-9000; F: 301-263-9025

August 30, 2007

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

Re: *Proposed Revision to Payment Policies Under the Physician Fee Schedule, and other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions for CY 2008, CMS-1385P*

Dear Mr. Kuhn:

The American College of Gastroenterology is pleased to provide these comments with respect to CMS' proposed rule, published in the *Federal Register* on July 12, 2007, on revisions to the payment policies relating to Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology for the (Calendar Year 2007) and other related topics.

INTRODUCTION

The American College of Gastroenterology is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers more than 9,500 physicians among its membership of over 10,000 health care providers of gastroenterology specialty care. Although the vast majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists, and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, educational efforts directed at promoting and optimizing quality care.

In addition to the College's comments, which follow, we also wish to endorse specifically the comments submitted jointly in this matter by the American College of Gastroenterology, the American Society for Gastrointestinal Endoscopy, and the American Gastroenterological Association.

Relative Value Units (RVUs)

The RVUs assigned to GI colonoscopies and other procedures are insufficient. Since the Medicare colorectal cancer screening benefit was enacted in 1997, CMS has cut

the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40% from a little over $300, to the current national average level of $186. Payment for these services continues to trend downward (these are raw dollars; if inflation were factored in the reduction would almost certainly be in excess of 50%). No other Medicare service has been cut this much since 1997 when Congress decided to make the eradication of colorectal cancer a national priority by encouraging every Medicare beneficiary over the age of 50 to receive screening.

Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. Sadly, and whether intentionally or inadvertently, CMS has consistently emasculated the effectiveness and utilization of that benefit, by relentless and devastating cuts. When one looks at the bottom line on this proposal, it is clear that this disastrous trend would continue with major new cuts.

CMS argues in this proposal and elsewhere that the SGR will automatically cut the reimbursement for all Medicare services by approximately 9.9 percent next year and that precipitous cut to the facility fees paid for cases performed in ambulatory surgery centers for ASC should be undertaken. When the new ASC payment reform policy is factored in, the effective rate of the one-year cuts, including CMS's outrageous proposal to cut the average GI facility fee in the ASC setting by 27%, could be 30% or more. The cumulative effect of these CMS proposals would be to force GI physicians to limit access to Medicare beneficiaries or force them out of business altogether. At this point, CMS has simply extracted too much money out of the system already; further cuts of the magnitude suggested will have potentially significant impact on patient access to gastroenterology specialty care. These impacts accordingly will threaten the health, as well as the lives of patients – not only by restricting access to screening for prevention or early detection of gastrointestinal cancers but emergent care for symptomatic problems. Delay in diagnosis or missed diagnosis will have a significant associated morbidity and mortality for GI patients.

Work Neutrality Adjustor

We strongly urge that CMS adjust for budget neutrality by reducing the conversion factor and not by reducing the physician work values. In this proposed rule, CMS announces that the work adjustor flowing from the five-year review of work values will be increased from -10.1% to -11.8%. Our rationale is as follows:

- It has been Medicare policy for many years that work neutrality adjustments would be made through the conversion factor. We recognize that for the first five-year review, CMS implemented a separate work adjustor. However, CMS indicated that the separate work adjustor proved very confusing and in 1999, CMS converted the work adjustor to an adjustment to the conversion factor. In fact, since 1998, CMS has implemented all work neutrality adjustments through the conversion factor.
- Adjustment of the work values could lead to undesirable effects outside of Medicare. For example, it could lead to inappropriate reductions in the fees paid by other third party payers. The Medicare relative value scale is used for a variety of other purposes such as in determining compensation levels in academic and group practice settings. A separate work adjustor could distort these arrangements in unintended ways. By contrast, we

believe that the various adjustments made in the calculation of allowable practice expense values has the same impact on other payers and private contracts as is present with adjustments to work values. Additionally, attaining budget neutrality through reducing physician work values would further undercut and de-construct the current RVUs from any coherent link back to their original basis in the Hsiao data and physician work RVUs would become more a meaningless arbitrary number, with no connection to actual measurement of specific physician work.

For all of these reasons, and if one must chose between two unfair and economically untenable alternatives, we strongly urge that CMS maintain budget neutrality for changes in work values by adjusting the conversion factor.

Yet, we still find the choice between these two economically untenable alternatives unpalatable, as they ultimately would promote the inevitable further crumbling of the Medicare system, to the detriment of patients/beneficiaries. Practices cannot continue to screen Medicare beneficiaries for colorectal cancer screening on the same basis and timetable as they do for private pay patients if we are looking at cumulative cuts in excess of 40% since the colorectal cancer screening benefit was enacted in 1997.

Additional Codes from the Five-Year Review

The ACG is distressed to see the increase in the work neutrality adjuster that resulted from the extraordinarily significant increase in the work values assigned to anesthesia services. This 32% increase in work values for anesthesia will cause an approximately one percent decrease in work values for every other code in the fee schedule, exacerbating already severe under payments to GIs.

Tax Relief and Health Care Act (TRHCA) – Section 101(d) Physicians Assistance and Quality Initiative (PAQI)

The ACG respectfully objects to CMS' proposal to use the $1.35 billion allocated as part of the Physician Assistance and Quality Initiative (PAQI) fund entirely to fund the Physician Quality Reporting Initiative (PQRI) in 2008. While ACG supports incentivizing the provision of quality care where practical for the practicing physician and as defined by well-established clinical guidelines, the College, as described above, is extremely concerned about the impending 9.9% cut in the conversion factor that will cause physician payments from Medicare to plummet. CMS was given the opportunity to use some of that money to reduce the scheduled payment cuts, but choose to instead use it for this quality reporting initiative. ACG rejects the argument that CMS is unable to apply this payment towards a conversion factor adjustment. While the College understands the technical challenges arising from assigning a fixed pool of money to an entitlement program, we believe that CMS has the technical capability to apply the money in the fund to offset some of the scheduled conversion factor decrease. The prospect of a 9.9% further cut is cataclysmic for the Medicare system and we believe that CMS is duty-bound to apply every resource to alleviate or ameliorate that destructive prognosis. ACG urges CMS to reconsider its position and use the PAQI to offset the scheduled decreases to the conversion factor for 2008.

Physician Self-Referral Provisions

CMS proposes that Section 414.50 of the regulations be changed so that (1) the professional component (PC) of a purchased test would be subject to the anti-mark-up provision now applicable only to purchased technical components (TC) under certain conditions and (2) that the anti-markup provision apply to all arrangements not involving a reassignment for a full time employee, defined as someone working 35 hours per week, of the billing entity.

The ACG has followed the self-referral issue for many years and has concerns about some of the changes proposed in this rule. Physicians throughout the country struggle with the issues of self-referral and often have to spend far too much on attorneys in order to navigate the confusing regulations of self-referral. These changes will make it even more difficult for physicians to participate in legitimate business ventures without the fear of inadvertent violations. Further, after such consultations and exhaustive study, some GIs, like other physicians, invest in a variety of practice arrangements intended to improve the quality of care offered and/or physicians' ability to schedule the timely/convenient provision of care. Precipitous changes in such laws can unnecessarily upset such arrangements and put at risk significant physician investments and practice structures.

For example, we are aware of GI practices that have used current exceptions to open their own pathology labs because they felt that the reports they received from general lab companies were in some way lacking. We have been told by our members that sometimes national non-specialized labs have issued incomplete reports on samples taken to look at less common GI diseases such as microscopic colitis, Barrett's dysplasia, eosinophilic esophagitis and others. Specialized GI pathologists are trained to recognize these diseases and in some cases, can offer higher quality care and better overall patient outcomes. Pathology services are critically important to timely, accurate diagnosis of common GI conditions as well, e.g., Helicobacter pylori. Others may send anatomic pathology specimens taken from their patient during ASC procedures to a laboratory. At the lab, the physicians will prepare slides from each specimen and send them to the physician practices for an on-site pathologist to interpret. In this instance, the lab prepares the slides and bills Medicare for technical services while the practice bills Medicare for the professional services rendered by its own employee or contractors. Other practices may have made the investment in their own labs. In either case, the GI pathologist may be part-time or full-time, an employee or contractors.

ACG strongly objects to CMS' proposed requirement that the pathologist be a full-time employee in order for a practice to bill and collect from the Medicare program for professional pathology services. For some practices with sufficient volume, a full-time employee may make sense. Others cannot support a full-time or employed pathologist, but still may desire to have their practices benefit from the expertise and higher-quality care that access to consistent, GI-specific pathology services provides as well as the ability of the GI and pathologist to provide on- site consultations.

Further, no matter how many hours a GI pathologist works, we are not aware of any evidence that the use of a dedicated GI pathologist increases costs to the Medicare program as most

specimens result from already scheduled GI procedures and CMS, through the existing Stark and anti-kickback rules, has sufficient protections in place to protect from any potential abuse. We are aware of no studies that demonstrate that a referring physician orders more anatomic pathology specimens from Medicare beneficiaries. Additionally, the peer-reviewed literature provides guidance in terms of numbers of biopsies, lesion removal, etc

The College is troubled by some of the characterizations articulated in the section of the proposed rule on the in-office ancillary services (IOAS) exception. First, CMS refers to "hundreds of letters from physical therapists and occupational therapists that the in-office ancillary services exception encourages physicians to create physical and occupation therapy practices." CMS does not elaborate any further on the propriety or harm of this activity or its relationship to areas of medicine, like GI, which are likely to have little to nexus to occupational or physical therapy. Without further clarification of the agency's specific concerns, it is difficult for affected stakeholders to provide the kind of focused, informed comments that advance good public policymaking.

In summary, we ask that CMS make no changes to the current ancillary office exception for pathology services and not pursue further any full-time requirement for the centralized building requirement. As explained above, any such changes could decrease the quality of GI specimen evaluation – and thus the ability to obtain timely and accurate diagnoses, without resulting in any additional protection or other benefit to the taxpayer. Further, requirement for full-time employment under the centralized building rules would represent undue interference in the practice of medicine.

TRCHA –Section 101(b) Physicians Quality Reporting Initiative (PQRI)

The College is dedicated to the provision of high-quality care and evidence-based medicine. Our journals further the dissemination of such research. The ACG is a member of the National Quality Forum (NQF) and has participated informally in the AQA. We agree with the Agency's finding that NQF meets the criteria of the NTTA (National Technology Transfer and Advancement Act) for a formal-consensus standards based organization and are particularly supportive of NQF's efforts to base its decisions on the clinical expertise of expert panels.

On the other hand, we have been troubled by the AQA's current lack of structure and agree with CMS' finding that it does not meet the criteria under the NTTA for a "voluntary consensus standards body." Indeed, it seems to lack scientific rigor in its approval process and it is not entirely clear what stakeholders have standing within the AQA.

We hope that over time, that HHS will defer to only one body for the selection and implementation of standards and that this process be driven by a deliberative consideration of the clinical evidence as well as practical consideration of the ability of physicians in clinical practice to implement and report on the measures chosen. Specialty societies like ACG – like most other stakeholders -- do not have unlimited resources with which to monitor and engage in measure development and implementation activities using different rules of development and standards of review. Consolidation of these efforts in an organization that meets specific structural standards

is a sensible approach and would allow organizations to focus their efforts as well as make the process more cost-effective.

The College disagrees with the agency's statement that "it is impractical to delay implementation of physician quality measures until the formal processes of NQF are completed." ACG firmly believes that it is better to take a deliberative approach that carefully considers the clinical evidence and administrative burden. A rush to judgment on measures can create a physician backlash and is not in the long-term interest of the Medicare program. If measures are subsequently rejected by NQF, physicians are likely to suffer from "measure whiplash" and confusion as measure sets change. It is far better to get measures right the first time.

The College supports CMS' proposal to reject for inclusion in the 2008 PQRI measure set those measures that have been specifically considered by NQF but which were rejected by them. This fact pattern applies to the GERD measures included in the 2007 PQRI. In contrast to the proposed rule, we would *also* urge the agency not to adapt any measures that have been adopted by the AQA *until* they have been endorsed by NQF. Likewise, we would urge CMS to *exclude* from the 2008 measure Physicians Consortium for Performance Improvement (PCRI) measures until such time as they have been endorsed by the NQF including the measures for:

- Assessment of GERD Symptoms in Patients Receiving Chronic Medication for GERD
- Testing of patients with Chronic Hepatitis C (HCV) for Hepatitis C Viremia
- Initial Hepatitis C RNA Testing
- HCV Genotype Testing Prior to Therapy
- Consideration for Antiviral Therapy in HCV Patients
- HCV RNA Testing at Week 12 of Therapy
- Counseling patients with HCV Regarding Use of Alcohol
- Colorectal cancer patients who have a pT and pN category and histologic grade for their cancer

While we understand that the TRHCA requires CMS to adapt structural measures such as those proposed for adoption/use of e-prescribing and adoption/use of electronic health records, we hope that CMS and the Congress realize that given the significant decline in reimbursement for GIs and the expense of such systems, a large infusion of funds is likely to be required to increase adoption of HIT by all but the largest physician practices.

Further, we support the adoption of the AQA Starter-Set measures such as colorectal cancer screening provided that they retain NQF endorsement by November 15, 2007. As indicated by the August 2007 report by the well-respected Partnership for Prevention (see http://www.prevent.org/content/view/129/72/), 14,000 additional lives would be saved each year if we increased to 90 percent the portion of adults age 50 and older who are up to date with any recommended screening for colorectal cancer. Today, fewer than 50 percent of adults are up to date with screening. However, such an increase is not possible with the sustained and worsening underpayments to GI documented elsewhere in this comment letter.

In the long-run, we support the agency's plan per the requirements of TRHCA to turn to medical registries as a less burdensome way to report quality registries and urge the agency to recognize

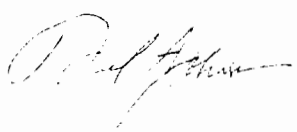
that many of these efforts are in their infancy. Given how new these efforts are, we urge CMS to give this project a long lead-time and avoid the adoption of overly stringent criteria that does not allow for innovation in registry development. Such flexibility will allow participation at a later date by registries created by medical societies and other key stakeholders that are now only on the drawing board.

Conclusion

We are deeply concerned that the cumulative cuts from the SGR, and the pending reform to the ambulatory surgery payment system will drive many gastroenterology practices (and ASCs) out of the Medicare system and/or out of business and compromise their ability to continue to provide gastroenterology specialty care to Medicare beneficiaries. This downward spiral must stop. CMS must also take great care in implementing mandatory pay-for-performance regimes so that any implementation burdens are offset by the quality benefits gained and improved patient outcomes are demonstrated. Lastly, the agency should not change the anti-referral rules without extremely careful consideration of the likely effects on the provision of timely and high-quality care; any changes deemed necessary should be targeted very carefully.

We appreciate the opportunity to submit our comments on this proposal and we would be pleased to answer questions or otherwise engage in dialogue with the agency about how to improve/remedy the deficiencies in the current proposal.

Respectfully submitted,



David A. Johnson, M.D. FACG
President

Edward Cattau, M.D. FACG
Chair, National Affairs Committee

NCQDIS

August 30, 2007

VIA HAND DELIVERY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385–P
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Acting Deputy Director Kuhn:

The National Coalition for Quality Diagnostic Imaging Services (NCQDIS) represents outpatient diagnostic imaging centers and departments throughout the United States. Through affiliated professional societies, NCQDIS represents centers and professionals involved in the provision of diagnostic imaging services. Medical imaging equipment and supply vendors are a part of NCQDIS as well. We appreciate the careful consideration and effort that has gone into developing the proposal for revision to the physician fee schedule in 2008.

NCQDIS finds much to agree with in the Proposed Physician Fee Schedule for 2008. In particular, we applaud CMS's recognition of the growing physician self-referral problem posed by the in-office ancillary exception. NCQDIS is the leading voice for independent diagnostic imaging facilities. Such facilities cannot generate utilization through self-referral. As currently implemented, the in-office ancillary exception creates a potential for inappropriate utilization and potential abuse of the Medicare program resulting in unnecessary program and beneficiary expenditures.

NCQDIS is pleased to submit the following comments on the Proposed Physician Fee Schedule for 2008:

Resource-Based PE RVUs:

NCQDIS strongly supports the position taken by CMS in the proposed rule to maintain the equipment usage assumption at the current level of 50 percent. We concur with CMS

that there is not sufficient empirical evidence to justify an alternative proposal on this issue. If the equipment usage percentage is set too high, the resulting reimbursement to facilities for the equipment would be inadequate to cover the practice costs associated with equipment.

We support the efforts of CMS to develop approaches that differentially classify equipment into mutually exclusive categories with category-specific usage rate assumptions and CMS' commitment to work with the physician community to examine equipment usage rate assumptions that ensure appropriate payments and encourage appropriate utilization of equipment. We are also concerned that imaging providers in rural and underserved communities would be disproportionately hurt by a change in the utilization percentage where the high fixed costs of expensive equipment is spread across a smaller volume of services.

NCQDIS also strongly supports CMS' decision to maintain the interest rate used in the calculation of equipment costs at 11 percent. We believe the data obtained by CMS from the Small Business Association provides an accurate representation and assumption of interest rate data for equipment purchase. In fact, NCQDIS has many members who report that interest rate charges have recently escalated well beyond 11 percent because of the negative financial impact on their facilities of the Deficit Reduction Act. The current turmoil in the financial markets is further increasing the cost of borrowing money to purchase expensive equipment. We urge CMS to maintain the interest rate assumption at 11 percent in 2008.

IDTF Issues:

- Liability Insurance - 42 C.F.R § 410.33(g)(6)

NCQDIS supports the changes proposed regarding liability insurance requirements, with the caveat that we are concerned about whether CMS has had discussions with insurance underwriters to determine whether there is any reluctance on the part of the underwriters to list the government as a certificate holder on the insurance policy. Without cooperation from these insurance entities, compliance with this IDTF performance standard may be beyond the control of the IDTF.

- Enrollment Changes Notification - 42 C.F.R § 410.33(g)(2)

NCQDIS strongly supports the proposed change to 42 C.F.R § 410.33(g)(2). We greatly appreciate CMS' understanding and positive response to the concerns raised by the IDTF industry when this standard was first implemented in 2007. The proposed changes provide the information desired by CMS in a timely manner while minimizing the administrative burdens on both IDTFs and the Medicare contractors caused by the prior time notification standard.

- Beneficiary Questions and Complaints - 42 C.F.R § 410.33(g)(8)

While NCQDIS generally supports the goal of responsiveness to beneficiary questions and complaints, we request clarification and further definition to limit the potential administrative burden that may result from an overly broad interpretation of this standard. The standard does not clearly define which questions and complaints would rise to the level of requiring the inclusion within the documentation standard. Therefore, we request that CMS clearly define those questions and complaints which must be documented. IDTFs respond to questions and complaints on a daily basis that are quickly and routinely resolved. For example, a beneficiary may question a co-payment amount; complain about a wait time, etc. These matters are usually quickly resolved. We request that the standard apply only when a beneficiary has formalized such question or complaint in a written format.

- Supervising Physician - 42 C.F.R § 410.33(b)(1)

NCQDIS supports the change and clarification made to 42 C.F.R § 410.33(b)(1) regarding the supervising physician language. We request additional clarification that the three site limitation **only** relates to the provision of general supervision, as currently, that guidance only exists in the preamble of the commentary of the proposed change. We would also like to clarify that while a physician may only provide general supervision to three IDTF sites, this would not preclude the physician from being listed as an interpreting physician at additional IDTF sites. In this day of highly technical radiological interpretations, some radiologists sub-specialize (e.g. neurological imaging, spine imaging, musculoskeletal and body). As such, a particular image may need to be sent for interpretation via teleradiology from another site (i.e., a fourth site) to a radiologist for interpretation who already serves as supervising physician for three IDTF sites. Radiologists routinely supervise individual tests at one or two IDTF sites a day (in some cases up to five or six per week). IDTFs with multiple locations frequently must contract with radiology practices that employ a large number of sub-specialty radiologists some of whom may be designated as a supervising physician for certain of the IDTFs but who also who provide interpretations for other IDTFs.

- Initial Enrollment Dates for IDTFs - 42 C.F.R § 410.33(i)

NCQDIS requests that CMS not implement its proposal to preclude an IDTF from being allowed to bill Medicare retroactively for services that are rendered prior to the provider being formally approved by the applicable Medicare contractor to participate in the Medicare program. Before an IDTF can even apply for enrollment and submit a completed CMS Form 855, it must have: 1) implemented a framework that is compliant with CMS requirements; 2) incurred significant capital expenditures to purchase imaging equipment and facility space; 3) contracted with radiologists for supervision and interpretative services; 4) hired, contracted or otherwise retained technologists and other office staff; and essentially begun operations. Even with optimal Medicare contractor review and approval time frames, an IDTF will have incurred significant expenses to satisfy the enrollment criteria prior to being able to submit a complete Medicare

enrollment application. As CMS is aware, many commercial payers require a Medicare provider number prior to enrolling in their plan. As such, an IDTF would need to be fully operational and incurring all operational expenses but would not be able to receive compensation for those services.

Additionally, we request that CMS clarify that the proposed changes are only applicable to new or initial enrollment applications and would not affect existing operations when minor changes or additions are made to an enrollment application, such as the addition of a new physician or piece of equipment.

We are also concerned about the statement in the proposed rule that CMS proposes to define the "date of filing" as the date on which the Medicare FFS contractor receives a signed provider enrollment application that the Medicare FFS contractor is able to process for approval. NCQDIS has received many reports from its members of applications turned back by the Medicare FFS contractors for extremely minor issues or corrections. As such, providers are experiencing lengthy delays in getting applications and amendments processed. As a way to lessen the potential financial burden on the IDTF providers that could result from a Medicare contractor's arbitrary determination of when it is "able to process for approval" an application, we would suggest that the "date of filing" be defined as date that the Medicare FFS contractor receives a signed provider enrollment application that is **substantially complete**. In this way, an IDTF would not be penalized by the clock starting over in the application process for what may be an immaterial application mistake/correction.

- Sharing of Space, Equipment or Staff - 42 C.F.R § 410.33(g)(15)

NCQDIS acknowledges and shares CMS' concern that certain leasing and sharing arrangements utilized in the marketplace today may lead to over-utilization. This concern regarding appropriate, quality imaging for Medicare beneficiaries compels us to recommend that any CMS policy initiative intended to eliminate certain suspect leasing or space sharing arrangements should be applied to all imaging providers, not just IDTF providers. We fear that unless the playing field is leveled for all imaging providers, the very over-utilization that CMS intends to curb will become an even greater reality because physicians and physician offices that are in a position to self-refer will enter into an ever-increasing number of Stark compliant arrangements that take advantage of "loopholes" and allow them to profit from such referrals.

Ensuring a comparable regulatory environment across sites of services will minimize the incentives to shift cases into less regulated sites where standards for operating the equipment and interpreting the images provide fewer quality and safety assurances than in the IDTF. We are particularly concerned that if CMS bans leasing and other sharing arrangements solely in the IDTF setting, and not at all sites of service, substitute arrangements will proliferate. Non-radiology physicians are aggressively requesting these arrangements. A shift in site of services is likely to result in even greater imaging over-utilization as providers relocate more imaging services to their office rather than sharing equipment on an as-needed basis in a quality-controlled environment. If CMS

implements a ban on leasing and other sharing arrangements, we urge the agency to issue that ban in all settings. This will ensure that all imaging providers furnishing services to Medicare beneficiaries (e.g., IDTFs, radiologists, non-radiologist physicians) are subject to the same rules and standards, thereby assuring consistently high quality in all sites of service.

NCQDIS is also requesting clarification of this provision to define the term "individual or organization" to exclude hospitals and non-referring radiologists. Arrangements between IDTFs and radiologists are not likely to result in overutilization or abuse because radiologists are not in a position to refer patients to IDTFs for diagnostic exams. Both the IDTF and the radiologists are dependent upon referrals from other physicians. Radiologists often have office space in an IDTF and may also provide radiology services to a local hospital or even another IDTF. These arrangements have been standard in the industry for years and should not be restricted. In addition to the diagnostic imaging services performed by radiologists described above, certain radiologists may also utilize the IDTF space, staff and equipment to perform certain interventional radiology procedures on patients during normal office hours, including pain management needle placement procedures, arthrograms, and biopsies. Interventional radiologists perform these invasive diagnostic procedures pursuant to an order by the referring physician. Similar to diagnostic imaging services, interventional radiologists who perform diagnostic services do not become the treating physician with respect to the patient and are not in a position to self refer.

Similarly, arrangements between IDTFs and certain hospitals (including critical access hospitals) are unlikely to result in overutilization or abuse because hospitals, like radiologists, typically rely on physicians for patient referrals and are not in a position to self-refer. Further, many rural and community based hospitals with insufficient resources to acquire expensive imaging equipment often obtain diagnostic services for their inpatients by entering into arrangements with mobile or fixed IDTF sites. So long as the arrangements are structured to comply with OIG guidance, the risk for waste, fraud and abuse is low while the potential for administrative and cost savings is high.

An additional concern relates to those IDTFs operated in a Medical Office Building or on the campus of a hospital which share common physical spaces (e.g., waiting areas, hallways, restrooms). As currently written, IDTFs would need to terminate existing space leases or request drastic physical plant changes from their landlords in order to comply with the proposed requirement of 42 C.F.R § 410.33(g)(15). Such a burden would be cost prohibitive in many instances.

Physician Self-Referral Provisions:

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

NCQDIS supports the proposed provision regarding the "mark-up" of Technical Component ("TC") or Professional Component ("PC") purchased or obtained under assignment by a "physician or medical group." However we request clarification that this provision relates solely to physicians and medical groups purchasing the TC and/or PC or obtaining a reassignment in order to bill globally and does not contemplate radiologists' reassignment relationships with IDTFs. Radiologists and IDTFs are not in a position to self-refer to each other or themselves because both are dependent upon referrals from other physicians in the community. Consequently, arrangements between radiologists and IDTFs are not likely to raise fraud and abuse concerns, and contractual arrangements are often structured so that the radiologist reassigns his billing rights to the IDTF so that global billing may be performed by the IDTF.

- In-Office Ancillary Services Exception

NCQDIS believes, like CMS, that the Congress included an exception for in-office ancillary services to allow for the provision of certain limited services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office and not the proliferation of sophisticated and expensive imaging or other equipment that has resulted in many physician offices. We further believe that it was the intent of Congress that such limited ancillary services were anticipated to be provided at the time of the initial visit and not days or weeks later as is actually often the case.

In fact, the issue of "patient convenience" was addressed by the Maryland Department of Health and Mental Hygiene, Board of Physicians, in **Declaratory Ruling 2006-1** regarding a challenge to the Maryland Self Referral Law. The Board found that none of the example cases presented by the physicians showed MRIs conducted on the same day as the referrals. In fact, the Board found that a large percentage of the self-referred MRIs were performed in other geographic locations than the office where the patient was first seen. As such, NCQDIS believes that as currently enacted, the in-office ancillary exception creates a potential for inappropriate utilization and a potential fraud or abuse of the Medicare program that drives up costs for the program and ultimately its beneficiaries. NCQDIS believes it is within the Administration's authority to close down many, if not all of the abusive relationships currently resulting from the in-office ancillary exception. These closures could be achieved by granting broad authority to the Office of the Inspector General in promulgating new rules under Section 1877 of the Social Security Act or in interpretation of the statute itself.

From the standpoint of quality measures NCQDIS has long conveyed to CMS and Congress its concern that imaging procedures performed under the in-office ancillary exception are far too often not of the same quality as imaging procedures performed by reputable IDTFs and radiology offices. This concern is due to several factors including test supervision performed by non-radiologists, use of older or lower strength imaging machines, less qualified technicians, and suboptimal maintenance and operation of the equipment. To the extent those procedures performed under the in-office ancillary exception are inadequately supervised, performed by unqualified technicians or on poor

quality equipment, lower quality images may result in missed or delayed diagnoses, further increasing Medicare program expenditures unnecessarily.

We believe all providers should be subject to the same quality and safety standards for the same procedures regardless of the site of care. As such, we believe the current quality standards that apply to IDTFs should apply across the board to all imaging providers.

NCQDIS would make the following recommendations in response to the specific queries posed by CMS in the commentary to the proposed Rule:

(1) whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services)

NCQDIS would strongly support the exclusion from the in-office ancillary exception of certain advanced imaging procedures. Specifically, we propose that Magnetic Resonance Imaging (MRI), Computed Tomography (CT) and Positron Emission Tomography (PET) be excluded. Imaging equipment required to perform these procedures requires a large capital expenditure and from a quality perspective, the equipment should be operated only by qualified trained technologists under the supervision of a radiologist qualified to perform and interpret the procedure being billed. As such, we do not believe the use of such advanced imaging in the in-office setting is appropriate or in the best interests of Medicare and its beneficiaries. The absence of these quality control measures in other settings can lead to beneficiaries needing images to be repeated later in an IDTF or other setting to ensure a quality image for interpretation. This unnecessarily exposes beneficiaries to additional radiation and is an expensive corrective measure for the Medicare program and beneficiaries.

Advanced imaging procedures are frequently subject to pre-authorization by commercial payors and, as such, the procedures are unlikely to be done at the time of the initial patient visit. As previously stated above, the ability to perform certain procedures at the initial visit was the basis for the in-office ancillary exception. In addition, the large fixed cost expense of operating the advanced imaging equipment in the in-office setting is incompatible with low utilization as a result of waiting for a patient with the appropriate clinical need for such equipment. The desire to cover such fixed costs could, therefore, result in inappropriate utilization in the in-office ancillary setting because the physician/owner of the equipment can self refer their patients as compared with free-standing imaging centers, such as IDTF's which are dependent upon a clinically appropriate referral in order to perform any imaging procedure.

(2) whether and, if so, how we should make changes to our definitions of same building and centralized building

We are unsure how changes in the definition will have a significant impact as long as the underlying exception remains. NCQDIS is concerned that non-radiology physicians are aggressively utilizing a broad interpretation of the same building and centralized building

definition in the in-office ancillary exception in order to offer advanced imaging procedures. Such activity creates the very over-utilization that CMS intends to curb because physicians and physician offices are in a position to self-refer and profit from such referrals. Thus, the frequently-used expanded definition of "in-office" has led to sharing of equipment and the other abuses of the exception that CMS has described in the proposed rules. Implementing standards comparable to those imposed on IDTFs may dampen the incentives for the inappropriate utilization of concern to CMS.

(3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists

NCQDIS reiterates its position that any such arrangements often provide physicians or physician groups with the means to generate self-referral revenue from imaging services. Unfortunately, the existing regulatory framework around the in-office ancillary exception can be subject to aggressive interpretation by attorneys advising physicians which contribute to the proliferation of supposedly Stark-compliant arrangements. These arrangements are likely to lead to over-utilization of imaging services and increased program expenditures due to self-referral. To the extent those procedures are inadequately supervised; performed by unqualified technicians or on poor quality equipment, lower quality images resulting in missed or delayed diagnoses can result, further increasing Medicare program expenditures. As outlined previously, we believe that the in-office exception should be curtailed to include only those limited services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office and which can be performed on-site on the day of the patient's visit.

(4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

NCQDIS restates its position that we do not believe that under any type of physician ownership arrangement the performance of advanced imaging procedures should be permitted under the in-office ancillary exception. Such arrangements can only lend themselves to the potential for overutilization of imaging services as detailed above.

- Unit-of-service (Per-Click) Payments in Space and Equipment Leases

NCQDIS believes this issue may become moot for IDTFs pursuant to the proposed prohibition on space, equipment and staff sharing under the proposed IDTF Performance Standards.

NCQDIS strongly supports the general prohibition of per-unit lease arrangements between referring physicians and DHS entities regardless of the lessee/lessor arrangement. We feel the more abuse-prone arrangement is when the physician is leasing time from the IDTF and as such we support the prohibition of "per-click" arrangements as described in the proposed rule (where referring physician is the lessor) and recommend expansion of the "per-click" prohibition to include arrangements when the physician is the lessee.

- Services Furnished "Under Arrangements"

NCQDIS supports the proposed change to the existing Stark regulations and concurs with the Medicare Payment Advisory Commission (MedPAC) position described in its March 2005 Report to Congress:

> *Physician ownership of entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers, which could lead to higher use of services.*

As such, we believe the proposed change to the definition of the term "entity" will preclude referrals that are based upon financial incentive and as such result in potential over-utilization of services. The existing exception runs contrary to the plain intent of the physician self-referral law.

We are pleased that CMS is moving forward with adoption of revisions to the Stark law's application to imaging services, and we support CMS in this effort. We appreciate the opportunity to provide our views on the implementation of the proposed rule and look forward to working further with CMS on this important matter. Please contact our Executive Director, Maggie Sayre, at (202) 460-3647 if you or your staff have any questions or need additional information.

Respectfully submitted,

Robert V. Baumgartner
Chairman, National Coalition for Quality Diagnostic Imaging Services
Chief Executive Officer, Center for Diagnostic Imaging
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Paul S. Viviano
Vice Chairman, National Coalition for Quality Diagnostic Imaging Services
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C. Christian Winkle
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Alpharetta, GA

Patricia R. Blank
Treasurer, National Coalition for Quality Diagnostic Imaging Services
Executive Vice President—Clinical Services and Support, InSight Health Services Corp.
Lake Forest, CA

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Society of Diagnostic Medical Sonography

August 28, 2007

Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Subject designation: Coding—Reduction in TC for Imaging Services

Dear Administrator Weems:

On behalf of the Society for Diagnostic Medical Sonography ("SDMS"), we appreciate the opportunity to comment on certain aspects of the Physician Fee Schedule Proposed Rule ("Proposed Rule") for CY 2008.[1] We focus our comments on the mandate in § 5102(b)(1) of the Deficit Reduction Act of 2005 ("DRA") that Medicare reimbursement for the technical component of imaging services performed in a physician office setting must be capped at the lesser of the Physician Fee Schedule ("PFS") or the Hospital Outpatient Perspective Payment System ("HOPD") payment for the service.[2]

Specifically, we are requesting that the Current Procedural Terminology ("CPT") codes for transcranial doppler ("TCD") be removed from the list of codes subject to the HOPD cap because TCD does not meet the statutory definition of "imaging." The five codes we are requesting be removed are as follows:

- 93886 Transcranial Doppler study of the intracranial arteries; complete study

[1] CMS-1385-P; Medicare Program; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions. 72 Fed. Reg. 38122 (Jul. 12, 2007).

[2] Pub. L. 109-171, § 5102(b)(1)

- 93888 Transcranial Doppler study of the intracranial arteries; limited study
- 93890 Transcranial Doppler study of the intracranial arteries; vasoreactivity study
- 93892 Transcranial Doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection
- 93893 Transcranial Doppler study of the intracranial arteries; emboli detection with intravenous microbubble injection

Additionally, a CMS- commissioned study proves that the costs of certain imaging procedures within the hospital radiology cost center are systematically under-estimated by CMS in the hospital setting. Thus, we believe that it is incumbent upon the Secretary to make appropriate adjustments to the PFS imaging cap for imaging procedures known to have an understated cost-estimate in the hospital setting.

We have communicated with the Centers for Medicare and Medicaid Services ("CMS") on these issues and other related issues in the past, and we would appreciate the opportunity to address the very negative and disproportionate effect of the DRA on ultrasound services.

For over 25 years, SDMS has been committed to the advancement of diagnostic medical sonography, education of the medical community, and the delivery of high quality diagnostic services including vascular ultrasound and echocardiography. Our members are committed to providing quality, noninvasive diagnostic services to patients; including Medicare beneficiaries. We respectfully request your consideration of our perspective on these important issues.

In summary, SDMS presents comments on the following issues related to the HOPD cap for imaging services under the Proposed Rule:

- Since the DRA mandated reimbursement reductions to imaging procedures and TCD cannot be properly classified as an imaging procedure, TCD cannot lawfully be subject to these reductions.

- In the 2007 PFS Final Rule, CMS removed certain codes from the list of codes subject to the HOPD cap because they did "not involve the generation of an image."[3] The 2008 Proposed Rule contains additional language. Since TCD also does not necessarily or inherently involve the generation of a image, TCD codes must be removed from the list of codes subject to the HOPD cap. At a minimum, CMS must identify and direct its carriers to recognize a modifier that providers can use when

[3] Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee
Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; 71 Fed. Reg. 69624, 69661 (Dec. 1, 2006).

providing TCD services without any imaging service to prevent those providers' appropriate reimbursement from being inappropriately reduced by the misapplication of the DRA caps.

- A recent study proves that CMS systematically under-estimates the costs of certain imaging procedures in the radiology cost center. We urge the Secretary to, in the short term, adjust HOPD hospital outpatient rates by making appropriate adjustments to the HOPD methodology based on the consultant's cost-to-charge ratio findings for "other radiology services."

I. CMS Must Adhere to the Plain Language of the DRA, and May Not Reduce Payment for Services That Are Not Clearly Imaging Such As TCD

A. Brief Background on TCD Procedure

A paper by clinicians at the American Academy of Neurology ("AAN") described TCD as "a non-invasive ultrasonic technique that uniquely measures local blood flow velocity (speed and direction) in the proximal portions of large intracranial arteries."[4] This is known as conventional TCD, which the AAN Paper specifically states is "non-imaging."[5] We understand that there is also a procedure called Transcranial Doppler Imaging ("TCDI")[6] which does involve the generation of an image, but the image is primarily used to determine correct placement of the doppler probe, not necessarily to diagnosis any medical condition. Different equipment is used to perform TCD and TCDI. Although TCD and TCDI are referenced in the CPT system using the same codes, the services are distinct and different and CMS cannot properly apply an "imaging" payment restriction to a non-imaging service.

B. TCD Cannot Be Subject to the Reductions Mandated by § 5102(b)(1) Because TCD is Not an Imaging Procedure Within the Meaning of the DRA

§ 5102(b)(1) of the DRA defines the imaging services subject to the HOPD cap as,

> imaging and computer-assisted imaging services, including x-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and

[4] Sloan, Michael A. et. al., Background Paper to the Official AAN Assessment of TCD (2004) at 3, *available at* http://www.aan.com/professionals/practice/guidelines/tcd_tta_0404.pdf (hereinafter AAN Paper).
[5] *Id.*
[6] A study published in 2002 stated that TCDI, "uses a duplex technique to simultaneously generate a gray-scale and color image, as well as a Doppler waveform." By contrast, the same study described TCD as, "a nonimaging pulsed Doppler technique that genrate[s] a waveform." Neish, Ariane S., MD et. al, *Screening for Stroke in Sickle Cell Anemia: Comparison of Transcranial Doppler Imaging and Nonimaging US Techniques*. Radiology, 222: 709-714, 710-11 (2002).

> fluoroscopy, but excluding diagnostic and screening mammography.

Thus, the HOPD cap can only be applied to "imaging services," including the enumerated services. It is a well established principle of administrative law that the plain language of a statute must be honored by a regulatory agency.[7] Regulatory agencies do not have the discretion to deviate from the plain language of a statute. However, we respectfully submit that CMS has improperly deviated from the plain language of the DRA in this case because conventional TCD, as opposed to TCDI, involves no imaging component whatsoever.

The description of TCD provided in the introduction to the cerebrovascular arterial studies section of the CPT codebook is illustrative. It states,

> A complete transcranial Doppler (TCD) study (93886) includes ultrasound evaluation of the right and left anterior circulation territories and the posterior circulation territory (to include vertebral arteries and basilar artery). In a limited TCD study (93888) there is ultrasound evaluation of two or fewer of these territories. For TCD, ultrasound evaluation is a reasonable and concerted attempt to identify arterial signals through an acoustic window.[8]

Importantly, the term "image" or "imaging" is not used in this description. Conventional TCD typically does not involve imaging. TCD is basically a tool used to measure the speed and velocity of blood flow though arteries in the brain. Additionally, at least one study has found non-imaging TCD to be more clinically effective than TCDI. A 1994 study compared conventional (non-imaging) TCD to TCD involving imaging in assessing intracranial hemodynamics in a patient population with an average age of 65 years.[9] The researchers found transtemporal success rates of 76 percent for traditional non-imaging TCD, versus 52 percent when using imaging.

In June of this year, the Society for Vascular Ultrasound and the American Society of Neuroimaging conducted a survey of their members about transcranial studies. The members of these organizations include physicians, vascular technologists, and other healthcare professionals dedicated to the advancement of techniques used to evaluate the nervous system. Specifically, the survey sought data

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[7] "[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161, 120 S.Ct. 1291, 1315 (2000) (internal quotations and citations omitted). Accordingly, a regulatory agency "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 2781 (1984) (footnote omitted).

[8] Current Procedural Terminology Professional edition 2007, AMA at 388.

[9] Fujioka K, Gates D, Spencer M: *A comparison of Transcranial Color Doppler Imaging and Standard Static Pulsed Wave Doppler in the Assessment of Intracranial Hemodynamics.* JVT 18(1)29-35, 1994.

on how many members perform transcranial studies, and if they perform these studies with or without imaging. Significantly, the results showed that 71.2% of the respondents performed TCD studies without using imaging at all.

Further, the five TCD codes that we are asking to be removed from the HOPD cap all refer to the procedure as a "study" and do not use the word "image" or "imaging" anywhere in the description. Therefore, since conventional TCD is not an imaging service within the meaning of the DRA, it cannot be subject to the HOPD cap.

II. CMS Has Twice Determined That Certain Diagnostic Procedures Must be Excluded From the HOPD Cap Because They Are Not Imaging, and This Same Reasoning Must Be Applied to TCD Procedures

CMS received comments in response to the CY 2007 PFS Proposed Rule requesting that certain CPT codes be excluded from the HOPD cap because they contained no imaging or were predominately non-imaging in nature.[10] The Agency did not comply with all the requests to exclude codes, but did remove five codes because they "do not involve the generation of an image."[11] As discussed earlier, conventional TCD does not involve the generation of an image.

The CY 2008 Proposed Rule provides additional support for our argument why TCD codes should be excluded from the HOPD cap. CMS stated that it,

> excluded any service where the CPT code describes a procedure for which fluoroscopy, ultrasound, or another imaging modality is included in the code whether or not it is used, or for which an imaging modality is employed peripherally in the performance of the main procedure[.][12]

In the case of TCDI, the image is typically only used to determine proper placement of the doppler probe on the skull. Thus, the image is only employed peripherally to the main procedure and is not used to diagnose any medical condition. In conventional TCD, an image is not generated at all.

The Proposed Rule further states that certain codes were excluded because,

> we are unable to clearly distinguish imaging from non-imaging services because, for example, a specific procedure may or may not utilize an imaging modality, or the use of an imaging technology cannot be segregated from the performance of the main procedure.[13]

We agree with CMS' determination that that CPT codes must not be subject to the HOPD cap where it is unclear if the procedures represented by the codes are truly "imaging" within the meaning of the DRA. The codes at issue may or may not involve

[10] 71 Fed. Reg. at 69661.
[11] *Id.*
[12] 72 Fed. Reg. at 38145.
[13] *Id.*

any use of imaging. This is precisely a case where, as CMS has said, the "specific procedure may or may not use an imaging modality." As such, the codes at issue should be excluded from the cap. It would be arbitrary and capricious for CMS to exclude some services based on this rule and then not exclude the services at issue here on that same basis.

III. The DRA Imaging Cap is Distorted by HOPD Cost-Estimates Known to be Inaccurate

We also believe that it is incumbent upon the Secretary to make appropriate adjustments to the PFS imaging cap for those affected imaging procedures where costs used to set the HOPD rates are known to be understated because of the application of a single "radiology" cost-to-charge ratio ("CCR") instead of an "other radiology service" CCR. CMS recently commissioned a report from RTI International[14] (the "RTI study") that definitively shows that the costs of certain imaging procedures within the hospital radiology cost center are systematically under-estimated by CMS in the hospital setting. These under-estimated costs translate into under-calculated payment rates in the HOPD setting.

By referencing lower hospital outpatient payment rates in setting PFS payment rates on imaging procedures, the DRA cap acts to import hospital-based cost and payment data into the PFS setting. The RTI report has definitively shown, and CMS has sufficiently acknowledged that hospital-based cost data is inaccurate with respect to certain radiology procedures. And while such inaccuracies may be alleviated by other factors in the hospital setting, these inaccuracies present a pressing and immediate problem with respect to the PFS.

A. HOPD Cost-Estimates for the Radiology Cost Center

HOPD reimbursement is premised, in part, on cost estimates derived from charges that have been adjusted by a CCR. For radiology services, CMS uses a single CCR to derive costs and calculate payment. The national aggregate CCR for the radiology cost center is 0.19. However, the RTI study found that, within the radiology cost center, magnetic resonance imaging ("MRI") and computed tomography ("CT") procedures have significantly lower CCRs than all other radiology services (0.17 and 0.19, respectively). Removing MRI and CT from the radiology cost center generates a significantly higher CCR of 0.28 for the remaining radiology procedures.[15] A higher CCR indicates that non-MRI and CT radiology procedures carry lower mark-ups than MRI and CT. Thus, on a micro-level, using a single CCR for all radiology services under-estimates the costs of non-MRI and CT procedures and therefore under-pays providers for these procedures. Use of a single CCR over-estimates the costs of these procedures and therefore over-pays providers for these procedures.

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[14] RTI International, A Study of Charge Compression in Calculating DRG Relative Weights (January 2007), *available at* http://www.cms.hhs.gov/Reports/Reports/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=ascending&itemID=CMS1196854&intNumPerPage=10.

[15] *Id.* at 11.

B. Impact of Radiology Cost-Estimates on PFS Imaging Services

The impact of different CCRs within a single cost center is mitigated to some extent in the hospital setting as the over-payments and under-payments flow through to the same entity (i.e., the hospital) and, indeed, the same department (i.e., Radiology). However, the DRA cap acts to import the known under-payments for imaging services into the PFS setting. Because the DRA provision references only those HOPD payments that are *lower* than the corresponding PFS payment, the use of CCRs that are known to be inaccurate imposes unfair and arbitrary caps on PFS providers which Congress never intended in passing the DRA. Thus, the under-payments are not balanced by over-payments in the PFS setting as they potentially can be in the HOPD setting.

RTI recommended CMS take a number of short term and long term steps to alleviate the impact of differential CCRs on cost estimates. In the short term, RTI recommended that CMS adopt separate regression-based CCRs for MRI, CT, and all other procedures in the Radiology cost center.[16] Because of the potential impact on other payment methodology changes CMS is adopting in the inpatient hospital setting, CMS declined to implement this recommendation for the 2008 IPPS update.[17] However, CMS acknowledged with respect to ancillary departments such as Radiology that:

> "[Such departments] typically include both inpatient and outpatient services within the same department and only a single CCR covering both inpatient and outpatient services can be calculated from Medicare cost reports. Although we believe that applying the regression method used by RTI to only inpatient services is unlikely to have much impact for the adjustments recommended by RTI, the preferred approach would be to apply the regression method to the combined inpatient and outpatient services. The latter approach would ensure that any potential CCR adjustments in the IPPS would be consistent with the potential CCR adjustments in the HOPD. We hope to

[16] *Id.* at 16.

[17] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Final Rule with comment period. 72 Fed. Reg. 47129 (Aug. 22, 2007), to be codified at 42 C.F.R. Parts 411, 412, 413, and 489. "Because of concerns that we and some commenters continue to have about premature adoption of the regression-based CCRs without the benefit of knowing how they will interact with other DRG changes, and the arguments in the comments summarized above concerning cost and claims reporting, we have decided to finalize our proposal to not implement the four regression-based CCRs for... radiology (MRI and CT scans) for FY 2008." *Id.* at 47192. "We note that for some categories of hospitals, the impact of adopting MS-DRGs is significant. The RTI work suggests that further changes to the relative weights will also be significant and potentially result in additional redistribution of Medicare payment. In our view, the 'interactions of various components' can be determined and before we adopt potential policy options in a final rule, the public should be fully informed on the potential impacts." *Id.* at 47194.

expand their analysis to incorporate outpatient services during the coming year."[18] (Emphasis added)

We understand and appreciate CMS' hesitation to enact RTI's recommended CCR changes in the hospital-setting without fully understanding the impact such charges would have in conjunction with other changes being implemented simultaneously. And we reiterate our observation that the impact of such inaccuracies is potentially balanced in the hospital setting between overpayments and underpayments to the same entity and department. However, these same concerns are not present in the PFS setting, and we feel it is incumbent upon the Secretary to shield the PFS setting from known inaccuracies in the HOPD rate-setting mechanism for radiology services and adjust the DRA cap to account for the higher CCR of non-MRI and CT imaging procedures in the HOPD setting.

IV. Conclusion

SDMS thanks the Agency for its thoughtful consideration of our comments. We believe that the five TCD codes should be removed from the list of codes subject to the DRA cap because TCD is not an imaging procedure within the meaning of the DRA, CMS has previously exercised its authority to remove other codes from this list that do not involve imaging, and a CMS-commissioned study proves that CMS systematically under-estimates the costs of certain imaging procedures in the radiology cost center. Again, we request a meeting to discuss these issues with you in greater detail.

Respectfully submitted,

Jean Lea Spitz

Jean Lea Spitz, MPH, RDMS, FSDMS
President
Society of Diagnostic Medical Sonography

cc: Alberta Dwivedi, Centers for Medicare and Medicaid Services

[18] *Id.* at 47191.

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WILMERHALE

August 28, 2007

HAND-DELIVERED

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Herb B. Kuhn
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Washington, DC 20201

Re: **CMS–1385–P**
CODING—REDUCTION IN TC FOR IMAGING SERVICES

Dear Mr. Kuhn:

The following comments are submitted on behalf of RADI Medical Systems, Inc. ("RADI Medical"), in response to the request for comments in the July 12, 2007, proposed rule on Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38,122 (the "Proposed Rule"). These comments focus on the limitation of the technical component for imaging services under the Medicare Physician Fee Schedule.

Specifically, at least two of the services listed in Addendum F are improperly classified as "imaging procedures" and, therefore, should not be subject to the technical component fee reduction.

RADI Medical is a Leading Developer of Coronary Flow Measurement Technologies

RADI Medical is an international medical device company that develops, manufactures, and sells products within the areas of cardiology and radiology, with an emphasis on intravascular sensors for coronary assessment, hemostasis management to control bleeding after arterial punctures, and devices for improving precision and accuracy in radiology interventions.

In 1997, RADI Medical introduced the PressureWire, a semiconductor-based pressure measurement instrument mounted on a guidewire. Coronary flow reserve measurement devices such as the PressureWire provide critical information in several clinical situations: to determine the severity of arterial stenosis, including coronary and non-coronary blood flow velocity measurements and ratios such as Fractional Flow Reserve; to determine whether a lesion requires intervention; and to assess the improvement of flow after intervention.

and Other Changes to Payment Under Part B," 71 Fed. Reg. 69,624, 69,661 (Dec. 1, 2006) ("2007 Final Rule"). Commenters requested that CMS remove several "non-invasive vascular diagnostic study codes (CPT codes 93875–93990 and G0365) because they either contain no imaging or are predominately nonimaging in nature." *Id.* CMS "determined that there are certain non-invasive vascular diagnostic study codes that do not involve the generation of an image" (namely, codes 93875, 93922, 93923, 93924 and 93965); these codes were removed from the list. *Id.*

Similarly, CPT codes 93571 and 93572 "do not involve the generation of an image." As discussed above, they entail the measurement of intravascular pressure or velocity. Although such data can be displayed visually in a graph, it does not provide an image of the blood vessel being examined. Thus, these codes should be removed from the Addendum F list of imaging services, just as other non-imaging codes were removed in the 2007 Final Rule.

This Change is a Proper Subject for This Comment Period

The Proposed Rule invites comments by August 31, 2007. Proposed Rule, 72 Fed. Reg. at 38,122. CMS is proposing additional changes to the Addendum F list, *id.* at 38,145, and has stated that it "will update the list through program instructions to [its] contractors," *id.* Thus, these requested changes fall directly within the category of changes that CMS will be considering in finalizing the Proposed Rule.

Accordingly, please remove codes 93571 and 93572 from Addendum F, as they are not "imaging services" under the DRA.

Please do not hesitate to contact us if you require any further information related to this request.

Best regards,

Barry J. Hurewitz
Counsel to RADI Medical Systems, Inc.

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genzyme

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August 31, 2007

Mr. Herb Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
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Washington, DC 20201

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions [CMS-1385-P]

Dear Mr. Kuhn:

Genzyme is pleased to submit comments regarding one issue addressed in the proposed rule published July 12, 2007, the proposed establishment of a new reconsideration process relating to the basis for and the amount of payment for any new clinical diagnostic laboratory test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008.

As a global leader among biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Genzyme specializes in the research and development of new treatments for rare and debilitating genetic diseases, renal disease, transplant, orthopedic injuries and cancer. However, Genzyme's commitment to innovation continues not only with a substantial research and development program focused on these fields, but also with the development of targeted laboratory tests and diagnostics products as well.

Clinical Laboratory Issues

CMS is proposing a new reconsideration process relating to the basis for and the amount of payment for any new clinical diagnostic laboratory test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008. First, this

reconsideration process would provide a 60-day opportunity for submission of comments challenging the basis for payment, whether payment is based on "crosswalking" (if a new test is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code) or "gapfilling" (if no comparable existing test is available).

If crosswalking is used, payment for the new test is based on payments for the existing comparable test codes. If gapfilling is used, Medicare contractors initially determine payment based on various sources of information, including: (1) charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payers; and (4) charges, payment amounts, and resources required for other tests that may be comparable (although not similar enough to justify crosswalking) or otherwise relevant. After the first year, the contractor-determined amounts are used to calculate the national limitation amount (NLA) for a test for year two set at the median of the contractor-determined payment amounts. Tests are then paid at the lesser of the NLA, the local fee schedule amount or the actual charges.

If a challenge to the basis for payment is successful, it would be changed prospectively (that is, beginning on January 1 of the following year). In addition, if CMS agrees to change the basis for payment from crosswalking to gapfilling, there would be a subsequent opportunity to challenge the new Medicare contractor-calculated gapfilled payment amounts.

Second, the reconsideration process would provide a 60-day opportunity for submission of comments challenging the codes used in any crosswalking. Once again, successful challenges would be applied prospectively. Third, the reconsideration process would provide a 60-day opportunity to submit comments challenging Medicare contractor-determined gapfilled amounts (which, as noted earlier, are subsequently used to determine the NLA). In this case, the timing of the reconsideration process would allow for corrections to be made to contractor-determined gapfilled amounts prior to determining the NLA for the following year.

Individuals submitting written reconsideration comments would also be given the opportunity to present their comments orally at the next clinical laboratory public meeting (generally held in July of each year). CMS expects less than five tests per year to undergo a subsequent reconsideration process but notes that it does not have any data to estimate the impact of the process.

Genzyme Supports the Proposed Reconsideration Process

Genzyme strongly supports the reconsideration process included in the proposed rule. We believe that such a process is much needed and that it would provide a workable means for addressing stakeholder concerns and reducing the level of conflict between CMS, its contractors and the laboratory community. It would also help ensure that Medicare payment amounts for clinical laboratory tests bear a reasonable relationship to the resources required to perform these tests. We wish to commend CMS for proposing

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PhRMA

August 30, 2007

VIA HAND DELIVERY AND E-MAIL
http://www.cms.hhs.gov/eRulemaking

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Washington, DC 20201

Re: CMS-1385-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Mr. Kuhn:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the Medicare proposed physician fee schedule (MPFS)rule published by the Centers for Medicare and Medicaid Services (CMS).[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in ensuring that Medicare beneficiaries have access to the most appropriate therapies, both in physicians' offices and other outpatient and inpatient settings. Given the importance of Medicare's payment system in supporting beneficiaries' access to appropriate care, we appreciate and support CMS' ongoing efforts to identify opportunities for improving the accuracy of Average Sales Price (ASP) calculations, the resulting ASP-based payment rates, and other policies affecting Medicare Part B drugs. Our comments on the proposed rule principally focus on the section on "Bundled Price Concessions." In addition, we discuss CMS' proposal concerning the transport of drugs acquired under the Competitive Acquisition Program (CAP) and discuss physician submission of claims for administering CAP drugs.

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[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule, 72 Fed. Reg. 38122 (July 12, 2007).

Finally, we have also addressed CMS' proposal to create a process for determining changes to the list of recognized compendia used to support Medicare coverage of medically accepted indications of off-label uses of anti-cancer medicines and the section on the physician quality reporting initiative.

* * *

A. Bundled Price Concessions

CMS has proposed to revise the methodology for determining the ASP for Part B drugs by defining "bundled" arrangements and requiring that drug manufacturers allocate bundled price concessions when reporting ASPs. CMS' proposal is based in part on MedPAC's January 2007 report to Congress,[2] which recommends that "the goal should be to ensure that ASP reflects the average transaction price for drugs."[3] In that report, MedPAC presented two options for allocating bundled price concessions. On the one hand, MedPAC opined that application of the Medicaid bundling rule, with some adjustments, might be simpler to administer than another alternative; however, it also remarked that the Medicaid bundling approach "might not capture contingent discounts" and that an approach that allocated bundled discounts to reflect the contingencies in a contract would "more accurately reflect[] the transaction price of drugs" when a discount for one drug or multiple drugs is contingent in whole or in part on the purchase of another drug.[4] Nevertheless, MedPAC did not state a preference for one particular approach over the other.

As CMS points out, MedPAC advised that the reporting requirements for allocating discounts should be clear and capable of being implemented in a timely fashion by manufacturers. CMS also stated that the final MPFS rule "may reflect the final Medicaid policy on bundled sales . . . to the extent that it is appropriate for ASP and the public has had the opportunity to comment on how the final Medicaid policy for bundled sales, if appropriately adopted for ASP purposes, would affect the calculation of ASP."[5] As CMS also notes, "there is a potential for great variation in the structure of bundled arrangements and in the characteristics of products included in those arrangements."[6]

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[2] MedPac, Report to Congress, Impact of Changes in Medicare Payments for Part B Drugs (January 2007).

[3] 72 Fed. Reg. 38122, 38150 (discussing MedPAC report).

[4] Id. (discussing MedPAC report).

[5] Id. at 38151.

[6] Id.

If CMS decides to implement a new treatment of "bundled arrangements" under ASP, PhRMA supports an approach that would provide appropriately consistent treatment of bundled sales between AMP and ASP. Predictability and transparency are essential for compliance reasons and are particularly important if CMS wants to promote consistency in the treatment of bundled price concessions for purposes of ASP reporting. Furthermore, because section 1847A (d) of the Social Security Act permits substitution of 103 percent of AMP for ASP-based payment in certain instances, it is imperative that CMS finalize a definition of bundled arrangement that is transparent, preserves beneficiary access to innovative therapies and maintains economic fairness. However, as both CMS and MedPAC have noted, there are differences in AMP and ASP, how each is used and the types of products included. If CMS uses the same definition, it should carefully examine what those differences may be and how they need to be reflected in the definitions for the two programs.

Moreover, PhRMA has serious concerns about the bundling provisions in the final Medicaid rule. Whether considered in the AMP and Best Price context or in the ASP context, the Medicaid rule's bundling provisions are not clear enough to be ready for implementation. The rule's definition of a bundled sale is confusing and potentially overbroad, and key questions about how to interpret that definition and allocate discounts on bundled sales remain unresolved. CMS and manufacturers alike must strive for clarity and certainty in the rules applicable to government pricing calculations; extending the Medicaid bundling definition to the ASP context without further clarification could undermine this objective.

The definition of a bundled sale from the proposed rule is as follows:

> an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological, or other drugs or biologicals or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases) or where the resulting discounts or other price concessions are greater than those that would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. [7]

The proposed rule also states in connection with the "Basis of Payment" that:

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[7] Id. at 38226, proposed new 42 C.F.R. § 414.802.

> For the purposes of paragraph (a)(2)(i) of this section, the total value of price concessions on all drugs sold under a bundled arrangement must be allocated proportionally according to the dollar value of the units of each drug sold under the bundled arrangement.[8]

These sections are substantially the same as the final AMP rule definition of bundled sale. The new definition of a bundled sale is confusing, and could be construed to sweep in many common contractual arrangements that previously would not have required a reallocation of discounts under the Medicaid rebate agreement[9] or any ASP guidance.[10] Although PhRMA and other commenters raised these concerns in response to the proposed Medicaid rule, the language of the final rule had minimal revisions and manufacturers remain apprehensive about the ability to apply this definition in a consistent, meaningful and practical manner. Below we briefly describe examples of some of the areas where greater clarity is needed. PhRMA is also preparing separate comments to CMS on the Medicaid rule that will provide further detail about the unresolved questions associated with that rule's bundling provisions, and we would urge CMS to review those comments in evaluating ASP bundling issues since it proposes to extend the Medicaid approach to ASP calculations. Issues that require further clarification include:

- Whether a contract with multiple products, without any contingencies of any type, is considered a bundled arrangement.
- What happens when there are contingent and non-contingent drugs within the bundled arrangement?
- In a case where the products in a bundled sale have some discounts that are contingent on a purchase or performance requirement and some discounts that are not contingent on anything, whether manufacturers

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[8] Id., proposed new 42 C.F.R. § 414.804(a)(2)(iii).

[9] 42 C.F.R. § 447.502 (emphasis added.) By contrast, the prior Medicaid definition of bundled sale, contained in the Medicaid Rebate Agreement, provides that:

> "Bundled Sales" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately." (Medicaid Rebate Agreement, § I(e).)

[10] CMS should take into account that the application of this definition, particularly if there is a lack of clarity, may result in different interpretations by manufacturers and even if similarly interpreted could have varying impacts on different products, e.g., it is possible that some ASPs may increase and some may decrease, depending on the reasonable assumptions previously made.

must allocate non-contingent discounts (as well as contingent discounts) across all the products in the bundled sale arrangement or whether the incremental discount that is actually contingent on a purchase or other requirement is allocated?

As noted above, the proposed ASP rule and the Medicaid rule define a bundled arrangement as an arrangement in which the rebate, discount, or other price concessions may be conditioned upon "*some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary).*"[11] We are concerned that this language may be construed too broadly.

To reduce some of the confusion, a bundled arrangement should be defined as an arrangement regardless of physical packaging under which the rebate, discount, or other price concessions is conditioned upon the purchase of the same drug or biological, other drugs or biologicals, the achievement of market share, or inclusion or tier placement on a formulary.

There are a number of other examples of issues that may not have been considered in connection with the extension of the Medicaid bundling rule for ASP. First, what happens when a bundled arrangement includes both drug products for which ASP is reported, and drug products which are not ASP eligible? How are those discounts allocated? CMS should provide guidance in such situations.

Another example of how the Medicaid bundling rule may not work well in the ASP context arises from language in the Medicaid rule preamble indicating that CMS might expect certain volume and/or market share arrangements to be allocated across periods (e.g., if the discount in the 2nd quarter is based on market share during the 1st quarter, then the additional discount earned for meeting certain market share requirements in the 1st quarter might be allocated across both periods).[12] If applied in the ASP context, such an approach may require recalculation of the 1st Quarter ASP, because the impact of the bundling allocation would not be known until after the 1st Quarter ASP was filed. CMS should clarify whether a recalculation of the first quarter ASP is required, or whether manufacturers may use the rolling average methodology for lagged price concessions.

As the discussion above illustrates, further clarity is required before extending the new Medicaid bundling rule to ASP calculations (or, for that matter, before applying the new rule in the Medicaid context). Specifically, we request that CMS: (1) address with

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[11] 42 C.F.R. § 447.502 (emphasis added).

[12] See 72 Fed. Reg. 38122, 39159.

more specificity the meaning of certain language in the final Medicaid rule; and (2) provide more meaningful examples of what is and is not a bundled sale within the context of the final rule definition. Given the importance of achieving clarity on these issues, PhRMA also urges CMS to delay the effective date of any bundling provisions added to the ASP regulations beyond January 1, 2008, so that CMS and manufacturers have the opportunity to work through all of the outstanding questions regarding the bundling provisions in the Medicaid rule and to develop a concrete common understanding of how those bundling provisions would work in practice.

B. CAP

CMS currently requires that CAP drugs be shipped directly to the location where they will be administered. However, in the proposed rule CMS requests comments on the feasibility of "narrowing the restriction on [the physician] transporting CAP drugs where this is permitted by State law and other applicable laws and regulations."[13] PhRMA is pleased with CMS' efforts to improve the CAP program and supports the easing of restrictions on transporting CAP drugs, where permitted by State and other applicable law and regulations. Easing these restrictions and allowing patients to receive care at satellite offices or in the home could increase patient access to needed medications.

As another step to improve the CAP, we recommend that CMS consider withdrawing the current requirement that physicians electing CAP must agree to file a claim within 14 calendar days of drug administration. This requirement may no longer be critical in light of changes made by section 108 of the Medicare Improvements and Extension Act, which is Division B of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA). That section requires that payment for drugs and biologicals supplied by the CAP vendor be made upon receipt of a claim for those products. The MIEA-TRHCA also requires CMS to establish a post-payment review process to assure that payment is made for a drug only if the drug has been administered to a beneficiary. Prior to this legislation, a CAP vendor could not get paid until the physician's drug administration claim was matched with the claim for the drug submitted by the CAP vendor.

In the initial CAP final rule, CMS made clear that the requirement that the physician submit the claim for drug administration services within 14 days was designed to allow the CAP vendor to be paid in a timely manner for drugs it had shipped. As the MIEA-TRHCA has now removed the claims match predicate to the CAP vendor's payment, the underlying rationale for the 14-day bill submission requirement is no longer necessary. To make the program more workable for physician practices that do not customarily submit bills in this timeframe, we recommend that CMS withdraw this

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[13] Id. at 38158.

requirement for physicians electing the CAP program. This step should also make the program more attractive to prospective CAP physicians.

C. Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

PhRMA appreciates the proposal by CMS to create a process for determining changes to the list of recognized compendia used to support Medicare coverage of medically accepted indications of off-label uses of anticancer medicines. This step reflects the growing recognition of the need for CMS to recognize additional authoritative compendia to ensure timely patient access to beneficial, medically appropriate cancer therapies.[14]

The statutorily required compendia system serves Medicare patients well by helping them gain access to medically appropriate therapies. However, several steps could be taken – including the recognition of additional compendia – that would improve the functioning of this system.

PhRMA therefore supports CMS' initiation of an open, transparent, and timely process for recognition of additional drug compendia under the relevant provision of Medicare law, Section 1861(t)(2) of the Social Security Act. However, we are recommending several changes to the process to ensure that it facilitates timely recognition of additional authoritative compendia.

Importance of Patient Access to Off-Label Drug Uses

Introduction of compendia into the Medicare statute in 1994[15] represented a clear policy choice to cover, in appropriate circumstances, the off-label anti-cancer drug uses that physicians prescribe for their Medicare patients. The purpose of this policy was to address barriers to cancer patients' access to medically appropriate off-label uses. The importance of access to these treatments is no less important, and no less recognized,

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[14] "Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications, American Society of Clinical Oncology, *Journal of Clinical Oncology,* July 1, 2006, 24:3206-3208. National Patient Advocate Foundation comments to CMS on draft decision memo for anticancer chemotherapy for colorectal cancer (CAG-00179N), Dec. 22, 2004.

[15] *See* Social Security Act §1861(t)(2)(B) (42 U.S.C. §1395x(t)(2)(B)).

today. As the National Cancer Institute has noted, off-label uses of medicines often represent the "standard of care" for cancer patients.[16]

Current Medicare-Recognized Compendia

Of the three compendia recognized in the original 1994 Medicare statutory provision, two remain in operation today – *United States Pharmacopoeia-Drug Information* (USP-DI) and the *American Hospital Formulary Service-Drug Information* (AHFS-DI). A recent amendment[17] to this 1994 provision inserted "or its successor publications" after the reference to USP-DI to ensure that USP-DI remained a recognized compendium in light of its acquisition by Thomson Healthcare. Thus, it is important for CMS to continue to recognize the Thomson DrugPoints compendium as the successor to USP-DI.[18] We urge CMS in the final rule to publicly recognize that Thomson DrugPoints is the successor publication to USP-DI under Section 1861(t)(2).

A 2005 survey of oncologists and oncology practice managers sponsored by the Association of Community Cancer Centers, the Biotechnology Industry Organization and PhRMA reaffirms that CMS should have a high level of confidence in the compendia currently designated by statute. Of the 28 oncologists surveyed, 17 said they rely on compendia for clinical decision making. The publication cited most frequently was USP-DI, followed by AHFS-DI.[19]

Both USP-DI/Thomson and AHFS-DI use sound approaches to making decisions on changes to their compendia. They combine evaluation of available evidence with input from outside experts to ensure medically appropriate treatment options are available to patients and physicians. For these reasons, PhRMA urges CMS to retain Thomson DrugPoints and AHFS-DI as approved compendia.

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[16] "Understanding the Approval Process for New Cancer Treatments," National Cancer Institute, http://www.nci.nih.gov/clinicaltrials/learning/approval-process-for-cancer-drugs/page5, accessed August 22, 2007.

[17] Section 6001(f) of the Deficit Reduction Act of 2005, amended both Social Security Act §1861(t)(2)(B)(ii)(I) and Social Security Act §1927(g)(1)(B)(i)(II).

[18] Thomson Healthcare has owned the USP-DI compendium since 2004 and this year transitioned the publication to the DrugPoints name.

[19] John E. Feldman, MD, FACP, "Off-Label Use of Anticancer Therapies: Physician Prescribing Trends and the Impact of Payer Coverage Policy," Covance Market Access Services, September 2005.

Process for Recognition of Additional Compendia

In addition to maintaining current compendia, we urge CMS to act expeditiously to recognize additional compendia. While we appreciate the steps CMS is proposing to take in the proposed rule to establish a process for recognizing more compendia, the approach proposed by CMS may unnecessarily delay recognition of additional compendia.

Medicare has operated without the benefit of the full complement of statutorily recognized compendia for several years. In order to alleviate current concerns about the lack of a sufficient number of recognized Medicare compendia and its potential to prevent beneficiaries from gaining timely access to medically appropriate care, we recommend that CMS take two steps: (1) act on pending requests for compendia recognition as soon as possible, rather than re-initiating review of these requests and (2) take steps to improve the efficiency of the new process it proposes for reviewing additional compendia.

Since early last year, CMS has carefully evaluated at least six clinical compendia. This review included a technology assessment conducted by the Agency for Healthcare Research and Quality (AHRQ) and evaluation and input from CMS' Medicare Evidence Development and Coverage Advisory Committee (MedCAC). In light of this extensive analysis and public review and input, CMS should act before the end of 2007 on any requests for recognition that it has received from publishers of the compendia subject to the AHRQ and MedCAC review process.

In particular, we reiterate our request made in February 2006[20] for CMS to recognize the *NCCN Drugs and Biologics Compendium*™ as soon as possible. This compendium – sponsored by the National Comprehensive Cancer Network – was among those evaluated by the AHRQ and MedCAC and is an authoritative, evidence-based listing of on-label and off-label cancer drug uses.

In addition, CMS should take steps to streamline and clarify the compendia review and decision- making procedures it is proposing. For example, we suggest that CMS consider reducing the post-comment period proposed for agency review – up to 120 days. We note that in evaluating Medicare national coverage issues, CMS publishes a final decision memo not later than 60 days after close of public comments. The agency also should clarify the sequence of steps intended in connection with the 30- and 45-day periods identified for acceptance and review of external requests for compendia changes.

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[20] Written comments submitted by PhRMA to CMS and the Medicare Coverage Advisory Committee, Feb. 27, 2006.

Criteria for recognition of additional compendia

To support the goals of timely access to high-quality care, continued discovery of new medicines and new uses for existing medicines, Congress recognized the value of a plurality of decision-makers in evidence-based policy-making. Reflecting the fact that evidence that is less-than-definitive can often provide a basis for Medicare coverage – particularly in areas where evidence emerges at the forefront of medical progress – the compendia-based system provides a mechanism that combines review of evidence with other factors, such as expert input, and employs multiple review organizations.

We support CMS' goal of maintaining a robust, evidence-based compendia policy, and we support a number of the compendia characteristics identified by the agency. We agree, for example, that any approved compendium should have an extensive breadth of listings; should achieve rapid throughput for inclusion of new listings; and should be publicly transparent in evaluating drug uses.

However, we are concerned that the criteria CMS is proposing for evaluation of compendia are unduly restrictive and could hinder timely recognition of additional evidence-based drug compendia. PhRMA believes that approved compendia should be based on the best available evidence; should draw on expert input in reaching medical judgments; and should be flexible in applying evidence to recognize beneficiaries' need for access to treatments for life-threatening diseases such as cancer. We recommend that CMS reformulate the criteria as a shorter list of broader criteria. Such an approach could achieve the same goals as a more detailed list, but give compendia publishers greater flexibility in how they meet them.

Important aspects of decision-making for compendia listing include: 1) being timely, because cancer is a life-threatening disease and oncologists require up-to-date therapies, 2) being evidence-based so that the appropriate therapies are available and 3) being pragmatic, in recognition of the fact that evidence is developed incrementally. Providing for listed compendia to reflect these characteristics will help assure that access to potentially lifesaving medicines is not unnecessarily delayed.

If CMS retains the current list of criteria, PhRMA requests several clarifications to ensure that authoritative compendia are recognized by CMS in a timely manner.

Compendium definition:

The language in the CMS proposal pertaining to the definition of "compendium" may be unduly restrictive. Specifically, requiring that a compendium be "indexed by drug" rather than "indexed by disease" places form over substance. CMS should determine approved listings on the basis of thoughtful criteria that speak to medical content and scientific evidence, rather than on the form in which that content is presented. We request that the agency delete this requirement in the final rule.

Process for including additional listings:

PhRMA appreciates CMS' proposed compendia characteristics that support timely, transparent processes for including new compendia listings, and making publicly available the criteria for weighing evidence and the process for making recommendations. We recommend that CMS modify the proposed characteristic "quick throughout from application for inclusion to listing" to say "quick throughput on inclusion of new listings." This will better reflect the various procedures compendia publishers use to incorporate new evidence-based listings into their publications.

Disclosure of conflicts of interest:

PhRMA supports CMS inclusion of a characteristic to ensure that potential conflicts of interest are disclosed and appropriately managed. CMS should provide more detail on the organizational locus of the "conflicts of interest" against which an approved compendium must guard. Given the need for compendia to draw on medical experts, who may be affiliated with a diverse set of entities and who may offer varying perspectives, it would also be important to specify disclosure of a potential conflict as one means for satisfying this criterion.

D. Physician Quality Reporting Initiative

PhRMA appreciates the opportunity to comment on the proposed rule regarding the Physician Quality Reporting Initiative (PQRI). PhRMA supports the appropriate use of sound performance measures as a means to improve the quality of health care and medical outcomes for Medicare beneficiaries.

Selection of Measures

PhRMA commends CMS for the selection and use of measures in the PQRI that are well grounded in current evidence and stakeholder consensus. Use of such measures, including measures to encourage adherence, appropriate use and monitoring of medications and vaccines, can improve patient outcomes and help control health care costs. For example, a recent study found that heart failure patients who received beta-blocker therapy had treatment costs $3,959 lower than those of patients who did not take these medicines. Patients treated with beta-blockers needed fewer overnight hospital stays and had increased survival of about three-and-a-half months.[21]

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[21] PA Cowper et al., "Economic Effects of Beta-Blocker Therapy in Patients with Heart Failure," *The American Journal of Medicine* 116, no. 2 (2004): 104-111.

Other recent studies have reported better health outcomes for patients, including Medicare patients, when prescription drugs were utilized and cost offsets between prescription medicines and other health services were realized. This research indicates the importance of a measurement system that promotes appropriate utilization of medicines and vaccines. Examples of these studies:

- A 2006 study showed that when asthma treatment guidelines were followed, use of medicines to control asthma increased 47%, and, in turn, outpatient and emergency visits decreased by 56% and 91%, respectively.[22]
- An evaluation of the impact of Medigap prescription drug coverage on the use of Medicare-covered hospital and physician care found that in 2005, a $1 increase in prescription drug spending was associated with a $1.63-$2.05 reduction in Medicare Part A and Part B spending.[23]
- A 2006 study in the *New England Journal of Medicine* reports that seniors in a Medicare+Choice plan with an uncapped prescription drug benefit had higher pharmacy costs, better adherence to prescribed drug therapy, better clinical outcomes (e.g., lower blood pressure, lower cholesterol and lower blood glucose), lower hospital and emergency costs, and lower mortality than patients in the same plan with a drug benefit capped at $1,000 per year.[24]
- A 2006 study showed the increasing rates of pneumococcal vaccination will save lives and reduce health spending by reducing length of inpatient hospital stays, ventilator support and ICU days. [25]
- A 2001 study showed that influenza vaccination was associated with a significant reduction in hospitalizations and deaths among persons over 65 years old. [26]

CMS should continue to rely on up-to-date, evidence-based consensus measures that can improve longer-term outcomes like reduced hospitalization.

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[22] M Cloutier et al., "Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity," *Pediatrics*, Nov 2006; 118(5):1880-7

[23] B. Shang, "The Cost and Health Effects of Prescription Drug Coverage and Utilization in the Medicare Program," Doctoral Dissertation, Pardee RAND Graduate School, October 2005, available at www.prgs.edu.

[24] Hsu et al., "Unintended Consequences of Caps on Medicare Drug Benefits," *New England Journal of Medicine*, 1 June 2006.

[25] Fisman DN,Abrutyn E, Spaude KA, Kim A, Kirchner C, Daley J. Prior pneumoccocal vaccination is associated with reduced death, complications, and length of stay among hospitalized adults with community acquired pneumonia. *Clin Infect Dis JT:* Apr 15 2006; 42(8): 1093-1101.

[26] Nordin, et a., "Influenza Vaccine Effectiveness in Preventing Hospitalizations and Deaths in Persons 65 Years or Older in Minnesota, New York, and Oregon: Data from 3 Health Plans, " The Journal of Infectious Diseases, 2001; 184: 665-70.

Consensus-Based Organizations

Division B of the MIEA-TRHCA states that any measures selected for inclusion in 2008 must have been adopted or endorsed by a consensus-based organization, and it references two specific organizations, the National Quality Forum and the AQA (formerly the Ambulatory Care Quality Alliance). According to the National Technology Transfer and Advancement Act (NTTAA) and the Office of Management and Budget (OMB) Circular A-119, a voluntary consensus-based organization is defined by openness, balance of interest, due process, an appeals process, and consensus among stakeholders. These attributes are key to ensuring that measures submitted to the Secretary have been adequately evaluated by stakeholders who agree that the measures will provide valid, meaningful results in a feasible, scientific-based manner.

PhRMA strongly supports CMS' reliance on measures adopted or endorsed by a consensus-based organization for measures used in PQRI in 2008 and in future years.

The National Quality Forum (NQF) meets these criteria, as it was specifically designed to comply with the requirements. PhRMA supports the role of NQF as a consensus body of various stakeholders as well as its important role as an endorser of practice standards and quality measures. In principle, PhRMA supports the use of NQF-endorsed measures in the PQRI.

In principle, PhRMA also supports CMS' reliance on measures adopted by the AQA Alliance in selecting measures for PQRI in 2008. The AQA, a quality alliance primarily focused on ambulatory care, also plays an important role as an adopter of physician-level quality measures.

However, as noted by CMS, the AQA as currently structured and operated does not meet the criteria for a voluntary consensus-based organization as described by the NTTAA and OMB Circular A-119. AQA utilizes some of the practices that define a voluntary consensus-based organization: openness, balance of interest, and consensus. But, it does not have a formal due process or appeals structure. As consensus does not require unanimity, it is important that the minority positions have the opportunity to voice positions and to appeal decisions. All of the criteria defining voluntary consensus-based organizations work together and are necessary to provide a process that allows stakeholders to cooperate in their efforts on adopting consensus standards. Additionally, it is important to note that AQA is currently in the process of considering changes to its structure and operation. Depending on any changes made, AQA could be closer to satisfaction of NTTAA and OMB criteria but also potentially further away from those standards. If changes were made to exclude some stakeholders from meaningful participation, it would unlikely be that the openness, balance of interest, and consensus criteria would be met.

PhRMA strongly believes that, in order for CMS to continue relying on AQA in updating PQRI measures in 2009 and beyond, AQA must adopt changes that enable it to meet the criteria for a voluntary consensus standard organization. As a member of AQA, PhRMA is working in support of this goal. CMS should monitor AQA's ongoing reorganization process to ensure that the alliance meets these NTTAA and OMB requirements for voluntary, consensus-standard bodies. Because of the important work that AQA is tasked with performing, it is critically important that it meets all of the criteria of being a true voluntary consensus standard organization. Moreover, CMS may need to reconsider its use of AQA measures if its restructuring causes it to move further from maintaining the characteristics of a voluntary consensus standard body that were in effect in December 2006 when AQA was referenced in the MIEA-TRHCA, as noted in the preamble. Additionally CMS is not limited to using measures endorsed or adopted by NQF or AQA; if measures are selected from other organizations, those organizations should also meet the criteria for a voluntary consensus standard organization.

Measure Maintenance Practices

Quality measures are based on standard practices in health care and evaluate the health care provider's ability to provide good patient care. The standard practices in health care are continually evolving in response to changes in scientific knowledge and medical technology. To ensure that quality measures do not become a barrier to medical progress, the measures also must evolve to remain current with the standard practices and to promote proper care. Thus, measure developers must have a maintenance process established to review and update quality measures. The process should be transparent so that anyone wishing to supply data on new scientific evidence or new technologies can do so. As CMS considers further measure updates in 2009 and beyond, it should give preference to measures developed by organizations that have established sound measure maintenance and update procedures.

Suggestions for Measure Development Projects

As measures are used in PQRI, gaps in the measures portfolio will become apparent. PhRMA urges CMS to work with a voluntary consensus-based organization, such as NQF, to identify priorities in filling these measurement gaps. Measure developers can them develop the identified concepts into measures and submit the measures for endorsement by NQF. One gap in the existing base of measures concerns medication therapy management (MTM) programs. Part D plans must offer MTM services to eligible beneficiaries who have multiple chronic diseases, use multiple medications, or exceed the cost threshold. These beneficiaries can benefit from additional assistance with understanding their medications and coordination of care

through an MTM program. However, many Part D beneficiaries are not aware of these services and do not realize that they are eligible for them.[27] Measures that evaluate how often patients are referred to and use these programs could promote the use of these services. While not the full set of measures that should be considered for MTM programs, this would be a starting point in this area.

* * *

PhRMA hopes that these comments will be useful to CMS in developing the final physician fee schedule rule for 2008. We look forward to further dialogue on opportunities to enhance beneficiaries' access to care through improvements in the ASP-based payment system, and hope that CMS will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning

Ann Leopold Kaplan
Assistant General Counsel

Maya Bermingham
Assistant General Counsel

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27 Based on a survey conducted by the University of the Sciences in Philadelphia's Health Policy Institute & Advanced Concepts Institute and presented at the AMCP Annual Meeting, April 2007.

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Congress of the United States

House of Representatives

Washington, DC 20515–0304

ENERGY AND COMMERCE
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ENERGY AND AIR QUALITY
HEALTH
ENVIRONMENT AND
HAZARDOUS MATERIALS

REPUBLICAN STUDY COMMITTEE

August 30, 2007

Mr. Douglas Stoss
Counsel to the Administrator
200 Independence Avenue SW Rm 314-G
Washington, D.C. 20201-0004

VIA FASCIMILE: 202.690.6262

Dear Douglas:

Thank you for taking the time to speak with Sean Noble earlier today. As discussed, I would greatly appreciate your including the accompanying materials in your comment period.

Sincerely,

John Shadegg

John Shadegg
Congressman
Arizona 3rd District
U.S. House of Representatives

JBS:jh

EmCare
Emergency Medicine. Customer Driven.

August 30, 2007

VIA HAND DELIVERY

Herb B. Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20021

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

Dear Mr. Kuhn:

EmCare, Inc. ("EmCare") is one of the nation's leading emergency medicine physician practice management organizations. Through its emergency medicine physicians, EmCare provides emergency care in over 340 hospitals in 39 states. These hospitals range from large urban hospitals with high volume emergency departments to smaller community hospitals with lower patient volumes, all of which depend on EmCare's physicians to deliver high quality care. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule regarding *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008*, which was published in the Federal Register on July 12, 2007 (the "Proposed Rule"). 72 Fed. Reg. 38122.

I. BACKGROUND

Of primary concern to EmCare is the Proposed Rule's negative payment update of 9.9 percent for the 2008 Physician Fee Schedule ("Fee Schedule"). This unprecedented payment cut will negatively impact all physicians. However, it will place significant additional burdens on emergency physicians who provide a critical safety net for the nation's healthcare system. As the Institute of Medicine documented in a series of reports issued in June 2006, the nation's emergency medical system is severely overburdened, under-funded, and highly fragmented. In addition, unlike any other physician specialty, emergency department physicians must treat all patients 24 hours a day, seven days a week, regardless of a patient's ability to pay.

This extraordinary proposed cut to the Fee Schedule will severely limit access to care for beneficiaries who depend on care received through hospital emergency departments. According to the Centers for Disease Control and Prevention, emergency department visits increased to an all-time high of 115 million in 2005, which is five million more than in 2004. The closure of emergency departments combined with the overall increase in visits has resulted in a 31 percent increase in visits per emergency department since 1995.

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The negative payment update for 2008 is further compounded by the 2006 Fee Schedule payment freeze and minimal Fee Schedule payment updates or reductions since 2002. We strongly recommend that CMS to take these critical considerations into account before adopting the final Fee Schedule rule for 2008.

II. IMPACT

After seven year of payment reductions, zero updates or minimal updates, emergency department physicians are now faced with the largest payment reduction ever under the Fee Schedule. As we have commented in the past, we urge CMS to work with Congress and the Administration to repeal the sustainable growth rate ("SGR") methodology under the Fee Schedule with a formula that recognizes reasonable inflationary costs. As recommended by the Medicare Payment Advisory Commission ("MedPAC") in its March 1, 2007 report on alternatives to the SGR system, it is incumbent to rescind the SGR system to ensure that physicians do not continue to experience negative payment updates under the Fee Schedule.

III. TRHCA – SECTION 101(d)

While we recognize that Congress must act to reform the current Fee Schedule methodology, CMS has certain authority under the Fee Schedule to make other changes that would help ameliorate the impact of the negative payment updates. To that end, CMS has repeatedly refused to remove payment for prescription drugs administered in physician offices from the pending pool that is subject to the SGR spending constraints.

This year, the Proposed Rule would remove the $1.35 billion that Congress set aside in the Tax Relief and Health Care Act of 2006 ("TRHCA") and use it for the Physician Quality Reporting Initiative ("PQRI") rather than as an offset to the SGR which would benefit all physicians. As does MedPAC and other groups, we strongly recommend that CMS apply the TRHCA funds to the Fee Schedule to reduce the scheduled 9.9 percent update. We believe that CMS has the means to overcome the "legal and operational problems" with this approach to use these funds to offset a portion of the cost of replacing the SGR. In our view, this will have a much more positive impact on all physicians than the PQRI, whose value has not yet been proven.

This approach would be particularly beneficial for emergency department physicians who provide a disproportionate amount of uncompensated care compared to other physician specialties, yet do not have the same ability to limit their financial losses as other physician groups. According to the latest Centers for Disease Control and Prevention survey, of the 115 million patient seen in an emergency department in 2005, nearly 17 million visits represented Medicare patients and 51 out of every 100 Medicare patients had at least one visit to an emergency department that year. Further reductions under the Fee Schedule will likely mean that even more patients will seek basic care in emergency departments as physicians seek to limit their financial losses.

IV. BUDGET NEUTRALITY ADJUSTMENT

Under the Proposed Rule, CMS has continued its 2007 policy, which uses the physician work relative values as a mechanism to maintain budget neutrality. From 1998 to 2006, CMS met the statutory budget neutrality requirements by adjusting the Medicare conversion factor. In doing so, CMS specifically rejected adjustments to the work relative values as "undesirable policy." Now, CMS proposes to continue the budget neutrality adjustment to the work values for 2008 and, in fact, to increase it from the 10.1 percent in 2007 to 11.8 percent for 2008. This means a nearly negative 12 percent adjustment to the 2008 work values in addition to the 9.9 percent payment cut. Such a move will result in an overall 2 percent cut for emergency physicians, thereby substantially obviating the increases to the primary care work values for evaluation and management services made in last year's rule updating the work value units. The conversion factor – and not the work relative values – is the most appropriate place to adjust for budget neutrality and we urge CMS to follow past precedent by using the conversion factor.

EmCare appreciates the opportunity to submit its comments and welcomes the opportunity to discuss them with you and your staff. Should you have any questions about our comments, please do not hesitate to contact me at (303) 495-1214.

Sincerely,

Steven G. Murphy, Senior Vice President
Government and National Services

675-1

AUG 31 2007

From: Mark Fritsch
To: Mark Fritsch;
Subject: STOP POD LABS NOW !!! - Phase II
Date: Friday, August 03, 2007 5:08:29 PM

Message sent to the following recipients:
Secretary Leavitt
Administrator Norwalk
Message text follows:

Mark Fritsch
219 E. Lake Shore Dr.
Chicago, IL 60611-1352

August 3, 2007

[recipient address was inserted here]

Dear [recipient name was inserted here],

As a member of our nation's laboratory medicine team, I want to commend the Centers for Medicare & Medicaid Services (CMS) on its recently published proposed physician fee schedule. Specifically, I strongly support the CMS proposal to amend the physician self-referral rules regarding reimbursement for laboratory services [72 FR 38179-38181].

The proposed imposition of anti-markup provisions on the technical and professional component of pathology services would hopefully put an end to abusive billing practices by so-called "pod" or "condo" laboratories which were inadvertently created when the Agency amended its in-office ancillary exceptions rules in 2005, leading to a loophole in the rule. The rule would effectively close that loophole, which has enabled the proliferation of pod labs, allowing health care providers to profit from the laboratory services they order.

The U.S. Department of Health and Human Services Office of Inspector General has stated that these types of arrangements, which may violate federal anti-kickback statutes, "can distort medical decision-making, cause over-utilization, increase costs and result in unfair competition" and "can also adversely affect the quality of patient care." Such practices, "may lead to patient and program abuse in the form of higher utilization of services and result in higher costs to the Medicare

program."

Â

I urge you to implement a strict anti-markup requirements on laboratory services immediately. We request that this rule go into effect on January 1, 2008. Failure to establish stringent regulations as soon as possible will only further hurt the practice of laboratory medicine and ultimately the patients we seek to serve.

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

Respectfully,

Sincerely,

Mark Fritsch, M.D.
312 255-8045

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DSA Leonard H. Goldberg, M.D., F.R.C.P. • Paul M. Friedman, M.D.
Arash Kimyai-Asadi, M.D. • Ming H. Jih, M.D.
Mohs Surgery • Dermatologic Surgery • Laser Surgery • Liposuction
DermSurgery Associates, P.A. • DSA Surgery Center, Inc.
7515 Main, Suite 240 • Houston, Texas 77030 • Phone 713-791-9966 • Fax 713-791-9927

Tuesday, August 28, 2007

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

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

Dear Acting Administrator Kuhn:

We are submitting comment to you regarding the 2008 Medicare Fee Schedule: Proposed Rule and the explicit withdrawal of the multiple procedure reduction rule (MPRR) exemption for Mohs surgical procedures. We appreciate this opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule. Along with our comments, we are submitting an electronic file containing letters and petitions from approximately 1000 people who share our concerns. These letters illustrate the impact that the proposed changes would have.

The Mohs surgery codes have had a longstanding and appropriate exemption from the Multiple Procedure Reduction Rule since 1991. This proposed CMS action/decision takes away the specific exemption accorded to the Mohs Micrographic surgery codes in the 1992 Medicare Physician Fee Schedule and maintained by CMS within all subsequent fee schedules since 1992 (see Federal Register, Vol. 56, No. 227, Nov 25, 1991, pgs 59541 and 59602). We believe that this CMS action will unduly impact not only those Medicare beneficiaries who have or will be diagnosed with skin cancer but also those surgical dermatologists who provide these services.

This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services'(CMS) own determination that the Mohs codes are and should be exempt from the Multiple Procedure Reduction Rule (MPRR). CMS agreed at that time that the Mohs procedures "are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be paid separately with no multiple surgery reductions." This conclusion is still correct and applicable today. Furthermore, because of the dual components of surgery and pathology associated with each Mohs surgery procedure, there is no gain in efficiencies when multiple, separate procedures are performed on the same date, making application of the reduction inappropriate.

We also believe this proposal is contrary to the AMA CPT/AMA RUC Modifier -51 Workgroup proposed criteria regarding procedures qualifying for exemption from this rule.

We believe this proposal will negatively impact Medicare beneficiaries' access to timely and quality care and application of the Multiple Procedure Reduction Rule will not likely generate significant cost savings and may paradoxically increase the cost of providing care to these patients.

We are concerned that the Proposed Rule reflects an alteration in the traditional role of the RUC in CMS policy formulation. At the request of CMS in 2005, the American Academy of Dermatology, the American College of Mohs Surgery, the American Society for Dermatologic Surgery, and the American Society for Mohs Surgery, worked through the AMA CPT/AMA RUC process to develop site-specific codes for the Mohs procedure. Two new site-specific codes, 17311 and 17313, were accepted by AMA CPT/AMA RUC to differentiate Mohs excision of cancers in different anatomic areas. However, there has been no change in the clinical performance of the procedure or in the separate and distinct nature of the Mohs procedure from any other procedure which might be performed on the same day. We believe the revised code descriptors to differentiate anatomic sites, in the absence of a change in work associated with the procedure, does not support the change in the multiple procedure exemption status of the new Mohs codes.

As noted in the Proposed Rule text, "RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately." This assumption is correct. Mohs micrographic surgery uniquely includes two distinct components, surgery and pathology, both of which are performed wholly by the Mohs surgeon, with the pathology component comprising half of the service. The nature of Mohs surgery requires that the entire procedure, including processing and interpretation of the histopathology slides, be completed before any consideration is given to the excision of additional tissue or to repair of the resulting defect.

The physician intra-service work for 17311 was acknowledged by RUC to be 80% of the total physician work of the procedure (78% for 17313), including both the surgery and pathology. Even when two Mohs excisions are performed for a patient on the same date, there is no overlap in work for treatment of the second site, which requires all the same components of excision and tissue processing/interpretation as the first site. There are marginal gains in "efficiencies" when treating more than one tumor at the same time. Likewise, there is no overlap between a Mohs procedure to remove a skin cancer and a subsequent, separate repair procedure that might be used to address the skin defect created by the Mohs procedure. The time required for the pathology component of the procedure results in an onsite waiting period for the patient. If a repair is performed, it requires return to an operating room, repositioning, re-anesthetizing, re-prepping, etc. It is performed with new instrumentation. It is not typically performed in the same room as the prior Mohs procedure. There is no overlap of work or practice expense for clinical labor time, medical supplies, or medical equipment between the Mohs procedure and a repair procedure.

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

The AMA CPT/AMA RUC Modifier -51 Workgroup proposed seven criteria to be used in determining whether a procedure code should be included on the Modifier -51 Multiple Procedure Reduction Rule Exemption List. Considering the arguments we have presented above, the Mohs codes meet three of the AMA CPT/AMA RUC Modifier -51 Workgroup criteria for procedures qualifying for MPRR exemption:

- Mohs micrographic surgery was declared exempt by CMS in 1991 and remained so through 2007. The procedure remains unchanged.

- The Mohs codes have very little pre- and post-service time and have a limited number of visits. As above, 78 - 80% of the total physician work of the Mohs codes is intra-service work. The pre- and post-service time for the Mohs codes is less on a percentage basis than that of the other codes remaining on the list of exemptions. The Mohs codes also have zero post-op visits embedded in the value of the codes.

- The Mohs codes are typically adjunctive to a repair service but are often performed as stand-alone procedures, in cases when wounds are allowed to heal secondarily. Second-intention healing is typical for tumors in certain areas, especially the medial canthus, conchal bowl, and posterior ear, among others.

Meeting three of the seven AMA CPT/AMA RUC Modifier -51 Workgroup criteria for exemption, any one of which merits consideration for inclusion on the list, appropriately justifies retaining the longstanding MPRR exempt status of the Mohs codes.

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

We feel strongly that removing the exempt status of the Mohs codes will negatively impact Medicare beneficiaries' access to timely and quality care. Currently, 30% of patients undergoing Mohs micrographic surgery in our practice have more than one tumor treated with Mohs on the same day. Application of the proposed rule to a second tumor treated on the same day will mean that reimbursement for the second procedure does not cover the cost of providing the service. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors.

In addition, patients who are immuno-suppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors. Many of these patients are also Medicare beneficiaries. These immuno-suppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma.

While application of the MPRR is perhaps intended as a cost-saving measure, application of this rule will not likely generate significant cost savings and may paradoxically increase cost of providing care to these patients. When Mohs procedures are performed with higher-valued

repairs such as flaps or grafts, application of the MPRR to the Mohs codes will result in reduced reimbursement for Mohs that doesn't cover the cost of the procedure. Likewise, for lower-valued repairs such as intermediate and complex layered closures, which are the most commonly performed repairs, reduced reimbursement will not cover the cost of the repair. This will force the Mohs surgeon to refer the patient to another specialist, such as a plastic surgeon or ocular-plastic surgeon, increasing the cost by use of anesthesia and OR services.

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

We would happily discuss our concerns in support of a continued exemption.

Respectfully,

Leonard Goldberg, M.D., F.R.C.P.

Paul Friedman, M.D.

Arash Kimyai-Asadi, M.D.

cc: American Academy of Dermatology (AAD)
American College of Mohs Surgery (ACMS)

Enclosure: CD with 964 Electronic Letters of concern

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SKIN SURGERY CENTER
SKIN CANCER SPECIALISTS

PETER B. ODLAND, MD
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SARAH B. PATTON, PA-C

August 29, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D C 20201

Fax number: 202 690.6262

Re: CMS 1385-P: 208 Medicare Fee Schedule
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

As a Mohs surgeon, I am deeply concerned regarding this proposed rule for multiple reasons. I appreciate this opportunity to offer comment on section II.E 2)P-122) of the 2008 Medicare Fee Schedule Proposed Rule

1 This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services' (CMS) own determination that the Mohs codes are and should be exempt from the Multiple Procedure Reduction Rule (MPRR)

2 Furthermore, because of the dual components of surgery and pathology associated with each Mohs surgery procedure, there is no gain in efficiencies when multiple, separate procedures are performed on the same date, making application of the reduction inappropriate

3. This proposal is contrary to the Relative Value Update Committee's (RUC) own policy regarding procedures qualifying for exemption from this rule

4. This proposal will negatively impact Medicare beneficiaries' access to timely and quality care

5. Application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care t these patients.

6. Finally, I am concerned that the Proposed Rule reflects an alteration in the traditional role of the RUC in CMS policy formulation.

First, the Mohs surgery codes have had a longstanding and appropriate exemption from the Multiple Procedure Reduction Rule since 1991 In its Final Rule for the 1992 Medicare Fee Schedule (Federal Register November 25, 1991, volume 56, #227, p 59602), the CMS (then HCFA) included specific comment regarding Mohs micrographic surgery. CMS agreed at that time that the Mohs procedures "are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of

procedures....They will be paid separately with no multiple surgery reductions " This conclusion is still correct and applicable today

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

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

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

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

Third, the RUC -51 Research Subcommittee identified seven criteria to determine whether a code should be included on the Modifier -51 Exemption List; 1- RUC rationale supporting placement on the list; 2- Exemption from the CMS Multiple Surgery Reduction; 33 Limited amount of pre- and post-service time and limited number of visits; 4- No add-on codes; 5- No codes where payment logic would not reduce payment when performed with another procedure; 6- Service is typically adjunctive to another service but can be performed as a stand-alone procedure; and 7- Service is performed with multiple other procedures that are so extensive that it is difficult to maintain a "Report With" list typically included in CPT

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

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

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

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

Fourth, removing the exempt status of the Mohs codes will negatively impact Medicare beneficiaries' access to timely and quality care. Currently, 10% of patients undergoing Mohs micrographic surgery have more than one tumor treated with Mohs on the same day. Application of the proposed rule to a second tumor treated on the same day will mean that reimbursement for the second procedure does not cover the cost of providing the service. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors. Additionally, patients who are immunosuppressed from organ transplantation, cancer chemotherapy, infection, or other diseases are at significantly higher risk for skin cancers and often have multiple tumors; many of these patients are also Medicare beneficiaries. These immunosuppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma.

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

Finally, we support the RUC process and recognize the value it brings to the annual physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this, the RUC defied the

predictions of critics who claimed that agreement would not be possible among the various stakeholders. The RUC and CMS also prevailed against the legal challenge that the RUC amounted to a Federal Advisor Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple surgical reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do not strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process

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

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

Sincerely,

Peter B. Odland, M.D

skin cancer
surgery center

David M Kao, MD, PC
Physician and Surgeon

August 30, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201

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

Dear Acting Administrator Kuhn:

On July 1st of this year, we were notified by CMS of a planned change in payment policy that in my opinion has the potential to negatively impact the care of my patients and could add significant cost to an already stressed healthcare budget. This planned change would remove Mohs surgery from a longstanding exemption from the multiple surgery reduction rule (MSRR, indicated by CPT modifier -51). This is a departure from a longstanding exemption agreed to by CMS and virtually all private insurance carriers since 1991. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; such a decrease in reimbursement would not cover the cost of providing the service.

If this proposed change is enacted, I will no longer be able to provide the same kind of high-quality, cost-effective services for my patients in need. I will be forced to change the way I deliver care in order to cover my costs of providing this service. The following paragraphs attempt to explain the rationale behind the need to exempt Mohs surgery from the multiple surgery reduction rule and the consequences of not doing so.

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

are treated on the same patient on the same day. Therefore, Mohs surgery codes are exempt from the use of modifier 51."

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

The consequence of applying the multiple surgery reduction rule to the Mohs codes would be a reimbursement reduction to a value less than the cost of providing the service. Therefore, I will no longer be able to perform more than one Mohs procedure on any patient on a single day. Multiple tumors are commonly diagnosed on one visit, occurring in 20% of my referral practice population. Treatment of only one tumor per day will inconvenience many patients and their friends and families who accompany them for treatment. It will also inconvenience employers when workers are absent from work more frequently for multiple treatments. More importantly, delays in treatment will further increase risk for high-risk patients such as organ transplant patients with multiple squamous cell carcinomas, and for patients with syndromes such as basal cell nevus syndrome. In addition to its application to multiple cancers treated on the same day, the MSRR would apply to repairs performed on the same day as Mohs surgery. According to this new proposal, when Mohs surgery is reimbursed less than a reconstructive procedure on the same day, even the first Mohs code will be subject to the multiple surgery reduction rule. Since costs would not be covered, this may require patients to have their Mohs surgery and their reconstruction done on separate days, or to be referred to other physicians for reconstruction, usually plastic, facial plastic, or oculoplastic surgeons, who work primarily in hospitals or ambulatory care centers where costs of care are higher. The result would be that healthcare costs will be higher than they are under the current policy of payment.

It is in my honest opinion that if this change in the Multiple Procedure Payment Reduction for Mohs Surgery is enacted that it will have a hugely significant impact on the way I can deliver care to my patients. I pride myself on being able to provide exceptional care without compromise to my patients, many of whom are elderly, but my hands will be tied if this change occurs. I will not be able to cover my expenses for the procedures I currently do on a daily basis. Many patients will have to return to my office approximately 3-5 days in a row to complete multiple Mohs procedures including repair/reconstruction when in fact it can actually be done in 1 day. I besiege you to reconsider this disastrous proposal and keep the MSRR excluded from Mohs Surgery.

Respectively,

David M. Kao, M.D.

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Sutter Medical Group

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Dermatology

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August 30, 2007

The Honorable Herbert Kuhn, Acting Administrator

Centers for Medicare and Medicaid Services, Dept. of Health and Human Services

Washington, DC 20201

RE: CMS 1385-P; 2008 MPPR for Mohs Surgery

My patients and I wanted to make you aware of a planned change in Medicare reimbursement policy by the Centers for Medicare and Medicaid Services (CMS) which will have a significant negative impact on the healthcare of my patients and potentially add unnecessary cost to the delivery of health care in this country. The undersigned patients concur with this assessment.

You are probably aware that over a million Americans per year are diagnosed with skin cancer, and it is especially common in Californians. Mohs micrographic surgery is a common way of treating some of these cancers and is considered to be the "gold standard" among treatments for skin cancer, allowing the physician to examine virtually 100% of the cancer margin at the time of surgery to insure complete removal of the tissue, while sparing as much uninvolved skin as possible. It also provides the patient with the highest cure rate of any treatment for skin cancer. Mohs surgery is an outpatient procedure that utilizes onsite laboratory analysis of excised tissue while the patient waits for the result.

We were notified in July of this year, that CMS was planning a change in payment policy that in our opinion has the potential to negatively impact the care of our patients, and would add significant cost to the already stressed healthcare budget. The change would remove Mohs surgery from the longstanding exemption from the multiple surgery reduction rule. This is a departure from a longstanding exemption agreed to by CMS and virtually all private insurance carriers since 1991. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; such a decrease in reimbursement would not cover the cost of providing the service.

If this proposed change is enacted, we will no longer be able to provide the same kind of high-quality, cost-effective services for our patients. We will be forced to change the way we deliver care in order to cover our costs of providing this service.

Sincerely,

Ann F. Haas, MD

PETITION TO PREVENT THE REMOVAL OF MOHS SURGERY CODES FROM THE EXEMPTION LIST FOR THE MULTIPLE PROCEDURE REDUCTION RULE

I, the undersigned, am a resident of California (NAME of STATE), I believe that the proposed removal of Mohs surgery from a list of procedures exempt from the multiple procedure reduction rule will restrict physicians from providing skin cancer patients who rely on Medicare with the high standard of care which all patients deserve and expect.

Therefore, I request that you, my legislative representatives, prevent this proposed change as it will only prove harmful to Medicare patients.

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PETITION TO PREVENT THE REMOVAL OF MOHS SURGERY CODES FROM THE EXEMPTION LIST FOR THE MULTIPLE PROCEDURE REDUCTION RULE

I, the undersigned, am a resident of California (NAME of STATE), I believe that the proposed removal of Mohs surgery from a list of procedures exempt from the multiple procedure reduction rule will restrict physicians from providing skin cancer patients who rely on Medicare with the high standard of care which all patients deserve and expect.

Therefore, I request that you, my legislative representatives, prevent this proposed change as it will only prove harmful to Medicare patients.

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PETITION TO PREVENT THE REMOVAL OF MOHS SURGERY CODES FROM THE EXEMPTION LIST FOR THE MULTIPLE PROCEDURE REDUCTION RULE

I, the undersigned, am a resident of California (NAME of STATE), I believe that the proposed removal of Mohs surgery from a list of procedures exempt from the multiple procedure reduction rule will restrict physicians from providing skin cancer patients who rely on Medicare with the high standard of care which all patients deserve and expect.

Therefore, I request that you, my legislative representatives, prevent this proposed change as it will only prove harmful to Medicare patients.

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PETITION TO PREVENT THE REMOVAL OF MOHS SURGERY CODES FROM THE EXEMPTION LIST FOR THE MULTIPLE PROCEDURE REDUCTION RULE

I, the undersigned, am a resident of California (NAME of STATE), I believe that the proposed removal of Mohs surgery from a list of procedures exempt from the multiple procedure reduction rule will restrict physicians from providing skin cancer patients who rely on Medicare with the high standard of care which all patients deserve and expect.

Therefore, I request that you, my legislative representatives, prevent this proposed change as it will only prove harmful to Medicare patients.

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PETITION TO PREVENT THE REMOVAL OF MOHS SURGERY CODES FROM THE EXEMPTION LIST FOR THE MULTIPLE PROCEDURE REDUCTION RULE

I, the undersigned, am a resident of California (NAME of STATE), I believe that the proposed removal of Mohs surgery from a list of procedures exempt from the multiple procedure reduction rule will restrict physicians from providing skin cancer patients who rely on Medicare with the high standard of care which all patients deserve and expect.

Therefore, I request that you, my legislative representatives, prevent this proposed change as it will only prove harmful to Medicare patients.

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PETITION TO PREVENT THE REMOVAL OF MOHS SURGERY CODES FROM THE EXEMPTION LIST FOR THE MULTIPLE PROCEDURE REDUCTION RULE

I, the undersigned, am a resident of California (NAME of STATE), I believe that the proposed removal of Mohs surgery from a list of procedures exempt from the multiple procedure reduction rule will restrict physicians from providing skin cancer patients who rely on Medicare with the high standard of care which all patients deserve and expect.

Therefore, I request that you, my legislative representatives, prevent this proposed change as it will only prove harmful to Medicare patients.

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Therefore, I request that you, my legislative representatives, prevent this proposed change as it will only prove harmful to Medicare patients.

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680

Jon C. Starr, M.D.

Dermatologic
and
Mohs Micrographic Surgery

August 30, 2007

To: CMS

Re: CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Dear Persons:

I would like to express my concerns about the planned change of applying the multiple surgery reduction rule to the Mohs surgery procedure codes. I think the proposed change could adversely affect the care of patients throughout the United States. That is, changing this rule would result in reducing the efficiency of treating skin cancer and limiting patient's access to this valuable resource. I would like to note the following history:

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

However, as of July 1st of this year, we were notified by CMS of a planned change in payment policy that in our opinion has the potential to negatively impact the care of our patients and could add significant cost to an already stressed healthcare budget. This planned change would remove Mohs surgery from a longstanding exemption from the multiple surgery reduction rule (MSRR, indicated by CPT modifier -51). This is a departure from a longstanding exemption agreed to by CMS and virtually all private insurance carriers since 1991. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; such a decrease in reimbursement would not cover the cost of providing the service.

If this proposed change is enacted, we will no longer be able to provide the same kind of high-quality, cost-effective services for our patients in need. We will be forced to change the way we deliver care in order to cover our costs of providing this service. The following paragraphs attempt to explain the rationale behind the need to exempt Mohs surgery from the multiple surgery reduction rule and the consequences of not doing so.

ADJUNCT CLINICAL ASSISTANT FACULTY, STANFORD MEDICAL SCHOO...

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

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

I do understand that there are surgical situations where the MSRR is appropriate – e.g. removing a patient's appendix while performing some other intraabdominal procedure. In the case of skin cancer treatment, however, those efficiencies are not realized. Each procedure is a separate and distinct procedure requiring a unique sterile setup, individual anesthesia, each specimen is processed individually and examined separately, and the closure is unique and distinct from other Mohs surgeries that might have been performed on that day.

The consequence of applying the multiple surgery reduction rule to the Mohs codes would be a reimbursement reduction to a value less than the cost of providing the service. Therefore I will no longer be able to perform more than one Mohs procedure on any patient on a single day. Multiple tumors are commonly diagnosed on one visit, occurring in 10% of my referral practice population. Treatment of only one tumor per day will inconvenience many patients and their friends and families who accompany them for treatment. It will also inconvenience employers when workers are absent from work more frequently for multiple treatments. I would prefer not to put our patients in this position and hope that you agree. Applying the multiple sugery reduction rule will only reduce the efficiency of caring for these patients.

I am always available to you should you have further questions for me on this matter. Please feel free to write or call me at your convenience.

Sincerely,

Jon C. Starr, M.D.

RALPH A. MASSEY,M.D., F.A.A.D.
ASSISTANT CLINICAL PROFESSOR UCLA SCHOOL OF MEDICINE

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August 29th, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services

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

Dear Mr Kuhn,

I am very concerned about the negative impact the proposed rule changes will have on patients requiring Mohs micrographic surgery for treatment of their skin cancers. Mohs surgery is a method of skin cancer removal that is separate in every way from any subsequent reconstruction of the resulting defect. If the proposed changes are implemented the practical result will be that patient will have to make two separate visits for the treatment of their skin cancer and then a subsequent repair, and will need to repeat this for each skin cancer that they have.

Presently many Mohs surgeons limit the number of Mohs surgery patients they treat in one day to allow time in the second half of the day to perform reconstructive surgery the same day as a convenience for their patients. However if the present rule changes are implemented the surgeon will be effectively paying out of pocket if he does this, as his overhead will be more than the reimbursement (after the 50% reduction).

I believe many Mohs surgeons will simply fill their day with more Mohs cases on one day and set aside the next day just for repairs. This way the patients get complete and appropriate treatment, the surgeons' schedule is more predictable and easier and the surgeon gets paid in full for all he does. However the patients will have to return to the office for two visits as apposed to having both treatments (the Mohs surgery and the reconstruction) performed on the same day.

Apart from the above the fact is that the rule change really makes no sense what so ever. There is no shared work between the Mohs surgery and any future repair, indeed most of the work of the Mohs surgeon is the pathologic interpretation of the tissue slides. Indeed the repair of a defect created during Mohs surgery does not have to be performed by the same surgeon or on the same day as the Mohs surgery. At present this is often done simply as a convenience for the patients.

Please be sensitive to the reality of what a huge impact this will have on the many elderly patients who are the most at risk for the kinds of skin cancer that would require Mohs surgery, and often have to travel some distance to find an appropriately specialized surgeon.

I hope you will consider the above and will not just implement a change that you think may save Medicare a few dollars, even if that change makes no sense in reality.

Ralph A. Massey, MD

RALPH A. MASSEY, M.D., F.A.A.D.

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☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

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Alan Spinowitz, M.D.
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August 28,2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201
Fax:202-690-6262

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

Dear Acting Administrator Kuhn:

I appreciate this opportunity to comment on the proposed elimination of the multiple surgery exemption for Mohs Surgery.

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

There is no overlap between a Mohs procedure to remove a skin cancer and a subsequent, separate repair procedure that might be used to address the skin defect created by the Mohs procedure. The time required for the pathology component of the procedure results in an onsite waiting period for the patient. If a repair is performed, it requires return to an operation room, repositioning, re-anesthetizing, re-prepping, etc. It is performed with new instrumentation. There is no overlap of work or practice expense for clinical labor time, medical supplies, or medical equipment between the Mohs procedure and a repair procedure. Therefore, it is inappropriate to subject 17311 and 17313 to the multiple procedure reduction rule for repairs performed on the same day as the Mohs procedure or for multiple Mohs lesion excisions performed on the same day.

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

Respectfully,

Alan Spinowitz, M.D.

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August 29, 2007

Thomas W. McGovern, MD
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The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201
FAX (202) 690-6262

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

Dear Acting Administrator Kuhn:

As the only fellowship-trained Mohs surgeon within a 90-minute to two-hour drive in any direction from Fort Wayne, I am profoundly concerned about the proposed change to the Multiple Procedure Payment Reduction for Mohs Surgery. I appreciate the opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

The proposal reverses a 16 year-old policy of the Centers for Medicare and Medicaid Services' (CMS) that the Mohs codes should be exempt from the Multiple Procedure Reduction Rule (MPRR). Because Mohs surgery includes both surgery and pathology services, no efficiency is gained by performing multiple procedures on each patient. The proposed rule contradicts the Relative Value Update Committee's (RUC) policy regarding procedures that qualify for exemption from the MPRR.

This proposal will directly impact my patients' access to care, since I will need to reduce surgery to one cancer per patient per day. I cannot cover overhead with a 50% reduction in reimbursement. About 20% of my patients have more than one cancer treated at a time, and many of them travel over an hour to see me or are driven by transportation service providers from nursing homes. I will more likely send patients to other surgeons for repairs after Mohs surgery, since I will not be adequately reimbursed for that aspect of my patients' care. During the past several weeks, many of my Medicare patients have expressed their extreme disappointment with the proposed rule.

On behalf of my patients, I ask that you reconsider this proposed rule and provide a permanent exemption for Mohs codes 17311 and 17313.

Thank you for your consideration.

Sincerely,

Thomas W. McGovern

Thomas W. McGovern, MD
Fellow, American College of Mohs Surgery
Fellow, American Academy of Dermatology

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SKIN SURGERY CENTER
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August 29, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Re: CMS 1385-P: 2008 Medicare Fee Schedule, Section II.E.2
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

As a Mohs surgeon I am submitting comment to you on the 2008 Medicare Fee Schedule: Proposed Rule regarding the explicit withdrawal of the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures. I appreciate this opportunity to offer comment on Section II.E.2 (P-122) of the 2008 Medicare Feel Schedule Proposed Rule.

This proposed CMS action takes away the specific exemption accorded to the Mohs Micrographic surgery codes in the 1992 Medicare Physician Fee Schedule and maintained by CMS within all subsequent fee schedules since 1992. I believe that his CMS action will unduly impact not only those Medicare beneficiaries who have or will be diagnosed with skin cancer, but also those surgical dermatologists who provide these services. I also believe that the NPRM fails to articulate adequate justification for this action.

First, CMS states that "the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list." This appears to be both irrelevant and factually incorrect. That the removal of these codes from the exempt list is presented in an NPRM is evidence that CMS recognizes the payment policy formulation responsibility lies with the agency and not CPT. I also do not believe that the CPT Editorial Panel explicitly took this action as stated.

Second, the NPRM correctly states that 1) the RUC valued each code carefully, 2) the RUC assumed each code is a separate procedure, and 3) the RUC did not consider efficiencies when the procedures are performed on the same day. The NPRM then relies on these statements to justify changing the existing longstanding CMS policy. While these three factors are correct, they do not justify the NPRM's stated conclusion that these codes should not be exempt from the multiple procedure reduction rule. It is no surprise that the RUC did not consider efficiencies since CMS has long recognized that there are no efficiencies inherent in these procedures when performed together. Therefore, factors cited as the reason for removal from the exempt list are, in reality, the very same factors that CMS has previously considered and recognized to justify exemption. Simply stating the factors does not provide any insight into the reasoning why a change is contemplated. The NPRM does not provide any explanation for this proposed change and certainly does not justify the reversal of a previously well-considered and long-standing CMS payment policy. CMS should defer from making this change and any proposal for change in the future should be based on sound rationale and factual data.

CMS agreed in the 1992 Medicare Fee Schedule: Final Rule that these "are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures... They will be paid separately with no multiple surgery reductions." This conclusion is still correct and applicable today.

We believe this proposal will negatively impact Medicare beneficiaries' access to timely and quality care and application of the Multiple Procedure Reduction Rule will not likely generate significant cost savings and may paradoxically increase the cost of providing care to these patients.

The American Academy of Dermatology (AAD), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS) and the American Society for Mohs Surgery (ASMS) support the RUC process and recognize the value it brings to the annual Medicare physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this, the RUC defied the predictions of critics who claimed that agreement would not be possible among the various stakeholders.

The RUC and CMS have also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple procedure reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do not strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process. I disagree with using the RUC for this purpose, but if CMS believes the RUC role should be expanded it should only be done by giving the RUC a public and well-articulated charge to take on this task.

In light of the concerns raised above I respectfully request reconsideration of the proposed rule. I provide the above rationale in support of the Mohs procedure base codes, 17311 and 17313, as appropriately exempt for the multiple procedure reduction rule, as are the other add-on Mohs codes. I therefore request reinstatement of the exemption for the MPRR.

Sincerely,

Annalisa K. Gorman, M.D.

GREAT FALLS CLINIC

GREAT FALLS CLINIC, LLP

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GFC-Specialty Center
3000 15th Avenue South
Great Falls, MT 59405
406-454-2171

GFC-Clinic Cancer Care
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GFC-Immediate Care Center
1220 Central Avenue
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GFC-Marketplace
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Great Falls, MT 59404
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GFC-Northwest Clinic
1600 Division Road
Great Falls, MT 59404
406-268-1600

GFC-Choteau Clinic
914 4th Street NW
Choteau, MT 59422
406-466-5255

GFC-Fairfield Clinic
324 Central Ave.
Fairfield, MT 59436
406-467-2304

Helena Physicians' Clinic
3330 Ptarmigan Lane
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August 30, 2007

CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008

(202) 690-6262

To Whom It May Concern:

I am writing to inform you of my concerns due to the new guideline to eliminate multiple surgical reduction status for Mohs Micrographic surgery (Mohs). I have practiced dermatology in Great Falls, Montana for 5 years. In Montana (which is the fourth largest state in area and has a population of nearly 1 million people), we currently have only four Mohs College Surgeons, including myself. Because Montana's population density is low, many of my patients travel hundreds of miles (sometimes 6-8 hours away) to see me for their cancer treatment.

I understand why the surgical portion of Mohs may be under consideration for reduction as the patient is already in the office, a surgical tray is already in use, and it would not add significant cost to prep and anesthetize the patient for a second Mohs surgery. However, this is only a small portion of what Mohs surgery entails.

Most of the cost and time of the Mohs procedure is not based on the actual removal of the cancer, but in the pathology laboratory. For example, suppose there were one patient with two Mohs surgical sites: While some of the same equipment for the surgical portion of the first site's layer can be used for the second site's layer, the supplies and other costs of the laboratory are separate for each surgical site. These laboratory costs include paying a specially-trained technician to process the tissue; the time and training of the Mohs surgeon reading the pathology; the actual cost of the slides, dyes, tissue mounting media, etc.; and the equipment, ventilation, and other capital expenditures this entails. Both specimens from each of the layers must be processed independently. I am certain my Mohs technician would not be pleased to hear me say she gets paid only half for the second site even though she is separately processing both sections of tissue.

In addition, the change means the patient may only be able to have one site treated each day in order for the clinic to receive the normal reimbursement and adequately cover our expenses. This would mean my patients would have the added inconvenience and expense of traveling back and forth or finding accommodations in Great Falls to have each successive surgery completed on other days. Many patients will not be able to afford this or will have time restrictions (due to family, employment, farming, etc.) that will not allow this.

The reduction already applies to the repair of the second Mohs defect, i.e, Mohs surgeons already get paid half for the second and any additional reconstructions. This is understandable due to the nature of repairing two surgical sites in one setting – using the same equipment, supplies and staff. Please consider, however, that in my professional and personal opinion, applying the proposed reduction to Mohs codes 17311 and 17313 would be inappropriate.

Sincerely,

Stewart West, M.D.

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HPRC

BIRMINGHAM, ALABAMA

Brian S. McCluskey, Ph.D.
President & Chief Executive Officer

August 30, 2007

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

Subject: **Physician Self-Referral Issues**

Dear Mr. Weems:

The purpose of this letter is to comment on the July 12 proposed 2008 Physician Fee Schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. My comments are in tended to highlight the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

I am a physical therapist, in private practice, in Birmingham, Alabama. I have been practicing for 34 years, the last two and one half years in my current location. I provide one on one treatment to each patient for about one hour. I don't use unlicensed personnel and I don't use modalities such as heat, ice, electrical stimulation, etc. The Alabama Practice Act requires I have a prescription from a physician to provide any physical therapy services. There are between 20 and 24 physical therapy clinics within a 2 mile radius of my office, most of which are physician owned.

The number of physician owned clinics in my area has grown over the past couple of years. The "in-office ancillary services" exception created a loophole that has caused this expansion. There was an attempt in Alabama last year through legislation to make it a violation of the Physical Practice Act for a physical therapist to work in a referral for profit situation. This was vehemently opposed by the physicians in this area. It is interesting to note that the new law would not have made it illegal for the therapist to

work in the doctor's office where the therapist was paying rent and not giving a kick back to the physician. This proposed legislation never made it out of Committee.

Another practice that is occurring in this area is many physicians (30 for this one clinic) are partnering to own a physical therapy clinic. This clinic then contracts with the physician's office to provide physical therapy in the doctor's office. Additionally, those doctors who don't have the room for in-office services send their patients to the clinic in which they have a financial interest.

I have had several patients that were referred to me by their primary care physician or an occupational medicine physician, who after receiving some treatment by me, required surgery. Following surgery these patients had physical therapy in the doctor's office and were not referred back to me, even though they wanted me to treat them. They told me the physician wanted them to be seen by his therapist. I also had a friend who saw an orthopedist and needed physical therapy. The doctor's office insisted the patient be treated in their office. The patient finally threatened them and they said she could be treated wherever she chose to go. This situation clearly points out that many patients are not given a choice of who they can see for physical therapy.

I believe this clearly illustrates the severity of the problem. The potential for abuse (and at times fraud) exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to over utilize those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, over utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

Thank you for your consideration of my comments.

Sincerely,

Jay H. Segal, P.T.
Director

HPRC

Human Performance and Rehabilitation Centers, Inc.

521 Montgomery Highway, Suite 109
Vestavia Hills, Alabama 35216
205-978-5454
205-978-5392
www.hprc.net

Fax

To: Mr. Kerry N. Weems	**From:** Jay H. Segal, PT
Fax: 202-690-6262	**Pages:** 3
Phone:	**Date:** 8/30/2007
Re: Physician Self-Referral Issues	**cc:**

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- **Comments:**

~~DRAFT~~

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ForTec Medical Inc.®

Your Medical Laser Rental Company

August 25, 2007

Donald H. Romano
Centers for Medicare & Medicaid Services
Center for Medicare Management
C4-25-02
7500 Security Blvd.
Baltimore, MD 21244

Dear Mr. Romano:

I am writing on behalf of ForTec Medicals' Southwest Region who has been adversely affected by the market trends created by the advent of physician owned equipment companies. ForTec Medical wholly supports the proposed CMS regulations published on July 2, 2007 that potentially will put an end to self-referral of physician owned surgical equipment companies, and companies that provide financial incentive to physicians for using their equipment on a per click basis.

I believe that a competitive, level playing field will greatly affect the Medicare healthcare system in a positive way. As a Sales Representative for ForTec Medical, I often found that my pricing structure and business model were made available for review by my physician-owned equipment company competitors. I firmly believe that in many instances, O.R. administration was pressured by physicians to use their company, even if my service had a greater financial benefit to the hospital.

A competitive, level playing field will create lower case pricing for hospitals, treatment options for patients, and an overall reduction in our governments' healthcare costs. Most importantly, patients will benefit from CMS's proposed regulations as it will open-up treatment options formerly unavailable because the physician-owned companies only offer only the modality that they happen to own. Companies like ForTec Medical give surgeons the option to choose the best treatment choice for the patient, unaffected by financial motive or gain.

Clinical efficacy will be the determining factor in patient care, not financial incentive, if these proposed regulations are made final. The newly proposed regulations will reinstate competition, promote competitive pricing, assure a level playing field, and help reduce healthcare costs.

Sincerely,

Shawn Moran
Southwest Regional Manager
ForTec Medical, Inc.

ForTec Medical Inc.®

Your Medical Laser Rental Company

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August 23, 2007

Dr. Donald Romano
Centers for Medicare & Medicaid Services
Center for Medicare Management
C4-25-02
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Mr. Romano,

I am writing on behalf of ForTec Medical, Inc. to express our strong support for the proposed Medicare regulations that were published on July 2, 2007. We are encouraged by your proposals knowing that they have the potential to return the fair market nature and integrity that this sector of healthcare is now lacking.

Founded in 1988, ForTec Medical, Inc. leases surgical lasers to hospitals throughout the US on a per case basis. Historically a "non-physician owned' business model, ForTec has built its' business by providing cutting edge quality surgical lasers and skilled technician support to its customers.

While ForTec welcomes healthy competition, we have seen a dramatic proliferation of physician owned laser LLC's over the past three years. We now find ourselves competing against our former customers in what has become an unfair and anticompetitive market. The fact that physicians; exercise control over the patient, have access to our pricing structure, and improperly influence the hospital's purchasing decisions are a few of the factors that have led to ForTec's inability to compete fairly. On a larger scale, these facts have led to today's anticompetitive market.

Our experience has confirmed the following:

1. Financial motivation is driving treatment choices. While options exist for treatment of diseases, physician ownership of equipment plays a key role in influencing what the patient will ultimately be prescribed. The greater the utilization of his/her equipment, the larger will be the financial return on investment.

2. Steerage is driven by physician's potential financial gain. We know of instances where hospitals that chose to honor equipment contracts have "lost" patients to competing facilities. In other words, physicians have steered patients to alternative facilities who were willing to engage with their LLC medical equipment company.
3. Over utilization exists as created by practices that, due to ownership, use treatments that yield lower efficacy outcomes. This trend often creates the need to retreat patients adding additional cost burdens to our healthcare system.
4. Physicians pressure hospitals to use their LLC despite not being the low cost provider. These bully tactics further contribute to escalating healthcare costs.

Without adoption of CMS's proposed regulatory changes, ForTec may be forced to allow physician ownership of our company simply as a means of survival. Furthermore, if left unchecked these scenarios will grow exponentially with LLC's forming around multitudes of surgical equipment across all surgical specialties.

We understand that this is an ongoing battle and in fact we have already learned of strategies being developed to circumvent the new proposed regulations if adopted. One such strategy includes a "cross ownership" business model in which LLC "A" would deliver laser cases to the investors of a separate LLC "B", and visa versa. Another includes where physician groups might simply try to re-characterize their "per service" rentals as block leases. CMS should be clear that any such scheme or "testing of the waters" will not be tolerated.

Finally, CMS needs to assert that any arrangement that involves rentals or leases of equipment and technical support will be considered as "performing" the DHS for the purposes of the definition of "entity".

We fully expect that many of the physician owned ventures and lobbies will seek to delay the implementation by claiming disruption to clinical services. In our experience, there are numerous independent businesses ready to service and purchase these assets and take over contracts without creating interruption of services.

We commend and applaud CMS's efforts to close these loopholes which are not in the best interest of the patient. Clinical efficacy, not financial gain, should be the motivating factor in patient care. The newly proposed regulations will reinstate balanced competition, fair market pricing, and help to reduce healthcare costs.

Respectfully Submitted,

Drew C. Forhan
President & CEO

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August 28, 2007

VIA US MAIL

The Honorable John B. Shadegg
306 Cannon HOB
Washington, DC 20515

Re: Center for Medicare & Medicaid Services' Proposed Changes to Federal Regulations

Dear Representative Shadegg:

I represent NextMed. NextMed is an Arizona business success story whose continued existence is under threat by the Center for Medicare and Medicaid Services' (CMS) proposed changes to the Federal regulations governing Medicaid and Medicare. NextMed seeks your assistance and influence in opposing the proposed changes. In particular, it asks for your assistance in opposing proposed rule changes that would have a detrimental impact on arrangements for urology services that are furnished by companies in which physicians are investors.

Background

In the early 80's, medical research developed a procedure known as lithotripsy. This break-through treatment allowed physicians to use shock waves to break up stones that form in the kidney, bladder, or ureters. This saved patients from costly, painful, and sometimes dangerous surgery. The problem was that the machines, known as lithotripters, were extraordinarily expensive. The Dornier HM3 (the first lithotripter) cost $2.5 million.

Because the volume of patients needing the treatment in any locale was insufficient to justify the expense of the machine, and because the introduction of lithotripsy would lower the number of patients using a hospital's operating rooms, few hospitals purchased lithotripters. Patients who could have been treated non-invasively in about an hour as an out-patient went under the knife. Out of physician frustration at the lack of access to the latest technology, physicians began pooling their resources and purchasing lithotripters for their shared use. Physicians were able to share the equipment by putting it on large trucks.

When NextMed was founded in 1996, the first and second generation lithotripsy equipment was aging and services were still being provided on big mobile trucks. These trucks provided services on a curtailed basis (once a week to once a month). While the initial physician owned companies created the market, NextMed and its physician investors saw the opportunity

to improve availability (from once a month to once a week, or once a week to twice a week) using third generation machines. NextMed also took the step of moving the treatment from inside the semi trucks to inside the medical facility.

But the machines were still expensive - today machines range in price from $425,000 to $900,000 – and the concept was not without financial risk. Therefore, in order to finance the lithotripters, NextMed looked to the doctors that would be using the machines in their medical practice. After all, physicians had funded the first generation machines, and NextMed reasoned that the physician end users of medical technology were best suited to choose the technology that was best for their patients or facilities. Also, when investing their own dollars, physicians would be forced to focus on the technology and its cost. NextMed would provide the management services, including managing the movement of the lithotripters and their maintenance, securing arrangements with hospitals, and hiring a highly qualified medical technician to assist the doctors in performing their procedures, while the doctors would bear the majority of the cost of the lithotripters and technicians' salaries.

The concept has been a success and NextMed currently provides service to over 350 facilities in more than 30 states. NextMed has also branched out and now offers physicians access to laser prostate ablation equipment, bringing the latest technology to bear on enlarged prostates. The lasers used for prostate ablation have a limited useful life. After just 2 ½ years a laser may become obsolete as newer and better lasers come to market. Urologists want to provide the highest level of care and accordingly want to have the newer lasers for treatment of their patients. Hospitals are not willing to replace lasers so quickly and often complain that they have closets full of unused lasers. So, as with lithotripsy, the free market has worked to spur medical innovation and better client care as physicians have formed new ventures to provide laser services or expanded their lithotripsy ventures to include the service.

During NextMed's existence, no one has claimed that the arrangements have caused any over utilization of the lithotripsy procedures. This makes sense because, unlike an MRI or other diagnostic exam, you can only get treatment with these machines if you have a previously diagnosed stone to warrant treatment. So the potential patients for the machine are limited by the prevalence of the condition. In addition, with all these machines the doctor is performing the procedure for which he or she receives a professional fee. Any incentive to perform unnecessary work is already present in the form of the physician's professional fee and is not made any larger by the minimal additional fee the physician might receive as fractional owner of the machine. In other words, if a doctor is inclined to perform unnecessary surgery on a patient in order to earn a fee, the nominal additional compensation he might receive as owner of the machine will not be the deciding influence.

CMS Proposed Changes

In spite of the success of these physician ventures in providing millions of patients with relief without invasive surgery, CMS has proposed rule changes that may outlaw or narrowly restrict certain previously acceptable financial arrangements. The arrangements are referred to by the terms "Under Arrangements", "Per Click Fee", "Percentage Fee Arrangements", and "Stand in the Shoes". CMS has also proposed changing the burden of proof rules governing

In the *ALS v. Thompson* case the court held that extracorporeal shockwave lithotripsy is not a DHS even though it is provided under arrangement with a hospital. It would be highly beneficial to patients and providers if CMS further confirmed this in its rule changes and also exempted other procedures that are not enumerated as a DHS and would not otherwise be a DHS if not performed in a hospital from the proposed prohibitions on under arrangements.

Per Click Fee Ban

One of the leasing arrangements employed by physician ventures and hospitals is to charge a fee based on usage. These arrangements are known as "Per Click" agreements. They work well for the hospitals as the hospitals take no risk of non-usage. Hospitals are risk averse and do not want to spend capital for new equipment that may become obsolete fairly quickly. Yet doctors want their patients to have access to the best therapy, and doctors are willing to join together to purchase new equipment and bear the risk of failure. However, the procedure still needs to take place in a medical facility. The ventures must enter into a relationship with the hospitals to allow for the procedure to take place and these arrangements generally take the form of a per procedure fee. To accommodate a hospital's fear that it will lose money on the procedure, urology ventures have accepted per click fee contracts. By doing so, the urology ventures take the entrepreneurial risks and the hospitals are able to avoid the risk that the volume will be lower than projected.

Preventing Per Click arrangements will restrict patients' care options by limiting those hospitals that are willing to lease medical technology that, while beneficial, is not used on a high volume procedure. Kidney stones are especially painful, and stents that are used to delay treatment are often very uncomfortable. If no hospital is willing to take the risk, Medicare beneficiaries may find themselves unable to schedule treatments on a timely basis or may find that the most up-to-date technology is not available to them.

Percentage Fee Prohibition

Another way that a hospital avoids risk is to agree to accept as compensation a percentage of its reimbursement for the procedure. Certain third party payors, such as Medicaid, provide low reimbursement rates while many private insurers and others reimburse more generously. Even Medicare is usually the second lowest payor for a procedure. The hospital or other health care entity does not want to pay more for a procedure to a venture under arrangement with the hospital, than the reimbursement the hospital receives for the treatment. This can occur because the hospital cannot predict how many procedures will be paid for at any particular rate. Yet, if compensation is based on the lowest payor, the service company likely will not be fairly compensated for its investment, efforts and risk. Accordingly, hospitals are willing to share the risks involved in their varying reimbursement rates by agreeing to accept a percentage of their reimbursement rate for any individual patient.

Percentage compensation arrangements permit the physician ventures to shoulder some of the risk, but at the same time receive a fair payment. Physicians are willing to take this risk. These are reasonable and valuable arrangements. There is no reason for CMS to prohibit them.

Stand in the Shoes

The proposed rules would provide that if a DHS entity, such as a hospital, owns or controls another entity, a referral by a physician to the entity owned or controlled by the hospital would be deemed as a referral to the hospital. In other words, the hospital would stand in the shoes of the other entity for applicability of the rules. As a result, services by physician investment ventures to ASCs would be prohibited. This change could have a profound effect on Ambulatory Service Centers (ASC) and as a consequence NextMed.

ASCs are private centers that provide surgery on an out-patient basis. Many of these centers are owned in part by hospitals. These centers are an important piece of the healthcare delivery system providing relief for the hospitals to concentrate on treating the most seriously ill. These centers rarely furnish Designated Health Services. Thus, when a physician is invested in a venture that contracts with an ASC, the physician's referrals to ASCs rarely are prohibited by current CMS rules. The CMS proposal to have a hospital stand in the shoes of an ASC that it owns or controls would have the effect of turning hundreds if not thousands of procedures that are not of themselves DHS into DHS. As a result, the proposed rule change would have a profound effect on the whole healthcare delivery system. If the proposal is finalized, physicians would likely withdraw from ownership in ASCs where hospitals are investors, thus limiting the availability of treatment options.

Burden of Proof

There is one more issue NextMed would like your help with and it is not nearly as arcane as the Medicare and Medicaid regulations. It has to do with the burden of proof. Incredibly, CMS wants to alter the burden of proof requirements for complying with its regulations in this area. It wants the physician to be forced to "prove the negative", namely that they are not violating the regulations. This is not just bad policy, its un-American and violates all notions of fundamental fairness and due process upon which this country was founded. If the Federal government is going to deny you a benefit because it believes you have violated one of its Byzantine rules, it can prove its case. After all, it has the weight of the federal bureaucracy behind it. This is especially important because the Stark law is a strict liability statute.

Conclusion and Request for Assistance

Urology therapeutic ventures have brought clinical benefits to thousands of Medicare beneficiaries while saving CMS millions of dollars through the efficiency of the shared service model. NextMed requests your assistance in maintaining those benefits by requesting CMS to:

1. Clarify that as a result of the ruling in *ALS v. Thompson*, lithotripsy will not be subject to the proposed "under arrangements" restrictions;

2. Clarify the proposed "under arrangements" provision to make certain that therapeutic services provided by urology ventures are not DHS services if they would be so only because of the site where the services are delivered;

3. Drop any prohibition of per click or percentage fees as related to these same therapeutic physician ventures in order to preserve the access and cost savings that the shared service model has created;

4. Clarify/modify the stand in the shoes provision to exempt hospital ownership or control in an ASC in order that legitimate joint ventures are not forced to abandon all ASCs with any hospital participation; and

5. Accept the burden of proof that the law has historically placed upon the one creating the rules.

NextMed appreciates the complexity of this matter. We remain ready to answer any questions concerning our requests that you may have. In that regard, I will be following up with your office in the near future. Thank you for your consideration.

Sincerely,
GORDON & REES LLP

Stephen W. Tully

SWT:nt

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MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

August 31, 2007

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

Re: Irregularity of Stark Rulemaking Processes; Request to Extend or Re-open Comment Period

Dear Mr. Kuhn:

MGMA is writing to request that the comment period in CMS-1385-P be extended or re-opened for at least 45 days with respect to the physician self-referral issues contained therein. The Agency's advance release, prior to official publication in the Federal Register, of the long and complex "Stark III" final rule, just days prior to the comment deadline on yet additional Stark rule changes proposed with the CY 2008 Medicare physician fee schedule rule, is extremely prejudicial to those wishing to file comments on the latter.

The long history of Stark law implementation has been a series of "moving targets" for medical group practice administrators trying in good faith to understand and comply with this extraordinarily arcane regulatory system. For an association like MGMA, that likes to inform its public comments on important rulemakings through consultation and input from its large and diverse membership, an 11th hour surprise such as the release of Stark III, makes a mockery of the public comment process.

MGMA is in the early stages of digesting Stark III, but it is already apparent that some changes there relate to and confuse proposals included in the fee schedule NPRM, comments on which we are forced to file today. Fundamental fairness demands that MGMA, its members, and thousands of other health care providers affected by these rules, be given time to properly consider the latest proposals in the context of what is now Stark III. Alternatively, CMS should defer any consideration of the Stark components of the CY 2008 fee schedule until it re-proposes them at a future date. If you have any questions, please contact Amy Nordeng in the Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

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Englewood, CO 80112-5306
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US Oncology

August 31, 2007

HAND DELIVERED

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

Re: CMS-1385-P

Dear Mr. Kuhn:

On behalf of the US Oncology[1] National Policy Board and the oncologists of the US Oncology physician network, I would like to thank you for the opportunity to comment on Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007.[2] As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

IMPACT

CMS Should Take Steps to Correct the Escalating Shortfall in Reimbursement for Chemotherapy Drug Administration Services

The Proposed Rule contemplates the adoption of changes to the work RVUs assigned to additional CPT codes and increases in the work of anesthesia services. These changes flow from the 5-year work review that was largely completed last year. As a result of these changes, CMS expects to revise the budget neutrality adjustment of 0.8994 applied to work RVUs in 2007 downward to approximately 0.8816. The Proposed Rule also reflects budget neutrality adjustments associated with the addition of six more CPT codes to the list of procedures subject to the hospital outpatient prospective payment system (HOPPS)-payment limitation on PFS

[1] US Oncology, headquartered in Houston, Texas, is one of the nation's largest cancer treatment and research networks. US Oncology provides extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced treatments and technologies, build integrated community-based cancer care centers, improve their therapeutic drug management programs and participate in many of the new cancer-related clinical research studies. US Oncology is affiliated with 1,122 physicians operating in 442 locations, including 90 radiation oncology facilities, in 38 states.

[2] 72 *Fed. Reg.* 38120 (July 12, 2007).

imaging services under Section 5102 of the Deficit Reduction Act of 2005[3] and continues the four-year phase-in of the bottom-up methodology for setting practice expense (PE) RVUs. As a result of these changes, the impact analysis in the Proposed Rule projects an aggregate *reduction* in payments to the hematology/oncology specialty in 2008 of 1%.[4] This projection ignores the potentially disastrous effect of the 9.9% negative update factor resulting from the Sustainable Growth Rate (SGR) formula that also will take effect in 2008 absent Congressional action.

The projected impact on the medical oncology sector as a whole belies the seriousness of the escalating shortfall in reimbursement for community-based chemotherapy services. As Exhibit 1 illustrates, the Medicare allowable amounts for drug administration services in 2007 will fail to cover approximately $466 million of the costs oncologists will incur when they provide chemotherapy services in their offices. The magnitude of actual losses expands to $759 million when bad debt at the level of approximately 23% of the beneficiary cost-sharing amount (the typical level of bad debt experienced by US Oncology affiliated practices) is taken into account.

A recently released OIG report[5] entitled *Review of Selected Physician Practices' Procedures for Tracking Drug Administration Costs and Ability to Purchase Cancer Drugs At or Below Medicare Reimbursement Rates* is supportive of our assessment. The report looked at the ability of twelve community-based oncology practices to purchase fifteen cancer drugs at or below ASP + 6%. These drugs accounted for over $2 billion of the $4.5 billion spend by Part B on drugs administered by physicians in the specialties of hematology (82), hematology/oncology (83), and medical oncology (90) in the claims database used by the OIG to select practices for survey. Although the OIG concluded that "[n]ine of the twelve practices reviewed could generally purchase drugs . . . at or below the MMA-established reimbursement rates from April 1 though June 20, 2005," the data presented in the report are misleading to the extent they ignore the losses oncologists incur when patients are unable to pay their co-payments. Even without taking bad debt into account, the data also raise significant concerns about the adequacy of drug payments under the ASP + 6% methodology. In reality, none of the practices surveyed were able to buy all of the study drugs at or below ASP + 6%. Moreover, ten of the twelve practices lost money on at least 20% of the study drugs needed by their patients and fully half lost money on 30% or more of their study drug purchases.

Despite the title of the recent report, the OIG did not actually review the adequacy of Medicare reimbursement for drug administration services because only one of the practices it surveyed tracked such costs on a procedure-code basis. The OIG did note the various types of chemotherapy administration services the practices considered un-reimbursed or under-reimbursed under the physician fee schedule (PFS). They included patient support services (e.g., nutritional and financial counseling, chemotherapy teaching and advice/phone calls, pre- and post-infusion nursing procedures) and pharmacy handling costs (e.g., inventory maintenance, drug admixing, biosafety cabinets and specialized products for decontaminating them, personal protective equipment for drug admixing, special containers for chemotherapy waste, drug waste

[3] Pub. L. 109-71 (Feb. 6, 2006).
[4] 72 *Fed. Reg.* at 38214.
[5] *Review of Selected Physician Practices' Procedures for Tracking Drug Administration Costs and Ability to Purchase Cancer Drugs At or Below Medicare Reimbursement Rates*, A-09-05-00066 (July 2007), available at http://oig.hhs.gov/oas/reports/region9/90500066.pdf.

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disposal charges). Although the report noted that "information related to several of these costs was available to CMS in determining PE RVUs and reimbursement amounts for drug administration services," it failed to identify the service elements that the report implicitly acknowledges have never been factored into the development of PE RVUs or the PFS. Similarly, the OIG made no effect to access the appropriateness of the PE data underlying the PFS.

Exhibit 2 shows the projected effect of the Proposed Rule on Medicare payments for drugs and for drug administration services billed by medical oncology. Exhibit 3 presents the same analysis assuming Congress reverses the negative 9.9% update and instead provides for a 0.5% update in 2008. The size of the underpayment for drug administration when bad debt is taken into account increases by almost 12.5% from $645 million to $725.5 million under the Proposed Rule and by almost 6% from $645 million to $683 million if Congress replaces the negative update with a 0.5% across-the-board payment increase.

Exhibit 4 illustrates the steady erosion in Medicare payments for those drug administration codes billed by oncologists under the MMA. The aggregated weighted change, based on utilization for the oncology specialties of hematology (82), hematology/oncology (83) and medical oncology (90)[6] was a reduction of 3% from 2005 to 2006 and 3% from 2006 to 2007. The projected change from 2007 to 2008 will be an *additional* decrease of 12% if the –9.9% update is implemented or 2% if Congress enacts a +0.5% update. Moreover, the adverse impact of the revised PE methodology on drug administration services will continue to grow from 2008 to 2010 as the phase in of the new methodology is completed, resulting in a projected aggregate weighted decrease in drug administration payments of 14% in 2010, assuming Congress takes steps to reverse the negative updates that are inevitable under current SGR formula.

Payment cuts of this magnitude, even assuming Congress takes steps to reverse or mitigate the negative update factor in the Proposed Rule, are contrary to the intent of the Medicare Prescription Drug, Modernization and Improvement Act of 2003 (MMA).[7] MMA § 303 revamped payment rates for Part B drugs from an AWP-based methodology to an ASP-based one and simultaneously changed the physician fee schedule (PFS) methodology specific to the drug administration codes billed by medical oncologists. Congress paired these required changes because it intended to match reimbursement for drugs and drug administration to the actual costs incurred for each service component by physicians who furnish chemotherapy in their offices. Unfortunately, the amendments the MMA made to the methodology for setting drug administration payments were inadequate to account for actual incurred costs once the 32% 2004 transition payments ran their course. The phase-in of the revisions made to the PE methodology last year has further exacerbated the problem.

Assuming Congress requires a PFS update of 0.5%, the weighted average decrease of 2% in drug administration reimbursement facing oncologists who furnish in-office chemotherapy next year contrasts sharply with the proposed increases in the reimbursement for drug administration in hospital infusion centers in 2008 under Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates."[8] As Exhibit 5

[6] Utilization is from CY2008 Proposed Rule 2008 NPRM UTILIZATION FILE posted on the CMS website.
[7] Pub. L. 108-173 (Dec. 8, 2003).
[8] 72 *Fed. Reg.* 42626 (Aug. 2, 2007).

illustrates, the proposed 2008 payment rates for the Ambulatory Payment Classification (APC) groups that include the drug administration services detailed in Exhibit 4 reflect payment increases ranging from 1.6% to 12.2%. We recognize the methodologies CMS uses to set PFS and HOPPS payments are quite different. Nonetheless, the disparate payment trends for drug administration services in the two settings is troubling, particularly given that Medicare does not reimburse physicians for beneficiary bad debt but pays hospitals that make reasonable efforts to collect 70% of their inpatient and outpatient beneficiary bad debt. We note too that over 80% of all community-based chemotherapy services are currently furnished in physician offices.

The depth of the projected cuts for drug administration services in physician offices under the Proposed Rule makes it clear **something must be done** to preserve access to in-office chemotherapy for Medicare beneficiaries. Assuming funding for the Physician Quality Reporting Initiative (PQRI) is not cut pursuant to provisions included an a Medicare reform package likely to be considered by Congress later this year, as Exhibit 6 illustrates, bonuses expected to be in the range of 1.5% to 2% of allowed PFS charges for qualifying professionals,[9] will not be enough to offset the shortfall in reimbursement for drug administration facing oncology practices. Moreover, the underpayment situation could be further exacerbated by decreases in drug payments if Congress also acts to require CMS to change from sales-volume weighting to HCPCS Code unit-of-measure weighting when it determines the ASPs for those HCPCS Codes that encompass more than one National Drug Code (NDC).[10]

We note that Reps. Lois Capps and Tom Davis have introduced the Comprehensive Cancer Care Improvement Act of 2007 (HR 1078), which would establish cancer care planning and the development of comprehensive cancer treatment summaries as reimbursable services under the PFS. We urge CMS to actively support this legislation and to work expeditiously to effectuate care planning payments in 2008 using temporary codes should the legislation be enacted this year. We note the approach taken in HR 1078 is generally consistent with a recommendation US Oncology has made previously on a number of occasions for the establishment of a payment for a specified bundle of chemotherapy coordination services under the PFS akin to the monthly payment nephrologists receive when they treat patients receiving dialysis or the weekly payment radiation oncologists receive for managing radiation therapy.

Furthermore, we urge CMS to take steps to ensure that the extensive pharmacy handling costs associated with cancer therapies, such as maintaining and managing drug inventories, drawing up and admixing drugs for administration, and operating quality assurance and drug safety programs, are adequately reimbursed in the physician-office setting. Although we disagree strongly with CMS' conclusion that reimbursement at ASP + 5% for separately payable drugs in the hospital outpatient setting will be sufficient to cover *both* drug acquisition costs and pharmacy handling costs in 2008,[11] we are encouraged by CMS' decision to collect data on pharmacy services costs on an uncoded revenue line on claims for an APC involving drug

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[9] 72 *Fed. Reg.* at 38206.

[10] *Calculation of Volume-Weighted Average Sales Price for Part B Prescription Drugs,* OEI-03-05-00310 (Feb. 2006), available at http://oig.hhs.gov/oei/reports/oei-03-05-00310.pdf (estimating that CMS' use of the sale-volume-based weighting methodology in 2005 in lieu of a HCPCS Code unit-of-measure-based weighting cost Medicare approximately $115 million in 2005). HR 3162, which has been passed by the House, includes a provision in § 612 that would mandate that CMS adopt the methodology favored by the OIG.

[11] 72 *Fed. Reg.* at 42735.

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administration. This exercise should help establish the actual costs associated with the safe handling of chemotherapeutic agents and help ensure that hospitals are appropriately paid for those costs beginning in 2010.

When the Medicare Payment Advisory Committee (MedPAC) studied the cost of pharmacy services in hospital outpatient departments in 2004, it concluded that those costs were "nontrivial" [12] and it recommended that CMS "define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs." [13] Implicit in MedPAC's recommendation is the recognition that pharmaceutical management and handling costs are linked to the nature of the drugs handled and to the complexities of drug protocol management, not to the setting in which the drugs are used. Therefore, we expect the assessment of pharmacy services costs in hospital infusion centers to be reflective of the equally "nontrivial" costs that physician offices incur when they handle similar drugs. A 2005 study commissioned by the National Patient Advocate Foundation to assess drug handling costs associated with chemotherapy treatments administered in both hospital outpatient departments and physician offices found the average cost per dose of chemotherapy administration was $36.03 plus the costs of drugs.[14]

We urge CMS to recognize the need to pay physician practices adequately for the pharmacy costs they incur when they administer chemotherapy in their offices and to use the data it likely will begin collecting from hospitals next year to work with the CPT Coding Panel and the RUC to establish codes and set appropriate payment rates under the PFS for drug handling services or to adjust appropriately the PE RVUs associated with the drug administration codes currently included on the PFS.

PHYSICIAN SELF-REFERRAL PROVISIONS

The In-Office Ancillary Services Exception

CMS Should Avoid Limiting In-Office Ancillary Services in Ways that Could Restrict the Provision of Comprehensive, Office-Based Cancer Care

We recognize CMS' concern about potential overutilization when physicians invest in expensive equipment and operate it as part of their office practice. This concern has been fueled by what many in the Congress and CMS have described as the proliferation of in-office diagnostic imaging. This particular concern already has been the focus of statutorily mandated reductions in reimbursement for imaging services. We also understand CMS' concern about the original intent of the in-office ancillary services (IOAS) exception being stretched by some physicians engaging in what are essentially turn-key designated health service (DHS) operations conducted by outside contractors who have little or no routine interaction with the group practice. Those

[12] MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program," chapter 6, p 142 (June 2005), available at http://www.medpac.gov/publications%5Ccongressional_reports%5CJune05_ch6.pdf.
[13] *Id.* at 2.
[14] Gary Oderda, University of Utah Pharmacotherapy Outcomes Research Center, "Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusion in Academic and Community-Based Oncology Practices" (Feb. 8, 2005), prepared for the National Patient Advocate Foundation and The Global Access Project, available at http://www.npaf.org/pdf/gap/utah_study.pdf.

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concerns are heightened when the DHS involved does not have to be provided on an "incident to" basis or is not needed by the physician to assist with diagnosis or treatment planning.

That being said, we urge CMS to carefully consider whether restructuring the IOAS rules is truly necessary to curtail perceived abuses, particularly if some of the other modifications suggested in the Proposed Rule are implemented. Further, if CMS concludes changes are necessary, we encourage the agency to tailor those changes narrowly (see discussion below) to avoid any negative impact or possible unintended consequences on treatment capabilities or beneficiary access, especially in the context of community-based cancer care. The importance, from a patient perspective, of maintaining a legal framework that allows specialists to continue practicing in multi-disciplinary community-based cancer centers equipped to deliver the full range of services needed by the typical cancer patient cannot be overstated in the face of evolving evidence suggesting that treatment in such settings can lead to higher survival rates.[15]

The physician self-referral prohibitions at Social Security Act § 1877 and the implementing regulations at 42 C.F.R. § 411.350 *et seq.* (hereafter referred to collectively as the Stark Law) always have contained a provision, dubbed by Congress as the in-office ancillary services (IOAS) exception. This provision was designed by Congress to ensure that concerns about possible physician self-dealing would not be allowed to undermine the ability of physicians to provide coordinated care in their offices.[16] The IOAS exception is one of only three exceptions specified in the statute that applies to both ownership and compensation arrangements. Furthermore, as the preamble to the Proposed Rule recognizes, Congress designed the IOAS provision to be significantly more flexible than most of the other Stark Law exceptions. For example, although fair market value compensation that has been set in advance is the hallmark of a number of Stark Law exceptions, Congress chose not to incorporate this requirement in the rules governing the provision of IOAS. Moreover, the IOAS exception is almost unique in allowing for profit sharing and productivity bonuses.[17]

Congress deliberately included provisions in the Stark Law giving physicians broad latitude to furnish ancillary services in their office and this latitude has been preserved over the almost two decades of the Stark Law's existence, in the face of numerous statutory and regulatory revisions. This is no accident. The IOAS provision was originally created in 1989 to balance concerns about physicians' self referrals against the long-recognized Medicare mandates: (1) to defer to a physician's judgment regarding the practice of medicine and the treatment of his or her patients

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[15] Robert O. Dillman, MD, and Sherri D. Chico, CTR, Cancer patient Survival Improvement Is Correlated With the Opening of a Community Cancer Center: Comparisons with Intramural and Extramural Benchmarks, J. of Oncology Practice, vol. 1, pp. 84-92 (September 2005).

[16] *See* Richard P. Kusserow and Harvey A. Yampolsky, *The Stark Law: Using Its History to Craft Its Future*, J. of Health Care Compliance, vol. 7, pp 5-12 (Nov./Dec. 2005) and Richard P. Kusserow and Harvey A. Yampolsky, *A Look Back at the Origin of the Stark Self-Referral Law*, J. of Health Care compliance, vol. 7, pp. 51-52, 81-82 (Nov./Dec. 1005) (reprints attached for ease of reference). The authors of these articles were personally involved in the development of the legislation that became the original Stark Law. Mr. Kusserow served as the Inspector General of the U.S. Department of Health and Human Services and Mr. Yampolsky as Chief Counsel to the Office of Inspector General when the Stark Law was enacted. They worked directly with Mr. Stark on the development of the physician self-referral legislation.

[17] 72 *Fed. Reg.* at 38181. *See also* 69 *Fed. Reg.* 16068 (March 26, 2004) (the preamble to the Stark II/Phase II regulations) where a chart highlights these and numerous other differences between the IOAS and other Stark Law exceptions.

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and (2) to preserve Medicare beneficiaries' freedom to access care from the provider of their choice. Congress sought to achieve this balance by purposefully limiting the scope of conduct prohibited by the Stark Law through the provision of a broad exception from the general rule that a physician cannot refer a patient for a DHS[18] to an entity – including his or her own solo or group practice – with which the physician (or an immediate family member) has a financial relationship. The IOAS exception was intended to ensure that physicians may continue to determine how care is to be delivered to their patients and that Medicare beneficiaries will continue to have access to appropriate care, provided in the most efficient and effective manner. Because many DHS are crucial to cancer care, the IOAS provision has proven to be indispensable to the delivery of comprehensive cancer care in the physician-office setting.

CMS too has been sensitive to the need for balance in the regulations it has promulgated to date to implement the Stark Law. It has consistently recognized that the IOAS exception is intended "to allow physicians to furnish DHS that are ancillary to the physicians' core medical practice in the location where the core medical services are routinely delivered."[19] To that end, CMS previously has narrowly tailored the restrictions it has imposed on the scope of permissible physician ancillary services. These restrictions have been designed to prevent sham arrangements, such as loose affiliations of physicians coming together merely to capture the profits from ancillary services, or to rein in the provision of ancillary services that are only tenuously related to a physician's office practice. However, these restrictions always have been carefully circumscribed so as to ensure they would not unduly limit physicians' clinical decision-making about the what, why, how and where of patient treatment.

Currently, the Stark Law and implementing regulations establish numerous standards that permissible IOAS must meet.

- The Eligibility Standard: Not every DHS can qualify as an in-office ancillary service. Certain durable medical equipment[20] as well as all parenteral and enteral nutrients, equipment and supplies are not considered in-office ancillary services, generally because they are products that do not need to be purchased directly from a physician and, in fact, typically have not been provided by physicians in their offices.
- The Supervision Standard: To qualify as a permissible IOAS, the DHS must be provided by or supervised by the ordering physician or another physician who is a member of, or otherwise in, the ordering physician's group practice. Further, the supervision provided must be in accordance with other applicable Medicare payment and coverage rules for the service at issue.

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[18] DHS are defined broadly at 42 C.F.R. § 411.351 to include: (1) clinical laboratory services, (2) physical therapy services and supplies, (3) radiology and certain other imaging services, (4) radiation therapy services and supplies, (5) durable medical equipment and supplies, (6) parenteral and enteral nutrients, equipment, and supplies, (7) prosthetics, orthothics, and prosthetic devices and supplies, (8) home health services, (9) outpatient prescription drugs, and (10) inpatient and outpatient hospital services.

[19] 66 *Fed. Reg.* 856, 888 (Jan. 4, 2001).

[20] Implanted and external ambulatory infusion pumps (which are occasionally supplied and billed through the DMERCs by medical oncologists when their patients need long-duration chemotherapy infusions) and canes, crutches, walkers, folding manual wheelchairs, and blood glucose monitors are not treated as DME for purposes of the IOAS exception so that physicians are free to provide these items to their patients for home use without fear of a Stark Law violation. 42 C.F.R. § 411.355(b).

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- The Billing Standard: DHS provided as IOAS must be billed by the referring or supervising physician, his or her group practice, an entity wholly owned by the group practice or a billing company acting as the agent of the physician, group or wholly-owned entity. Certain specified billing numbers must be used. These requirements are intended to ensure the entity that furnishes the DHS is indeed an integral part of the group practice.
- The Location Standard: DHS furnished as an IOAS must be provided in the same building where the solo practitioner or group actually practices medicine or in a location that serves as a centralized site for the group's provision of DHS. This standard also is intended to ensure the DHS is provided as an integral part of the activities of the medical practice.
- The Group Practice Definition: Group practices that provide IOAS must meet the unique, detailed and stringent Stark Law definition of a group practice. The criteria embedded in the group practice definition are specifically designed to ensure that only those physicians that practice as a unified group, rather than a loose affiliation developed solely for purposes of sharing DHS, can profit from the provision of ancillary services.

When these IOAS standards were established, they were deemed by CMS to be consistent with Congressional intent to protect the sanctity of the physician office practice yet sufficient to prevent abuse. At least in the case of oncology, we are convinced that conclusion is still true.

The ability to furnish IOAS has proven to be essential to the provision of integrated, comprehensive, high-quality cancer care in the community-based setting. For example, it allows medical oncologists to provide outpatient chemotherapy drugs directly in their offices, as well as perform simple blood chemistries to establish appropriate chemotherapy dosages, assess whether patients scheduled for chemotherapy are fit to undergo treatment that day, and determine the need for adjuvant therapy with white- and/or red-cell stimulating agents.[21] Perhaps more importantly, the existing regulations let medical oncologists, radiation oncologists and, at times, other types of physician specialists work together cooperatively in integrated, multidisciplinary practices at cancer centers equipped to furnish both chemotherapy and radiation therapy services. Clinical collaboration and communication between these subspecialties has grown increasingly important in a world where the optimal treatment for a majority of all new cancer patients will be a multi-modality approach where the patient receives both chemotherapy and radiation therapy during their illness.

Imaging is also integral to cancer treatment in myriad ways. Without CT services in their offices, radiation oncologists would be unable to generate the images that drive the development of the computerized treatment plans they use to target the radiation beam in the most therapeutically effective, yet tissue-sparing manner. As CMS itself has recognized, it is reasonable to conclude that CT imaging has, in essence, become an ancillary but integral part of modern radiation therapy procedures.[22]

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[21] As of Jan. 1, 2008, the Tax Relief and Health Care Act of 2006 – Medicare Improvements and Extension Act of 2006 (Pub. L. 109-432) § 110 will require oncologists to include information about the patient's hemoglobin or hematocrit levels on each claim for a drug furnished for the treatment of anemia.

[22] 59 *Fed.Reg.* 16053, 16065 (March 26, 2004).

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The Stark rules governing IOAS also permit medical and radiation oncologists to incorporate sophisticated imaging technologies, such as PET, for disease staging and treatment monitoring into their practices. The role of imaging in cancer care is such that each imaging event is likely to reflect a critical point of clinical management. Further, proper disease staging and progress monitoring, using both conventional and functional imaging, is central to the implementation of evidence-based cancer care using clinical practice guidelines such as those developed by the National Comprehensive Cancer Network (NCCN) or the American Society for Clinical Oncology (ASCO) and used as the basis for CMS' Cancer Care Quality Demonstration in 2006.

Staging and treatment monitoring through sophisticated imaging also are central to the Cancer Care Pathways being developed by US Oncology network practices through an evidence-based approach that involves defining sets of treatment options designed to deliver high-quality, high-value cancer care. The US Oncology physician network, through the Pharmacy and Therapeutics Committee of the National Policy Board, is currently developing Pathways to include radiation treatment and CT and PET diagnostic imaging. This sort of evidence-driven approach to integrated, coordinated cancer care would not be possible without an appropriately tailored IOAS exception.

Because of the importance of preserving the crucial role that IOAS play for specialists tasked with taking care of patients fighting cancer, we will respond separately to the three specific IOAS issues on which CMS is soliciting comments.

1. Services That Should Qualify under the IOAS Exception

As noted above, in the typical integrated cancer center, the IOAS exception is the means by which the physicians are able to deliver chemotherapy, radiation, imaging and lab services, all of which are equally important to achieving truly integrated cancer treatment. Any changes that would exclude any one of those services from the list of DHS eligible for the IOAS exception would undermine the ability of oncology practices to follow appropriate treatment guidelines and provide the current standard of care. The reality is that each of these four services is truly ancillary to the practice of oncology. The ability to provide in-office imaging or lab allows medical and radiation oncologists to assess treatment efficacy and to make clinically significant, timely corrections in treatment when a therapy is not working and to reassure patients about a brighter prognosis when a treatment is proving effective. Moreover, imaging services are now inextricably linked to the provision of radiation therapy in that CT or PET/CT scans form the basis for the development of the computerized treatment plans needed to guide the delivery of such therapy.

Changing the IOAS rules so as to impede the integration of chemotherapy, radiation, diagnostic imaging or lab into community-based oncology practices could have the unintended consequence of driving services to more expensive settings and would be a disservice to Medicare beneficiaries. Being able to obtain all services related to their cancer treatment within "their" oncology practice at "their" cancer center allows patients to interact with familiar staff attuned to explaining procedures, listening to patient concerns, and dealing honestly, openly, and sensitively with patients facing acute distress, fear of complications of treatment, fear of disease recurrence, and fear of death. Allowing each of these DHS to be conducted within oncology

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practices reduces the psychological burden of cancer treatment on patients and the burden on their caregivers. It reduces productivity losses that occur when cancer patients and their caregivers have to expend extra energy and take extra time off from work to obtain services at a variety of locations. It also reduces the anxiety patients experience when they must wait for results of tests conducted outside their oncologist's practice to be communicated back to their physician, sometimes in less than timely fashion.

Over the past two decades, there have been many advances in the diagnosis and treatment of cancer. At the same time, there has been a dramatic shift from hospital-based care to community-based outpatient cancer services. Community based services provide an overwhelming majority of cancer care in the United States. In 2002, Boston Healthcare Associates, Inc. published the results of an independent survey that concluded that approximately 80% of all cancer patients in need of outpatient modalities such as radiation therapy and chemotherapy were treated in a community based setting. The most important result of the emergence of outpatient community based cancer practice was improved access to care.

Throughout the country, state-of-the-art cancer care has been evolving toward specialized centers where patients can receive outpatient chemotherapy; radiation therapy; imaging and treatment planning services; clinical lab services; access to clinical research trials, etc., in one place without driving from site to site.

With radiation therapy, chemotherapy infusion, PET and CT services under one roof, community cancer centers optimize access to new protocols requiring concomitant therapies and single site controls. Patients and physicians have access to state-of-the-art radiation therapy, PET, CT, chemotherapy infusion, pharmacy, laboratory and other services in one location, providing unparalleled continuity of care. PET and CT accommodate treatment planning and set-up as well as aid in staging, planning, and evaluation of response to treatment for cancer patients under treatment at the cancer center.

In addition to these core treatment services, community cancer centers often offer an array of support services aimed at easing the treatment experience for the patient. One of the chief advantages of integrated cancer centers is the ability to consolidate and focus support services such as nutritional counseling, family and patient education, financial counseling, and other support services needed by patients. Because the support community is focused on a single disease and a single patient population, it can better address the unique physical and psychological needs of cancer patients and their friends and families. This specialized community of patients, medical staff, counseling, and other support professionals who occupy a cancer center provides extraordinary comfort to patients unmatched in any general facility.

Integrated cancer care centers have a national track record of dramatically improving the continuity of care of cancer patients. A single integrated team of cancer caregivers provides care to cancer patients throughout their entire course of care, where otherwise many patients would go from one physician or provider location to another, often with significant, disruptive travel in between, and may find it difficult to establish important relationships with their caregivers.

The inclusion of imaging services at the same site as chemotherapy and radiation therapy allows the scanning and monitoring of all cancer patients treated at the center with the same scanning equipment evaluated by that single integrated team of specialists, where otherwise films would often be taken on different machines at different sites with different staff, making comparisons difficult. The evaluation of the growth and/or diminution of tumors is a very precise science; and it is vital to proper quality care that the same equipment be used and judged by the same trained specialist to ensure accurate readings.

Also, and possibly most importantly, this integrated cancer care center allows the treatment of patients with a combination of both chemotherapy and radiation therapy in a single facility, where otherwise many patients would be required to travel from one site to another every day for weeks and months. Medical studies have shown time and time again that one of the most significant barriers to effective cancer treatment is simply the ability of the patient to physically receive the treatment. When the different facets of the patient's course of treatment are dispersed among different sites in and outside of the community, the patient faces greater unneeded obstacles to receiving the care he/she needs. This dispersal of care facilities exacerbates the transportation challenges faced by many patients and essentially mandates that a friend or family member also dedicate significant time during a workday to deliver the patient back and forth to care sites. In the worst case scenario, such logistical issues can result in patients choosing more radical and less effective surgical options to treat their disease even though a more time-intensive course of chemotherapy and radiation therapy may be a better choice and save healthy tissue.

Medical and radiation oncology are inextricably linked in the treatment of cancer. Many patients receive chemotherapy and radiation concurrently, making it critical that both of their treating oncologists (i.e., their medical oncologist and radiation oncologist) coordinate in an on-going fashion. For example:

- in patients with unresectable and resectable head and neck cancers, research indicates that chemotherapy enhances survival in combination with radiotherapy compared with radiation alone.[23]
- the therapeutic approach on diagnosis of pathologic stage III non–small cell lung cancer (NSCLC) relies on adjuvant chemotherapy,[24] because postoperative radiotherapy alone remains controversial.[25]
- combined chemotherapy and radiotherapy for cervical cancer improve survival and reduce distant recurrence rate as compared to radiotherapy alone.[26]

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[23] Cohen EE, Lingen MW, Vokes EE. The expanding role of systemic therapy in head and neck cancer. *J Clin Oncol* 2004;22:1743-1752.

[24] National Comprehensive Cancer Network Web site. Small cell lung cancer practice guidelines-v.1.2008. Available at: http://www.nccn.org/professionals/physician_gls/PDF/sclc.pdf. Accessed August 28, 2007.

[25] Postoperative radiotherapy in non-small-cell lung cancer: systematic review and metaanalysis of individual patient data from nine randomised controlled trials. PORT Metaanalysis Trialists Group. *Lancet* 1998;352:257-263; Sawyer TE, Bonner JA. Postoperative irradiation in non-small cell lung cancer. *Semin Radiat Oncol* 2000;10:280-288; Sawyer TE, Bonner JA, Gould PM, et al. Effectiveness of postoperative irradiation in stage IIIA non-small cell lung cancer according to regression tree analyses of recurrence risks. *AnnThorac Surg* 1997;64:1402-1407; discussion 1407-1408.

[26] Green J, Kirwan J, Tierney J, Vale C, Symonds P, Fresco L, Williams C, Collingwood M. Concomitant chemotherapy and radiation therapy for cancer of the uterine cervix. *Cochrane Database of Systematic Reviews* 2005, Issue 3. Art. No.: CD002225. DOI: 10.1002/14651858.CD002225.pub2.

- concurrent chemoradiotherapy reduced risk of death at two years compared to radiotherapy alone in patients with stage I-III non small cell lung cancer.[27]
- for patients with high-risk breast cancer treated with radical mastectomy and adjuvant chemotherapy, the addition of radiation therapy leads to better survival outcomes; a chemotherapy and radiation regimen, compared with chemotherapy alone, is associated with a 32% reduction in breast cancer mortality and a 27% reduction in overall mortality compared with chemotherapy alone.[28]
- chemotherapy given with radiation shrinks and eliminates tumors more effectively than either treatment alone in patients with moderately advanced laryngeal cancer and allowed over 80% of the patients in the study to avoid surgery and keep their larynx.[29]

Additionally, some radiotherapy is given with chemotherapy in extraordinarily time-sensitive regimens, such as Zevalin® plus Rituxan® which must be followed by an infused radioactive agent within a narrow time frame. If the oncology practice were unable to offer both radiation and chemotherapy on site, any delay the patient experienced in traveling from one service provider to the other could both impair the treatment efficacy and result in significant financial losses if the radioactive agent cannot be administered within the required time frame. Any change of the IOAS that jeopardizes the ability of medical and radiation oncologists to operate within an integrated group would significantly impair the current standard of oncology care.

The ability to provide in-office imaging is also a cornerstone to modern day medical and radiation oncology. In the long run, integrating diagnostic imaging into oncology practices saves money and improves patients' quality of life by reducing the time and energy that otherwise might be spent on exploratory surgery or completing ineffective courses of therapy. To stage a disease properly, a CT and/or PET scan must be performed to determine the appropriate treatment course (i.e., surgery, radiation, chemotherapy or no therapy). Thereafter, the experience of our network indicates that as much as 35% of monitoring CT or PET scans (i.e., scans performed during the course of treatment to evaluate the progress of the treatment) significantly alter the course of treatment. In sum, the seamless integration of chemotherapy, radiation, diagnostic imaging and lab services into cancer care has contributed significantly to improvements in outcomes and the decision making process. As a result, numerous types of cancer are now being seen as treatable chronic diseases rather than as a death sentence.

The ability of oncology practices to offer in-office chemotherapy, radiation, imaging and lab services also facilitates participation in clinical trials. Trial sponsors prefer to contract with trial sites that can provide as many of the services as possible that are required under trial protocols to assess the changes induced by the experimental drug, device or procedure. It reduces trial costs, simplifies trial data gathering and permits more efficient trial oversight. When physicians are able to offer trial options in the community setting without requiring patients to change providers

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[27] Rowell NP, O'Rourke NP. Concurrent chemoradiotherapy in non-small cell lung cancer. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD002140. DOI: 10.1002/14651858.CD002140.pub2.

[28] Ragaz J, Olivotto IA, Spinelli JJ, Phillips N, Jackson SM, Wilson KS, et al. Locoregional Radiation Therapy in Patients With High-Risk Breast Cancer Receiving Adjuvant Chemotherapy: 20-Year Results of the British Columbia Randomized Trial. J Natl Cancer Inst 2004;97:116–26.

[29] American Cancer Society Website. Detailed Guide: Laryngeal and Hypopharyngeal Cancer Chemotherapy. http://www.cancer.org/docroot/CRI/content/CRI_2_4_4X_Chemotherapy_23.asp?sitearea=. Accessed August 28, 2007.

or to make visits to unfamiliar or inconvenient facilities for trial-associated imaging (which typically charge more than the trial site for the same test), more patients enroll in trials and trials can be completed more rapidly. For many patients, clinical trials represent the best hope (in some cases, the last hope) of treatment for their cancer.

As CMS considers revisions to the IOAS rules, we urge the agency to be mindful that eliminating or restricting oncologists' ability to offer chemotherapy, radiation, imaging or lab in their offices could exacerbate the challenges trial sponsors already face finding enough cancer patients to fill their trials.[30] There are over 400 new anti-cancer therapies currently in the research pipeline at U.S. pharmaceutical and biotechnology companies, many of which target the most lethal and/or the most common forms of cancer. Nonetheless, nationally only about 3% of all cancer patients participate in trials.[31] Although the situation has improved since the implementation of CMS' clinical trial National Coverage Decision in 2000,[32] Medicare beneficiaries are still under-represented in the ranks of cancer trial participants relative to the prevalence of the disease in the Medicare population. Any new policies that adversely impact clinical trial accrual likely will drive manufacturers to increase the proportion of trial participants recruited overseas, a fact that could undercut the ability of the Food and Drug Administration to adequately oversee the development of new therapies and the ability of CMS to make evidence-based coverage decisions based on data applicable to the specific population it serves.

We also note the increasing importance of the role of in-office pharmacies in the treatment of cancer patients and therefore the increasing need to preserve them under the IOAS. More and more cancer therapies are being formulated as oral medications. Many oral anti-cancer drugs stocked and dispensed through pharmacies operated by oncology practices are not readily available at local retail pharmacies because they are very costly, and relatively few patients need them. Cancer patients often feel more comfortable obtaining their oral anti-cancer medications in the same office setting where experts they already know and trust are available to answer their questions about drug administration protocols, missed doses and side effects. This comfort level, coupled with the convenience of taking needed medications home from the same office visit that generated the prescription, appears to improve patient adherence to the prescribed drug regimens. As a result, many physicians are of the view that having an in-office pharmacy (where local pharmacy laws allow) improves patient access to advanced oral cancer medications and patient compliance with oral treatment regimes as well.

Further, limiting DHS services that qualify for in-office delivery under the Stark Law to those "needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment," as suggested in the preamble to the Proposed Rule,[33] could have a significant negative impact on quality of care. For example, in the oncology context, clinical laboratory and imaging services often are performed at the time of a scheduled patient visit for chemotherapy or

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[30] ABC News, "Experts Weigh In: Shortage of Patients in Cancer Trials" (Aug. 1, 2006), available at http://abcnews.go.com/print?=2261005..

[31] John McKenzie, ABC News, "So Few Volunteers for Cancer Studies" (Aug. 1, 2006), available at http://abcnews.g.com/print?id=2261005 (quoting Dr. Robert Comis, Board President, Coalition of Cancer Cooperative Groups).

[32] "Impact of the Year 2000 Medicare Policy Change on Older Patient Enrollment to Cancer Clinical Trials," *Journal of Clinical Oncology,* vol. 24, pp 141-44 (Jan. 1, 2006).

[33] 72 *Fed. Reg.* at 38181.

radiation therapy, although the test results may be intended to provide baseline or follow-up data that the patient's physician will not use until a subsequent patient encounter. Moreover, the determination of whether a service is needed at the time of a particular office visit or later in treatment is a subjective matter not appropriate for regulation under a strict liability law such as the Stark Law. The physicians of the US Oncology network strongly believe good medical practice dictates that the IOAS rules permit oncologists and oncology groups to deliver all ancillary services necessary to the care of their cancer patients. Certainly, the timing of the provision of such services relative to face-to-face physician encounters should not be a determinative factor with regard to a practice's ability to provide needed services to its patients.

2. Definition of "Same Building" and "Centralized Building" in the IOAS Exception

CMS expressed concern in the preamble to the Proposed Rule about the location requirement in the Stark IOAS rules, particularly the current definitions of the "same building" and a "centralized building". CMS seemed particularly concerned about physicians' use of a "centralized building" to provide IOAS and also questioned the need for multiple centralized buildings.

For several reasons, many oncology practices use a "centralized building" for the provision of at least some of the IOAS involved in the comprehensive treatment of cancer patients. Many practices offer one or more outreach offices that provide local access to routine services or even sub-specialists (e.g., a pediatric oncologist) a few days a week. Such offices save patients in rural areas from traveling long distances for every physician encounter, an important consideration to patients battling cancer. In more urban areas, geographically dispersed physician office locations minimize cancer patients' tiring trips through traffic or on mass transit.

Additionally, the equipment necessary for cancer diagnosis and treatment is extremely expensive, and its purchase can only be justified by sufficient patient volumes to sustain reasonable equipment utilization levels. Without the use of centralized facilities to furnish certain DHS, many group practices could not afford to furnish their patients the best-available, evidence-based treatment options and the more sophisticated services that underlie recent improvements in cancer outcomes. Use of centralized buildings for DHS reduces overhead and unnecessary duplication of often costly equipment. Furthermore, the centralized building option helps address the fact that imaging and radiation therapy equipment cannot always be physically accommodated in every location. Moreover, without the centralized building provision, groups would be unable to provide diagnostic imaging such as PET to their patients through mobile units, which allow important technology to be offered in locations that are otherwise unable to accommodate it within the building.

CMS also noted commenters' assertions that the Congress did not intend for a group practice to have multiple centralized DHS locations (other than for the provision of lab services). In the absence of any statutory language or other evidence of such intent, such comments appear to be largely motivated by certain providers' desire to reduce or eliminate competition. The commenters ignore the previously mentioned fact that physician groups (particularly large ones) serve significant geographic areas through locations that meet either the same or centralized building tests. Eliminating the option of multiple centralized buildings would cause groups to

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either abandon those markets or replace those sites with locations that satisfy the same building requirements, where possible, which can result in unnecessary expenditures. Prohibiting multiple centralized buildings would reduce competition and create an economic benefit in favor of one class of provider, to the detriment of other physicians who would otherwise serve patients in that market. Such governmentally sanctioned protectionism would not only contradict the statutory language but also inappropriately serve select private businesses' interests to the detriment of consumers and taxpayers.

We fear that changes to the current definition of a "centralized building" for the provision of certain ancillary services would discourage oncologists from operating outreach offices and could potentially raise the cost of care to the healthcare system as a whole. Because of the adverse impact that restricting the current flexibility of the IOAS rules would have on cancer care, in lieu of adding requirements to or imposing carve-out limitations on the ancillary services that oncologists can furnish in their offices, CMS should adopt other approaches to controlling perceived self-referral abuses, such as the reassignment provision detailed in the Proposed Rule. CMS should not make changes to the IOAS provisions that will undermine the progress being made in oncology outcomes or upset the balance Congress intended to achieve when it included the IOAS exception in the Stark Law.

3. Non-Specialist Referrals for Specialized Services Using Equipment Owned by the Non-Specialists

As noted previously, many medical and radiation oncologists practice in integrated groups that operate comprehensive cancer centers, wherein the medical and radiation oncologists invest in highly specialized equipment, such as linear accelerators, used to deliver care to their patients. Medical oncologists frequently refer patients to their radiation oncologist colleagues for radiation therapy, and that intra-group referral is made possible under the current IOAS rules. The lack of any definition in the preamble for "nonspecialist physician" or "specialized services" raises uncertainty as to whether the same concerns raised in the IOAS section of the Proposed Rule would apply to a medical oncologist's referral to a radiation oncologist for radiation services provided on equipment owned by the medical oncologists' and radiation oncologists' group practice. However, since this type of integrated care is both unquestionably beneficial to cancer patients and widespread in oncology, we strongly contend that medical and radiation oncologists should be able to continue to practice as members in a single, integrated group practice offering the full spectrum of cancer-related services (i.e., chemotherapy, radiation, imaging and lab services) under the IOAS exception.

By contrast, most oncology practices currently do not have radiologists as members of their group practices since most do not need radiologists to support group practice activities on a full-time basis. However, many oncology practices own, operate and maintain the imaging equipment needed to provide the disease staging and progress tracking essential to informed cancer treatment planning and decision-making. They also may own certain radiation therapy equipment that is equipped with image-guided radiation therapy (IGRT) technology. The technicians who operate the imaging and radiation equipment and who interact with practice patients during imaging and radiation visits typically are employed by the oncology groups and supervised by the group's physicians.

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Since the Proposed Rule is asking for comments on this issue, rather than offering proposed language at this time, it is unclear whether either of the above situations is something CMS would contemplate regulating. If it is, the physicians of the US Oncology network believe integrating imaging, medical oncology and radiation therapy into one practice improves the quality of care cancer patients receive. Further, diagnostic imaging is the starting point of all oncology treatment planning and provides crucial support throughout the course of treatment. Being able to offer in-office imaging services facilitates timely receipt of diagnostic results and, in turn, allows oncologists to report those results, answer patients' questions and, if necessary, realign treatment plans more rapidly. The oncologists tasked with making treatment decisions should be in a position to control how the radiation and imaging equipment is calibrated, maintained and operated; how their technicians are trained; how results of imaging studies are reported; how their patients are treated during radiation and imaging sessions; and how their patients are advised of the outcomes of their diagnostic procedures. In-office radiation and imaging also facilitate the ability of community-based oncologists to participate in clinical trials, which offer patients – particularly those who have failed on conventional therapy –access to treatments that would otherwise be unavailable unless they traveled to a major academic medical center, which might be hundreds of miles away.

The specialist/non-specialist distinction described in the Proposed Rule does not adequately distinguish between relationships that may be abusive and others that are not. In fact, implementing such a distinction in this context could prevent ownership arrangements that have sound clinical justifications and provide patient benefits. CMS should realize that any change in the IOAS rules that would restrict the types of radiation and/or imaging equipment ownership described above would undermine the ability of oncologists to provide the type of integrated, coordinated comprehensive cancer care that yields the best outcomes for patients dealing with this difficult disease.

Services Furnished "Under Arrangement"

CMS Should Amend the Proposed Definition of "Entity" to Avoid Inadvertently Implicating Billing and Management Services Companies in Stark Law Violations

The Proposed Rule would revise the definition of an "entity" under the Stark Law. "Entity" is a key term under the Stark Law since a physician may not make a referral to an *entity* for DHS if the physician (or an immediate family member) has a financial relationship with that entity, unless a statutory exception applies. Under the current regulations, entity primarily is defined in terms of whether a person or business organization "furnishes" a DHS. Specifically, a person or organization furnishes a DHS if it is "the person or entity to which CMS makes payment for the DHS, directly or upon assignment" or the "person or entity to which the right to payment for the DHS has been reassigned" under certain circumstances.[34]

The revised definition in the Proposed Rule would expand the definition of entity by stating that a person or entity is considered to be furnishing a DHS if it either: "(i) has performed the DHS,

[34] 42 C.F.R. § 411.351.

or (ii) presented a claim or caused a claim to be presented for Medicare benefits for the DHS."[35] The US Oncology physician network believes CMS has unintentionally broadened the definition of entity in a way that could be read to include management and billing companies. Based on the discussion in the preamble to the Proposed Rule, it appears CMS did not foresee or intend this result. Nonetheless, defining entity in this way could have significant negative consequences for management and billing arrangements throughout the healthcare industry. Because billing or management services companies submit claims for DHS on behalf of their physician or provider clients, for purposes of the Stark Law, they arguably "cause a claim to be presented" for DHS, thereby inadvertently implicating the billing or management services companies in potential Stark Law violations. It is important to avoid such misconceptions since violations of the Stark Law are subject to strict liability standards.

To protect billing and management services companies from these unintended consequences, we suggest revising subparagraph (1)(ii) of the proposed definition of entity at 42 C.F.R. § 411.351 to read as follows:

> (ii) Presented a claim or caused a claim to be presented *under its Medicare provider or supplier number* for Medicare benefits for the DHS (emphasis added).

This suggested revision would eliminate any possible misapprehension that the Stark Law generally implicates billing or management services companies as "entities" subject to the law's prohibitions.

CMS also has requested comments more generally on whether and how the definition of entity should be changed. In particular, it asked for comments on the appropriateness of using MedPAC's proposed definition of "entity."[36] If CMS chooses to adopt the MedPAC definition (or any revision to the definition of entity), the US Oncology physician network urges it to review closely the definitional change to ensure it does not broaden the reach of the prohibitions against physician self-referrals beyond what is strictly necessary to prevent abuse.

Unit-of-Service ("Per-Click') Payments in Space and Equipment Leases

CMS Should Continue To Allow "Per-Click" Payments for Space and Equipment Leases

The Proposed Rule contains a provision that would prohibit unit-of-service or "per-click" payments to physician lessors of space or equipment for services provided by the lessee to patients referred by the lessor physician. The preamble to the Proposed Rule also asks for comments on whether time-based or unit-of-service payments to an entity lessor by a physician lessee also should be prohibited to the extent that these payments reflect services provided to patients sent by the lessor to the physician lessee.

As CMS explicitly acknowledged in the Stark II/Phase I regulations, the legislative history of the Stark Law clearly indicates that "Congress intended that time-based or unit of service based payments be protected [under the Stark Law and regulations] so long as the payment per unit is

[35] 72 *Fed. Reg.* at 38224.
[36] 72 *Fed. Reg.* at 38178. *See also supra* note 15 at p 170.

at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals."[37] The Phase I and Phase II regulations incorporated the Congressionally mandated approval of such per-click arrangements, and many arrangements have been structured accordingly since their publication. While CMS does possess authority under § 1877(e)(1) of the Stark Law (the space and equipment lease exceptions) to impose other requirements by regulation to protect against program or patient abuse, it is open to question whether that authority allows the agency to override a clear Congressional mandate.

We also respectfully note that frequent changes in regulatory standards are extremely disruptive to the continued provision of services to Medicare beneficiaries and other patients across the country. A number of the regulatory revisions discussed in the Proposed Rule, such as the proposed limitation on per-click compensation, could lead to tremendous disruption if finalized since they will require many common arrangements to be unwound. Most of these arrangements were originally structured in good faith reliance on the existing regulations, which were last clarified in 2004 after CMS had taken several years to consider and address the issues raised in the 1998 proposed Stark II regulations and the comments submitted on the 2001 Stark II/Phase I regulations. In some instances, the Stark II/Phase II positions, in turn, contradicted positions that CMS had espoused earlier. The uncertainty created by so many policy "about-faces" makes it extremely difficult to conduct legitimate business operations and, in turn, could have a negative impact on patient access to high-quality services.

Unit of service/time-based/per-click compensation methodologies were sanctioned by Congress and later by CMS and therefore should not now be set aside by CMS. However, if CMS chooses to implement the proposed restriction on per-click payments, we respectfully request that the agency provide clear, detailed and practical guidance on how arrangements are to be analyzed in light of this and the other revisions to the Stark Law that all may have an overlapping impact on many common business arrangements.

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

CMS Should Clarify that the Proposed Revision to the Anti-Markup Provision Does Not Apply When the Physician or Group Performs Diagnostic Test Components Through a Block Lease

The Proposed Rule seeks to modify the provisions in 42 C.F.R. § 414.50 in order to prevent physicians and group practices from purchasing the technical component (TC) or the professional component (PC) of most types of diagnostic tests, and marking them up when they bill Medicare for the services that actually were furnished by an outside supplier. We understand the basis for CMS' concern about the potential for over-utilization in these types of arrangements when, as CMS postulates in the preamble discussion, the physician or group is paying the outside supplier on a unit of service ("per-click") basis.[38] In this context, it is readily apparent how the practice might add an unwarranted profit margin onto the cost per test that it pays the outside supplier.

[37] 66 *Fed. Reg.* at 876.
[38] 72 *Fed. Reg.* at 38180.

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By contrast, it is common throughout the industry for a physician or group to perform the TC of a diagnostic test through a block lease (*i.e.,* a flat fee lease for a portion of one or more days) for equipment, space and potentially support staff. In other words, a physician may pay an outside lessor a fixed amount for a specified period of time to lease the space, equipment and/or technicians needed to perform certain diagnostic tests. The Stark Law currently permits block leases if the lessee performs the tests in the same building where non-DHS services are rendered or a centralized building used by the practice for the provision of DHS, but in either case, the lease must fulfill all of the requirements of 42 U.S.C. § 1395nn(e)(1)(B). We believe block leases are readily distinguishable from per-click arrangements and thus should not be subject to the same anti-markup provision. In particular, block leases require the lessee to undertake significant business risk, which is not the case when diagnostic tests are purchased on a per-click basis. Block leases allow physicians and groups to share in the capital costs of equipment that would not be economically feasible for one physician to incur.

Further, as a practical matter, it would be extremely difficult to implement the anti-markup provision in the context of a block lease since there is no way to determine the supplier's net charge for each individual test. Since the lease payment is fixed but the number of tests performed on any given day is not, if the lease payment is allocated among the actual number of scans performed on a particular day, the "per scan" net charge could fluctuate on a daily basis. Because block lease arrangements do not pose a significant risk of program abuse, CMS should exempt them from the anti-markup provision in the Proposed Rule. Such an exemption would be analogous to the exception proposed for PCs ordered by independent laboratories

CMS Should Clearly State that Any Revisions to the Anti-Markup Provision Are Directed at and Limited to Diagnostic Tests

The title of the section of the preamble in the Proposed Rule that relates to the Anti-Markup Provision refers exclusively to "diagnostic tests."[39] However, the section of the preamble that follows discusses various related issues, including CMS' request for comments on applying an anti-markup provision to non-specified TCs that are performed in a centralized building. We would appreciate CMS providing clarification in the Final Rule that any changes ultimately implemented to the Anti-Markup Provision relate exclusively to the provision of diagnostic tests.

Need for a Grace Period

CMS Should Allow Industry a Grace Period to Come Into Compliance with Any Changes

In light of the complexity of the Stark Law, the proposed number of changes to the regulations detailed in the Proposed Rule, the lack of any specific proposed language in many cases, and the fact that codification of many of these proposals could require the revision or unwinding of many arrangements throughout the healthcare industry, we strongly encourage CMS to provide a grace period for compliance. The fact that so many variations in regulatory approach are presented in the preamble to the Proposed Rule makes it virtually impossible to know which provisions will be finalized and what language they will contain. As a result, physicians and other entities subject the Stark Law cannot do much advance preparation for changes that may eventually

[39] 72 *Fed. Reg.* at 38179-80.

materialize. Once new regulations have been finalized, virtually every healthcare provider will have to review the final language to determine which, if any, arrangements need to be modified, and then negotiate necessary changes and replace or unwind the arrangements. Health care contracts often take months to negotiate, and it is to be expected that revisions to these contracts will similarly require months to accomplish. Therefore, we ask that CMS provide a grace period of at least one year from the date final regulations are published to allow companies to come into compliance with any revisions to the Stark regulations.

On a final note, while we understand and share the government's concerns with abusive arrangements, CMS should not ignore the challenges of the healthcare industry in complying with the Stark Law. Even the current level of regulation creates tremendous administrative burdens for those providers, which are exacerbated by the fact that many of the regulations leave "gray" areas. Because the Stark Law is a strict liability statute, providers face tremendous potential liability if they do not comply with those often-ambiguous parameters. We urge CMS to balance the appropriate goal of eliminating abusive arrangements with the need to provide medically necessary, high-quality care to Medicare beneficiaries in an efficient, clinically appropriate, convenient and commercially reasonable manner. Further, in accordance with the goals often stated in prior Stark regulatory preambles, we hope CMS will continue its efforts to provide "bright line" guidance. Particularly in the context of the strict liability Stark Law, the industry needs clear, consistent guidance on the types of arrangements that are legally permissible.

DRUG COMPENDIA

Insuring Availability of Compendia

CMS Should Not Allow the Number of Available Compendia To Fall To One and Should Approved the NCCN Drugs and Biologics Compendium without Further Process

Section 1861(t)(2) of the Act specifies three compendia for use in determining "medically acceptable indications" for anti-cancer drugs. One of these is no longer in publication. Another has changed ownership and name. CMS notes that it confronts the issue of whether the United States Pharmacopoeia-Drug Information, the third compendium, which has been acquired by Thomson Micromedex and renamed DrugPoints, constitutes a "successor" publication and hence would be retained for use under the authority of section 1861(t)(2) of the Act. If the Secretary does not so determine, the number of compendia available could fall to one, which we believe would be undesirable.

We think it is incumbent on the agency to recognize a reasonable number of compendia. If only one compendium is listed, not only would therapeutic choices available to Medicare beneficiaries be potentially restricted, but decisions as to which "medically acceptable indications" are covered would in practice be left largely to a single, non-governmental organization. Candidate compendia differ in a number of dimensions that potentially affect how they marshal and review evidence and as to which uses are supported by that evidence; having more than one prevents the peculiarities of a single compendium from determining Medicare coverage and payment for anti-cancer drugs.

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We urge that the Secretary insure that the number of approved compendia not fall to one. If the Secretary is prepared to conclude that DrugPoints does not qualify as a successor publication, we request that the Secretary: (1) make available the reasoning for this decision for public comment, in accord with our comments below about removal of a compendium, (2) add one or more other compendia under the authority of 1862(t)(2) so the number does not fall to one, and (3) retain DrugPoints at least until one or more other compendia have been added or DrugPoints has been reaffirmed as authoritative under 1862(t)(2).

Further, CMS has received a request to add to the list of recognized compendia the National Comprehensive Cancer Network's ("NCCN") Drugs and Biologics compendium. This request has been before the agency for an extended period, and the agency has already thoroughly assessed the compendium's characteristics.[40] The candidacy of this compendium is already well known within the oncology community. We believe the Secretary should add this compendium to the list and should do so as soon as possible, without invoking the lengthy, additional process for review proposed in this rule. We urge CMS to add the NCCN compendium by the start of calendar year 2008.

Revisions to the List of Compendia

CMS Should Establish Different Processes for Adding and Removing Compendia

Section 1861(t)(2) of the Social Security Act contemplates revision of the list of compendia in two ways: (1) potential addition of "other authoritative compendia" to the three listed in the statute and (2) revision of the list "as appropriate." Exercising either of these provisions requires the Secretary to interpret the meaning of the terms "authoritative" and "as appropriate." We believe the explicit separation, in the statute, of the provision for adding "other authoritative compendia" from the provision for "revising" the list of compendia is important. Our interpretation is that Congress intended for CMS to establish different processes for accomplishing these actions.

Specifically, the use of the words "other authoritative compendia" makes it explicit that the specified compendia "are authoritative" and appears to allow the Secretary to establish criteria and a process for adding other "authoritative" compendia. Significantly, because § 1861(t)(2)(B)(ii)(I) contains the authority to add compendia , there would appear to be no need for the additional provision allowing the Secretary to "revise" the list unless the purpose of revision was to remove compendia from the list. Because all compendia on the list must be authoritative, it would appear that the list can only be "revised" when one or more listed compendia become "unauthoritative" and the statute appears to allow the Secretary to establish a process for revising the list that is different from the process for adding authoritative compendia. We discuss this issue in more detail below.

According to the proposed rule, CMS believes that a clearly articulated process for addressing which compendia should be listed is desirable. As we discuss below, we are concerned about the

[40] This review included an evaluation by the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) which found that the NCCN compendium attained more of the "desirable characteristics" than the other compendia evaluated, including the compendia specified by law.

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proposed definition of a compendium and believe the proposed process is not clear, would take longer than necessary, and could lead to poorly justified and arbitrary decisions.

Proposed Definition of a Compendium

CMS Should Not Judge the Acceptability of Compendia Based on Indexing Approach

CMS proposes a definition of a compendium that we believe is problematic.

First, CMS proposes that a compendium, at least for the proposed purposes, "includes a summary of pharmacologic characteristics of each drug or biological and *may* include information on dosage, as well as recommended or endorsed uses in specific diseases."(emphasis added). We believe the reasoning or the drafting here is faulty, since it appears to not require information on "medically accepted indications" – that is, information on recommended or endorsed uses in specific diseases. Without this information, we fail to see how a compendium can be understood to achieve the purpose of section 1861(t)(2)(B)(ii)(I) of the Act. In addition, we believe a compendium should include information on dosage if it is to be taken seriously as a resource for clinical use.

Second, CMS proposes to require that a compendium be *indexed* by drug or biological, rather than by disease. The discussion in the preamble suggests CMS may be in fact concerned with the *central organizing principle* of a compendium, since clearly any compendium could be indexed by either drug or disease or both. The preamble states, "We believe that the use of compendia to determine medically-accepted indications of drugs and biologicals in the manner specified in section 1862(t)(2)(B)(ii)(I) of the Act is more efficiently accomplished if the information contained is organized by the drug or biological . . . ."

We dispute this notion. A compendium may in fact be more useful to and more efficient for clinicians if it is organized by disease, whether or not such organization also constitutes a disease treatment guideline. Particularly in an era of electronic data bases, to consider the method of organization as a critical defining element of whether something is an authoritative compendium appears in no small measure irrelevant. We believe the operative question should be whether a compendium contains reliable information about "medically accepted indications" in a fashion that is readily accessible to its various users, including prescribing clinicians, beneficiaries and Medicare contractors. We are concerned that insistence on organization by drug or biological may lead CMS to exclude authoritative compendia, reasonable in other characteristics, from consideration under 1861(t)(2) in an arbitrary fashion. In short, the Secretary should not exclude from consideration a compendium as "authoritative" and/or find its exclusion "appropriate" because it is not "indexed" by drug or biologic or because it is indexed by drug and biologic as well as by disease.

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Proposed Criteria by Which Compendia Are To Be Judged

CMS Should Articulate Objective Criteria for Assessing Compendia and Implement an Expedited Decision-Making Process that Allows for Public Comment before Decisions Are Finalized

We are very concerned by the vagueness in how CMS proposes to apply criteria in judging whether a compendium should be added to (or possibly deleted from) the list. The preamble describes the "MedCAC-recommended desirable characteristics," and we agree that these criteria appear desirable and most would be appropriate for determining which compendia should qualify as authoritative or otherwise be appropriate under 1862(t)(2).[41] However, CMS notes that it will "consider a compendium's attainment" of these characteristics, without giving any indication of how it will do so. The preamble notes that none of the currently designated compendia, and in fact none of the six compendia reviewed by the MedCAC, meet all of these criteria. Thus it appears CMS will be compelled to exercise significant judgment regarding which criteria will be considered most important or how they will be weighted. Presumably a compendium could fail to exhibit several characteristics and would still be acceptable, but CMS has not spelled out, for instance, whether some characteristics are more important than others and if one or more of the characteristics would be considered critical, so that a deficiency in a particular area would be fatal to a compendium's candidacy. Further, there is no assurance that CMS would evaluate all candidate compendia similarly (e.g., against the same criteria and weighting those criteria identically).

The preamble then goes on to state that CMS may consider "additional reasonable factors" in making its determinations. This notion is extraordinarily broad, providing little indication of what the agency might ultimately consider "reasonable." Finally, the agency proposes to consider a compendium's grading of evidence and the process it uses. No detail is provided on how this consideration is to be undertaken or whether it will be applied identically in each case.

We recognize CMS faces a difficult problem in this area. The number of requests is likely to be small, the number of possible considerations large, and the task of clearly articulating *ex ante* a fully developed scheme for review is substantial. However, the likely outcomes of the current proposal are unclear and unpredictable. In these circumstances, we think that the agency at least should articulate for public review and comment its reasoning in particular cases. CMS's proposed process allows for comment on the requests, but not on CMS's decision. We urge CMS to revise its proposed procedure to permit comment by the public on CMS's reasoning relating to any request (whether generated internally or externally) for revision. Specifically, we recommend that, similar to National Coverage Determinations ("NCD"), CMS publish a "proposed decision" for each compendia reviewed and allow the public 30 days to submit comments on its proposal and then publish a "final decision" after considering those comments.

Lastly, we believe the proposed timeline is too long. We believe the entire process can be accomplished in six months, similar to the timeline for NCDs and ask CMS to explain why it believes this process should take longer.

[41] We note that one of the characteristics is "quick throughput," the desirability of which and connection to the authoritative character of a compendium, depends, in part, on the definition of "quick."

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Possible Removal of Compendia

CMS Should Adopt a Separate, Deliberative Process for Considering the Removal of Compendia

The physicians of the US Oncology network believe the issue of public notice and comment is particularly critical should CMS need to address any request for removal of a compendium. Once compendia are included on the list for use in determining medically accepted indications, they become inextricably linked to not only Medicare coverage, but to how clinicians treat patients and to the standard of care. The two currently listed compendia have been used by Medicare since at least 1994 and are of central importance in determining coverage in this area. Any compendium subsequently added will similarly become woven into the fabric of clinical and coverage decisions.

We see this matter as particularly concerning because requests for removal of compendia may originate with other compendia for competitive reasons. In our view, the potential for such an occurrence reinforces the need for a thorough, deliberative process that includes identification of the requestor (as CMS has proposed) and the opportunity for public comment prior to removal.

Any compendium should be removed only after systematic review and evaluation demonstrates material failures in its reliability as authoritative, after the sponsor has had an opportunity to address any ostensible deficiencies, and after notice to the public and full opportunity to comment on the agency's reasoning in proposing removal. The public's interest would be best served if this notice were accomplished by publication in the *Federal Register.* Removal of any compendium will necessitate revisions of local coverage policies, a time-consuming process involving its own notice-and-comment requirements, and we believe CMS should make appropriate accommodation for this process in its timelines.

Specifically, we advocate the following steps for addressing any request for removal:

1. Publication of a notice of request for removal that identifies the requestor, includes the complete text of the request including the reasons why the compendium should be removed, and includes solicitation of public comment on the request.
2. Publication of a complete review of the compendium against the criteria used to determine whether a compendium is authoritative and a proposal for its retention or removal from the list. The review should include consideration of any public comments; identify any specific shortcomings and deficiencies of the compendium proposed for removal; and articulate the specific justification for the proposal.
3. Provision of an opportunity for public comments on the proposed decision and a reasonable period of time (e.g., until publication of the next edition of the compendium) to allow the compendium to cure any cited deficiencies.
4. Publication of a final decision, that includes specific reasons for retention or removal, after a review of comments on the proposed decision and a determination as to whether the compendium cured the cited deficiencies.
5. Provision for continued use of the indications in the removed compendium until such time as CMS and local contractors can develop new coverage determinations that take into account the removal of the compendium.

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Because the process for removal of a compendium from the list should be deliberative and thoroughly vetted, a longer timeframe than the six-month timeline we have recommended for adding compendia would be appropriate. Specifically, the need to allow a compendium to cure any cited deficiencies and to allow CMS and its contractors to develop new coverage determinations would require that the timeframe for removing a compendium from the list more than one year.

When "Use" is "Not Indicated" in a Compendium

CMS Should Deny Coverage Based on a Single Compendium's Assessment Only If that Compendium Has Expressly Identified a Use as "Not Indicated"

We are concerned about a possible interpretation of the statute by CMS or its contractors in this area that could affect the views of CMS and the public about how many and possibly which compendia should be included on the list. Section 1862(t)(2)(B)(ii)(I) specifies that if an indication is supported by one citation in one compendium that indication must be covered by Medicare unless either (1) the Secretary makes a determination that the use is not medically appropriate, or (2) the use is specifically identified as "not indicated" in one or more compendia.

This last point is very important: a compendium must specifically state that a use is "not indicated" in order for that citation to contradict any listing in any other compendium supporting use. In our view this means the citation must specifically use the words "not indicated." If a citation says "not recommended" or "recommended in some cases" or "equivocal" or uses any words other than "not indicated" then this provision does not apply. "Not recommended" has an entirely different meaning than "not indicated." "Not indicated" is an absolute term that conveys to physicians that a use is dangerous and that no benefit is provided by a drug. "Not recommended" does not mean that. "Not recommended," "recommended in some cases," "equivocal" or other, similar terms may mean that the benefits are unknown or may not outweigh the risks but these terms do not mean "not indicated." As a corollary, we believe any citation using the words such as "recommended in some cases" or "equivocal" satisfies the requirement for a "use that is supported by one or more citations" in a compendium.

CMS has articulated its view of the appropriate policy on this pint in the Medicare Benefit Policy Manual, Chapter 15 § 50.4.5, using the term "not indicated." We request that CMS affirm, in the 2008 PFS Final Rule, its agreement with this policy.

Summary of Key Compendia Recommendations

In summary, the US Oncology physician network believes CMS should:

- Maintain a reasonable number of compendia. In particular,
  - Either determine that DrugPoints is a successor publication, approve it as an "other authoritative compendium" without interruption of service, or approve other compendia before it is removed.
  - Approve the NCCN's Drugs and Biologics Compendium before the end of the year.

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- For future additions to the list of compendia, provide for a comment period on CMS' proposed decision.
- For any possible future deletions from the list of compendia, including any possible removal of DrugPoints, follow a careful and deliberate process, with adequate opportunity for public input, as outlined above.

RESOURCE-BASED PE RVUs

Equipment Usage Percentage

CMS Should Ensure that Any Change in the Assumption about Equipment Utilization Used to Set PE RVUs Is Reflective of Data Stratified by Equipment Type and Minutes of Equipment Use across a Broad Spectrum of Physician Practices

Under the current PE methodology, CMS assumes all capital equipment is used 50% of the time based on potential use of 150,000 minutes per year (i.e., six days or forty eight hours per week, fifty weeks per year). This means CMS assumes capital equipment is used 75,000 minutes per year or four hours per day, six days per week.

The equipment portion of the payment rate for a given service (e.g., an MRI) is calculated on a per minute basis with the amount per minute determined by the total minutes of use (i.e., 75,000) multiplied by the number of minutes the equipment is in use for the service. Therefore, in addition to reviewing the equipment use percentage, CMS also needs to review the total number of minutes the equipment is in use per year.

This is an important distinction because the minutes of use per year is a more accurate reflection of real use than a percentage and is more easily calculated by many physician practices. Moreover, for physician practices that open five days a week, which is typical for most practices, the total potential time of equipment use may be less than 150,000 minutes because those practices may only be open forty or forty-five hours per week. Similarly, 50% usage for those practices would be less than 75,000 minutes per year, meaning the costs of equipment for those practices may not be appropriately accounted for by CMS.

US Oncology network practices own or lease many types of imaging equipment including mammography equipment, ultrasound equipment, MRI, CT, PET, and PET/CT scanners, but the predominant imaging equipment used by network practices are CT, PET and PET/CT scanners. We have undertaken a systematic review of how PET (including PET/CT) and CT scanners are used. US Oncology network practices have a total of 37 PET (including PET/CT) scanners and 66 CT scanners. Based on the annualized first half 2007 utilization data, the median and mean number of minutes that the PET scanners will be in use in 2007 is 33,906 and 37,852 per year respectively and the median and mean number of minutes the CT scanners will be in use is 30,218 and 34,563 respectively per year. Further, only 2 PET scanners and 4 CT scanners will be used more than 75,000 minutes per year. In addition, 95% of PET machines and 94% of CT machines operated under 75,000 minutes (or the current assumption of 50% utilization per the CMS 150,000 minute standard) and 57% of PET machines and 56% of CT machines operated under 37,500 minutes (or 25% utilization per the CMS 150,000 minute standard).

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We believe our data supports continuing the current CMS assumptions of 50% usage and 75,000 minutes of total use per year. Further, if CMS wishes to review these assumptions going forward, we recommend that it work closely with the physician community to design appropriate surveys that capture equipment use, stratified by equipment type, across a wide range of practices and that data be collected both on a percentage of use and a total minutes of use basis. We further urge that before CMS proposed to change its utilization assumptions with respect to either the total minutes/yr equipment is in use or the percentage of total minutes the equipment is in use per year that CMS work closely with the physician community to determine (1) whether its assumption that 150,000 minutes/yr represents the potential total use of equipment is actually correct, and (2) the total number of minutes equipment is "used" for a single procedure. The second point is critically important because our estimate of the number of minutes our PET, PET/CT, and CT scanners are in use "per procedure" is significantly different from the data contained on the CMS website and in the RUC database.

Coding – Payment for the IVIG Add-On Code

CMS Should Defer the Decision about the Need for an IVIG Pre-Administration Service Fee in 2009 until Next Year

The US Oncology physician network applauds CMS' decision to continue reimbursing providers in 2008 for pre-administration services associated with intravenous immune globulin (IVIG) treatments. We encourage you to delay making a decision about the appropriateness of discontinuing payment for IVIG pre-administration services in 2009 absent more current information about the then-existing IVIG market showing more adequate supplies and more affordable prices than exist today.

Currently, US Oncology, operating as the buying agent for its affiliated practices, has somewhat limited access to IVIG. Despite our continuing best efforts to negotiate additional supplies, we only are able to secure product from the IVIG manufacturers on an allocated basis. Each of the manufacturers with whom we deal claims not to have any additional product available and the supply situation does not appear to be improving.

We estimate our practices are able to meet only about 75-80% of their immune globulin needs through the existing US Oncology IVIG agreements. Beyond this, practices in the USON network must search for product from secondary distributors. We and the physicians with whom we work are always concerned when practices must acquire IVIG or other pharmaceutical products from secondary distributors because of the product integrity risks that may attach. We also understand some affiliated practices are, at times, unable to locate adequate IVIG supplies in the secondary market. In those instances, these practices have little choice but to turn away new cancer patients that, due to their illness or to the side effects of their treatment, need IVIG treatments to replace depleted antibody stores and ward off susceptibility to serious infections. Our practices then invest additional time and effort to locate other providers with access to enough IVIG to treat the patient. They deserve to be compensated for this administrative work.

Reimbursement for the two IVIG products that our network physicians use about 90% of the time – Carimune and Octagam – is not always adequate to cover acquisition cost. In fact, currently Octagam costs network physicians $68.90/gram even though reimbursement is only

$66.97/gram. The situation is not quite so dire with respect to Carimune in that the product costs $48/gram and is reimbursed at $53.66/gram. Of course, the acquisition costs for product that physicians must purchase in the secondary market is typically higher. Given that dosing for IVIG products varies widely depending on the patient's condition, but typically ranges somewhere between 5 grams to 30 grams, allocation of the pre-administration fee across the dose barely allows physicians to break even or make a minimal profit on the IVIG products used by our affiliated practices when they are able to buy the necessary product under contract. We suspect pricing pressure on many community oncologists is significantly worse. As a result, we are of the view that it would be premature for CMS to make a decision now about the need for continued payment of the IVIG pre-administration service fee in 2009. Rather, it should wait until it undertakes next year's PFS rulemaking and asses the market situation at that time.

TRHCA – SECTION 101(B): PQRI

Mechanism for Submission of Data on Quality Measures via Electronic Health Record

CMS Should Work with US Oncology to Permit PQRI Reporting for Its Network Physicians via Electronic Health Record in CY 2008

Section 110(b) of the Tax Relief and Health Care Act of 2006[42] (TRHCA) established the Physician Quality Reporting Initiative (PQRI). US Oncology and its network physicians have long been supporters of developing evidence-based guidelines for cancer care, educating physicians on those guidelines, promoting adherence to guidelines and measuring how well physicians follow them. Therefore, the US Oncology physician network supports the concept behind the creation of the PQRI.

However, we have reservations about using only claims data to measure quality and, in the case of the PQRI, it has determined that the costs of implementing the PQRI will be far greater than the potential bonus payments associated with the PQRI unless a medical practice uses an electronic health record (EHR) that can report the PQRI quality measures in a completely automated fashion. Therefore, participation of US Oncology physicians in the PQRI will likely be limited to only those practices with an EHR.

The US Oncology physician network is not prepared to comment on the 2007 PQRI at this time. Nonetheless, we want to urge CMS to provide an opportunity to comment on the 2007 program in next year's proposed PFS rule so that the CY 2009 PQRI development can be informed by the CY 2007 experience.

In addition, US Oncology is very interested in using the EHR capabilities of the practices it manages to collect and report QPRI data in registry format for in CY 2008. We would like to explore the feasibility of doing this with CMS and believe our EHR and data collection capabilities meet the requirements set forth in the proposed rule: HIPAA and CHI compliance, capable of interfacing with the CMS clinical warehouse electronic data exchange interface (EDI), and ability to collect key data elements. We believe that provider based data collection

[42] Pub. L. 109-432).

processes have advantages over registries maintained by specialty societies and encourage CMS to test provider based registries such as ours.

TRHCA – SECTION 110: ANEMIA QUALITY INDICATORS

CMS Should Define Whether Physicians Are To Report Hemoglobin or Hematocrit, When They Are to Measure the Required Data and Where They Are to Enter the Data on the Claim Form

Section 110 of TRHCA requires that "[e]ach request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual." Even though this reporting is mandated for drugs furnished on or after January 1, 2008, the requirement must be implemented through notice and comment rulemaking.

The Proposed Rule is silent on a number of important issues related to implementation of this TRHCA provision. These include:

- When does the information on the hemoglobin or hematocrit level need to be obtained in relation to the administration of the drug given for the treatment of anemia?
- The manner in which, and the placement of, the hematocrit or hemoglobin information must be included on the claims form.

We recommend that CMS not establish any specific requirement for when the hemoglobin or hematocrit information should be obtained and should only require that "the most recent hemoglobin or hematocrit level" be placed on the claim. This is because physicians regularly obtain hemoglobin levels from patients undergoing chemotherapy in order to determine whether they can tolerate chemotherapy and the timing and frequency of these determinations depends on the chemotherapy regimen being administered not on when erythropoiesis stimulating agents ("ESAs"), such as erythropoietin or darbepoietin, are administered. Unlike chemotherapy cycles, ESAs are administered regularly (e.g., weekly or biweekly) while patients are receiving chemotherapy because it takes up to eight weeks for them to stimulate red blood cell production and hemoglobin levels are not obtained before each ESA dose and physicians do not obtain hemoglobin or hematocrit levels before each ESA dose is administered. Requiring that a hemoglobin or hematocrit level be obtained prior to each dose of an ESA, would result in many medically unnecessary blood tests and could inappropriately affect patient care. ESAs are administered to prevent severe anemia and avoid blood transfusions so ESA administration is based on the physician's expectation of how the chemotherapy regimen will affect the red blood cell count over the next few weeks rather than on what the red blood cell count is at any particular time. In other words, depending on the chemotherapy regimen, it may be entirely appropriate for a patient to receive an ESA irrespective of the hemoglobin level because without the ESA the hemoglobin level will fall dramatically resulting in the need for a red blood cell transfusion two or three weeks hence.

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With regard to how the information should be reported on a claim, we note that historically, information on hemoglobin or hematocrit levels has been placed in Box 19 of the CMS 1500 form. However, as of June 2, 2007, the CMS 1500 form has been modified to allow reporting of hemoglobin levels in Box 24A (call the "shaded area of Box 24A). Unfortunately, many billing vendors and provider software systems cannot currently accommodate reporting of hemoglobin or hematocrit levels in Box 24A because most billing vendors and software suppliers have been focused on assuring their systems are compliant with the National Provider Identifier (NPI) requirements that went into effect in May 2007 and have not has time to address the change in instructions for reporting hemoglobin or hematocrit levels.

US Oncology manages over 1,100 oncologists in 442 practices and our latest estimate is that less than 50% of our systems can accommodate the reporting of hemoglobin in Box 24A. Therefore, US Oncology recommends that CMS allow hemoglobin or hematocrit reporting to be placed in either Box 19 or Box 24A. We also recommend that CMS continue to allow reporting of hemoglobin or hematocrit in either Box for the foreseeable future or at least until it has 100% assurance that all physicians can accommodate reporting in Box 24A.

Recommendations:

1. CMS should explicitly state in the final rule that "the most recent hemoglobin or hematocrit level obtained should be placed on a claim containing a request for payment for a drug administered for the treatment of anemia in connection with treatment for cancer."

2. CMS should allow the hemoglobin or hematocrit levels to be placed in either Box 19 or Box 24A of the CMS 1500 claim form.

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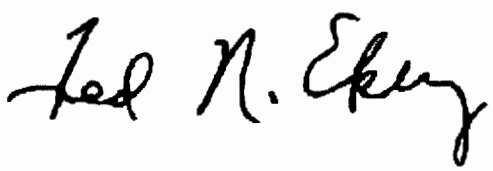
In closing and on behalf of the National Policy Board of US Oncology and our nationwide network of cancer care specialists, thank you for this opportunity to provide our comments on Proposed Rule CMS-1385-P. As you know, we are grateful for the opportunity to engage in substantive discussions and practice site visits with CMS officials, and we continue to stand ready should you have any questions about the issues, concerns, suggestions and data analyses discussed above.

Sincerely,



Fred Ekery, MD
Chairman, National Policy Board
US Oncology

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Exhibit 1

2007 Actual

	Allowable Cost	Reimbursement	Estimated Net	Net of Bad Debt
Oncology Sector	$ 6,310,618,991	$ 5,844,178,324	$ (466,440,667)	$ (758,649,583)
5-Physician Practice	$ 3,518,096	$ 3,258,060	$ (260,035)	$ (422,938)
Per Beneficiary	$ 9,382	$ 8,688	$ (693)	$ (1,128)
Estimated Percent Loss:			-7.4%	-12.0%

Oncology Sector

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 5,088,815,091	$ 4,071,052,073	$ 1,017,763,018	$ (254,440,755)	$ 4,834,374,336	$ 4,947,853,737	$ 140,961,354	$ (113,479,401)
Drug Admin	$ 755,363,233	$ 604,290,586	$ 151,072,647	$ (37,768,162)	$ 717,595,071	$ 1,362,765,254	$ (607,402,021)	$ (645,170,182)
Demo								$ -
Total	$ 5,844,178,324	$ 4,675,342,659	$ 1,168,835,665	$ (292,208,916)	$ 5,551,969,408	$ 6,310,618,991	$ (466,440,667)	$ (758,649,583)

Five Physician Practice

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 2,836,954	$ 2,269,563	$ 567,391	$ (141,848)	$ 2,695,107	$ 2,758,370	$ 78,584	$ (63,263)
Drug Admin	$ 421,106	$ 336,885	$ 84,221	$ (21,055)	$ 400,051	$ 759,726	$ (338,619)	$ (359,675)
Demo								$ -
Total	$ 3,258,060	$ 2,606,448	$ 651,612	$ (162,903)	$ 3,095,157	$ 3,518,096	$ (260,035)	$ (422,938)

Per Beneficiary

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 7,565	$ 6,052	$ 1,513	$ (378)	$ 7,187	$ 7,356	$ 210	$ (169)
Drug Admin	$ 1,123	$ 898	$ 225	$ (56)	$ 1,067	$ 2,026	$ (903)	$ (959)
Demo								$ -
Total	$ 8,688	$ 6,951	$ 1,738	$ (434)	$ 8,254	$ 9,382	$ (693)	$ (1,128)

1/ Utilization based on 2005 Utilization Data from 2007 NPRM published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90), Facility and Non Facility.

3/ Relative Value Units based on Addendum B published in the FR Published in the December 1, 2006 Vol.71, No.231. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Drug Cost based on Average Sales Price (ASP) published by CMS quarterly without Prompt Pay Discount (2%) including the six month lag from cost to reimbursment.

5/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in July 2006 for the three Oncology Specialties Only; Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

Exhibit 2

2008 Conversion Factor $34.1352

	Allowable Cost	Reimbursement	Estimated Net	Net of Bad Debt
Oncology Sector	$ 6,411,054,369	$ 5,856,213,315	$ (554,841,054)	$ (888,035,711)
5-Physician Practice	$ 3,574,087	$ 3,264,770	$ (309,317)	$ (495,069)
Per Beneficiary	$ 9,531	$ 8,706	$ (825)	$ (1,320)
Estimated Percent Loss:			-8.7%	-13.2%

Oncology Sector

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 5,190,591,393	$ 4,071,052,073	$ 1,038,118,279	$ (259,529,570)	$ 4,849,640,782	$ 5,012,175,836	$ 178,415,557	$ (162,535,054)
Drug Admin	$ 665,621,922	$ 573,534,587	$ 133,124,384	$ (33,281,096)	$ 673,377,876	$ 1,398,878,533	$ (733,256,611)	$ (725,500,657)
Demo	$ -							$ -
Total	$ 5,856,213,315	$ 4,644,586,660	$ 1,171,242,663	$ (292,810,666)	$ 5,523,018,657	$ 6,411,054,369	$ (554,841,054)	$ (888,035,711)

Five Physician Practice

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 2,893,693	$ 2,269,563	$ 578,739	$ (144,685)	$ 2,703,617	$ 2,794,229	$ 99,465	$ (90,611)
Drug Admin	$ 371,076	$ 319,739	$ 74,215	$ (18,554)	$ 375,400	$ 779,858	$ (408,782)	$ (404,458)
Demo								$ -
Total	$ 3,264,770	$ 2,589,302	$ 652,954	$ (163,238)	$ 3,079,018	$ 3,574,087	$ (309,317)	$ (495,069)

Per Beneficiary

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 7,717	$ 6,052	$ 1,543	$ (386)	$ 7,210	$ 7,451	$ 265	$ (242)
Drug Admin	$ 990	$ 853	$ 198	$ (49)	$ 1,001	$ 2,080	$ (1,090)	$ (1,079)
Demo								$ -
Total	$ 8,706	$ 6,905	$ 1,741	$ (435)	$ 8,211	$ 9,531	$ (825)	$ (1,320)

1/ Utilization based on 2005 Utilization Data from 2007 NPRM published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90), Facility and Non Facility.

3/ Relative Value Units based on Addendum B published in the PR Published in the July 12, 2007 Vol.72, No.133. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Conversion Factor based on expected CY2008 Conversion Factor Published in the July 12, 2007 PR Vol.72, No.133.

5/ Drug Cost based on Average Sales Price (ASP) published by CMS quarterly without Prompt Pay Discount (2%) including the six month lag from cost to reimbursement.

6/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in July 2006 for the three Oncology Specialties Only; Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

Exhibit 3

2008 Conversion Factor $38.0870

	Allowable Cost	Reimbursement	Estimated Net	Net of Bad Debt
Oncology Sector	$ 6,411,054,369	$ 5,933,275,059	$ (477,779,309)	$ (845,720,451)
5-Physician Practice	$ 3,574,087	$ 3,307,731	$ (266,356)	$ (471,479)
Per Beneficiary	$ 9,531	$ 8,821	$ (710)	$ (1,257)
Estimated Percent Loss:			-7.5%	-12.1%

Oncology Sector

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 5,190,591,393	$ 4,071,052,073	$ 1,038,118,279	$ (259,529,570)	$ 4,849,640,782	$ 5,012,175,836	$ 178,415,557	$ (162,535,054)
Drug Admin	$ 742,683,667	$ 604,290,587	$ 148,536,733	$ (37,134,183)	$ 715,693,137	$ 1,398,878,533	$ (656,194,867)	$ (683,185,397)
Demo	$ -							$ -
Total	$ 5,933,275,059	$ 4,675,342,659	$ 1,186,655,012	$ (296,663,753)	$ 5,565,333,918	$ 6,411,054,369	$ (477,779,309)	$ (845,720,451)

Five Physician Practice

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 2,893,693	$ 2,269,563	$ 578,739	$ (144,685)	$ 2,703,617	$ 2,794,229	$ 99,465	$ (90,611)
Drug Admin	$ 414,037	$ 336,885	$ 82,807	$ (20,702)	$ 398,990	$ 779,858	$ (365,821)	$ (380,868)
Demo								$ -
Total	$ 3,307,731	$ 2,606,448	$ 661,546	$ (165,387)	$ 3,102,608	$ 3,574,087	$ (266,356)	$ (471,479)

Per Beneficiary

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 7,717	$ 6,052	$ 1,543	$ (386)	$ 7,210	$ 7,451	$ 265	$ (242)
Drug Admin	$ 1,104	$ 898	$ 221	$ (55)	$ 1,064	$ 2,080	$ (976)	$ (1,016)
Demo								$ -
Total	$ 8,821	$ 6,951	$ 1,764	$ (441)	$ 8,274	$ 9,531	$ (710)	$ (1,257)

1/ Utilization based on 2005 Utilization Data from 2007 NPRM published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90), Facility and Non Facility.

3/ Relative Value Units based on Addendum B published in the PR Published in the July 12, 2007 Vol.72, No.133. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Conversion Factor based on H.R. 3162 - Children's Health and Medicare Protection Act of 2007.

5/ Drug Cost based on Average Sales Price (ASP) published by CMS quarterly without Prompt Pay Discount (2%) including the six month lag from cost to reimbursment.

6/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in July 2006 for the three Oncology Specialties Only; Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

Drug Administration Reimbursement Changes based on CY2008 Physician Fee Schedule Proposed Rule

Exhibit 4

Code	Description	MTUS	ALCHG	2005	2006	2007 (CF $37.8975)	2008 (CF $34.1352)	2009 (CF $38.0870)	2009 (CF $38.2774)	2010 (CF $34.0669)
90760	Hydration iv infusion, init	164,661	$ 10,274,679	$ 64.80	$ 63.29	$ 61.39	$ 54.27	$ 60.56	$ 59.71	$ 53.14
90761	Hydrate iv infusion, add-on	483,999	$ 9,707,027	$ 20.69	$ 20.09	$ 18.95	$ 16.38	$ 18.28	$ 17.32	$ 15.42
90765	Ther/proph/diag iv inf, init	654,800	$ 49,677,496	$ 79.24	$ 77.31	$ 75.04	$ 66.22	$ 73.89	$ 72.73	$ 64.73
90766	Ther/proph/dg iv inf, add-on	455,361	$ 11,570,406	$ 26.54	$ 25.77	$ 24.25	$ 21.16	$ 23.61	$ 22.68	$ 20.18
90767	Tx/proph/dg addl seq iv inf	1,853,584	$ 76,667,935	$ 43.72	$ 42.45	$ 39.79	$ 34.14	$ 38.09	$ 36.08	$ 32.11
90768	Ther/diag concurrent inf	392,670	$ 9,437,259	$ 25.37	$ 24.63	$ 22.74	$ 19.46	$ 21.71	$ 20.96	$ 18.65
90772	Ther/proph/diag inj, sc/im	3,353,647	$ 61,835,850	$ 19.13	$ 18.57	$ 19.33	$ 18.43	$ 20.57	$ 21.72	$ 19.33
90773	Ther/proph/diag inj, ia	343	$ 6,550	$ 19.52	$ 18.95	$ 18.19	$ 16.38	$ 18.28	$ 18.09	$ 16.10
90774	Ther/proph/diag inj, iv push	157,239	$ 8,841,107	$ 58.94	$ 57.60	$ 57.23	$ 51.54	$ 57.51	$ 57.99	$ 51.61
90775	Ther/proph/diag inj add-on	1,645,556	$ 42,890,554	$ 27.71	$ 26.91	$ 26.15	$ 22.87	$ 25.52	$ 25.07	$ 22.31
96401	Chemo, anti-neopl, sq/im	279,767	$ 14,770,136	$ 53.09	$ 52.68	$ 58.36	$ 58.37	$ 65.13	$ 71.67	$ 63.79
96402	Chemo hormon antineopl sq/im	97,529	$ 4,374,071	$ 36.69	$ 45.86	$ 42.45	$ 36.18	$ 40.37	$ 38.66	$ 34.41
96405	Chemo intralesional, up to 7	122	$ 12,934	$ 108.01	$ 113.31	$ 121.65	$ 120.16	$ 134.07	$ 147.46	$ 131.24
96406	Chemo intralesional over 7	136	$ 19,309	$ 145.53	$ 145.91	$ 145.15	$ 136.20	$ 151.97	$ 160.00	$ 142.40
96409	Chemo, iv push, sngl drug	220,823	$ 26,427,830	$ 125.69	$ 122.41	$ 119.76	$ 106.16	$ 118.45	$ 117.89	$ 104.93
96411	Chemo, iv push, addl drug	355,770	$ 24,583,087	$ 72.99	$ 70.87	$ 68.97	$ 61.10	$ 68.18	$ 67.37	$ 59.96
96413	Chemo, iv infusion, 1 hr	1,825,490	$ 307,375,446	$ 177.61	$ 172.81	$ 165.99	$ 144.39	$ 161.11	$ 156.46	$ 139.25
96415	Chemo, iv infusion, addl hr	1,187,430	$ 45,593,889	$ 40.21	$ 39.03	$ 37.14	$ 32.43	$ 36.18	$ 35.22	$ 31.34
96416	Chemo prolong infuse w/pump	107,610	$ 19,380,237	$ 190.88	$ 185.70	$ 179.63	$ 157.02	$ 175.20	$ 170.72	$ 151.94
96417	Chemo iv infus each addl seq	650,250	$ 53,380,373	$ 86.66	$ 84.51	$ 81.48	$ 71.34	$ 79.60	$ 77.70	$ 69.16
96420	Chemo, ia, push tecnique	198	$ 21,581	$ 113.20	$ 110.66	$ 109.90	$ 100.02	$ 111.59	$ 113.88	$ 101.35
96422	Chemo ia infusion up to 1 hr	236	$ 46,134	$ 198.29	$ 192.90	$ 181.91	$ 162.48	$ 181.29	$ 183.16	$ 163.01
96423	Chemo ia infuse each addl hr	199	$ 16,322	$ 80.80	$ 78.83	$ 78.07	$ 71.34	$ 79.60	$ 81.44	$ 72.48
96425	Chemotherapy,infusion method	680	$ 118,368	$ 184.24	$ 179.26	$ 178.50	$ 162.48	$ 181.29	$ 184.88	$ 164.54
96440	Chemotherapy, intracavitary	15	$ 4,563	$ 396.41	$ 405.12	$ 370.64	$ 309.60	$ 345.45	$ 321.24	$ 285.91
96445	Chemotherapy, intracavitary	420	$ 151,118	$ 393.00	$ 393.76	$ 360.03	$ 300.39	$ 335.17	$ 311.39	$ 277.13
96450	Chemotherapy, into CNS	1,227	$ 280,468	$ 338.05	$ 325.54	$ 300.15	$ 252.26	$ 281.46	$ 263.92	$ 234.89
96521	Refill/maint, portable pump	74,858	$ 10,417,986	$ 152.73	$ 153.11	$ 145.91	$ 125.96	$ 140.54	$ 135.50	$ 120.60
96522	Refill/maint pump/resvr syst	5,068	$ 620,653	$ 110.28	$ 110.66	$ 110.28	$ 100.36	$ 111.98	$ 114.16	$ 101.60
96523	Irrig drug delivery device	216,849	$ 5,821,439	$ 28.89	$ 28.04	$ 27.67	$ 24.58	$ 27.42	$ 26.89	$ 23.93
96542	Chemotherapy injection	1,913	$ 386,025	$ 216.77	$ 192.52	$ 182.29	$ 157.70	$ 175.96	$ 170.05	$ 151.34
	Weighted Change From 2005			**0%**	**-3%**	**-6%**	**-17%**	**-7%**	**-9%**	**-19%**
	Weighted Change From 2006				**0%**	**-3%**	**-15%**	**-5%**	**-6%**	**-17%**
	Weighted Change From 2007					**0%**	**-12%**	**-2%**	**-3%**	**-14%**

Change From 2007

90760	Hydration iv infusion, init	**-12%**	**-1%**	**-3%**	**-13%**
90761	Hydrate iv infusion, add-on	**-14%**	**-4%**	**-9%**	**-19%**
90765	Ther/proph/diag iv inf, init	**-12%**	**-2%**	**-3%**	**-14%**
90766	Ther/proph/dg iv inf, add-on	**-13%**	**-3%**	**-6%**	**-17%**
90767	Tx/proph/dg addl seq iv inf	**-14%**	**-4%**	**-9%**	**-19%**
90768	Ther/diag concurrent inf	**-14%**	**-5%**	**-8%**	**-18%**
90772	Ther/proph/diag inj, sc/im	**-5%**	**6%**	**12%**	**0%**
90773	Ther/proph/diag inj, ia	**-10%**	**1%**	**-1%**	**-12%**
90774	Ther/proph/diag inj, iv push	**-10%**	**0%**	**1%**	**-10%**
90775	Ther/proph/diag inj add-on	**-13%**	**-2%**	**-4%**	**-15%**
96401	Chemo, anti-neopl, sq/im	**0%**	**12%**	**23%**	**9%**
96402	Chemo hormon antineopl sq/im	**-15%**	**-5%**	**-9%**	**-19%**
96405	Chemo intralesional, up to 7	**-1%**	**10%**	**21%**	**8%**
96406	Chemo intralesional over 7	**-6%**	**5%**	**10%**	**-2%**
96409	Chemo, iv push, sngl drug	**-11%**	**-1%**	**-2%**	**-12%**
96411	Chemo, iv push, addl drug	**-11%**	**-1%**	**-2%**	**-13%**
96413	Chemo, iv infusion, 1 hr	**-13%**	**-3%**	**-6%**	**-16%**
96415	Chemo, iv infusion, addl hr	**-13%**	**-3%**	**-5%**	**-16%**
96416	Chemo prolong infuse w/pump	**-13%**	**-2%**	**-5%**	**-15%**
96417	Chemo iv infus each addl seq	**-12%**	**-2%**	**-5%**	**-15%**
96420	Chemo, ia, push tecnique	**-9%**	**2%**	**4%**	**-8%**
96422	Chemo ia infusion up to 1 hr	**-11%**	**0%**	**1%**	**-10%**
96423	Chemo ia infuse each addl hr	**-9%**	**2%**	**4%**	**-7%**
96425	Chemotherapy,infusion method	**-9%**	**2%**	**4%**	**-8%**
96440	Chemotherapy, intracavitary	**-16%**	**-7%**	**-13%**	**-23%**
96445	Chemotherapy, intracavitary	**-17%**	**-7%**	**-14%**	**-23%**
96450	Chemotherapy, into CNS	**-16%**	**-6%**	**-12%**	**-22%**
96521	Refill/maint, portable pump	**-14%**	**-4%**	**-7%**	**-17%**
96522	Refill/maint pump/resvr syst	**-9%**	**2%**	**4%**	**-8%**
96523	Irrig drug delivery device	**-11%**	**-1%**	**-3%**	**-14%**
96542	Chemotherapy injection	**-13%**	**-3%**	**-7%**	**-17%**

1/ Utilization is from CY2008 Propose Rule 2008 NPRM UTILIZATION FILE published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

3/ Relative Value Units based on Addendum B published in the PR Published in the July 12, 2007 Vol.72, No.133. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Conversion Factors for 2008 ($34.1352 included 9.9%) based on Estimated Sustainable Growth Rate and Conversion Factor, for Medicare Payments to Physicians in 2008

5/ Conversion Factor for 2008 $38.0870 .5% increase is based on H.R. 3162 - Children's Health and Medicare Protection Act of 2007.

6/ Conversion Factor for 2009 $38.2774 .5% increase is based on H.R. 3162 - Children's Health and Medicare Protection Act of 2007.

7/ Conversion Factor for 2010 $34.0669 11% decrease is based on H.R. 3162 - Children's Health and Medicare Protection Act of 2007.

Exhibit 5

Comparison of 2007 and 2008 HOPPS Payment Rates for Drug Administration APCs

APC	2007 Payment Rate	2008 Payment Rate	Percent Change
0437	$ 24.25	$ 25.71	+6.0
0438	$ 48.82	$ 2.93	+8.4
0439	$ 97.41	$ 109.25	+12.2
0440	$ 111.20	$ 116.62	+4.9
0441	$ 152.75	$ 155.27	+1.6

Exhibit 6

2007 Actual with PQRI

	Allowable Cost	Reimbursement	Estimated Net	Net of Bad Debt
Oncology Sector	$ 6,310,618,991	$ 5,858,101,197	$ (452,517,794)	$ (744,726,710)
5-Physician Practice	$ 3,518,096	$ 3,265,821	$ (252,274)	$ (415,177)
Per Beneficiary	$ 9,382	$ 8,708	$ (673)	$ (1,108)
Estimated Percent Loss:			***-7.2%***	***-11.8%***

Oncology Sector

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 5,088,815,091	$ 4,071,052,073	$ 1,017,763,018	$ (254,440,755)	$ 4,834,374,336	$ 4,947,853,737	$ 140,961,354	$ (113,479,401)
Drug Admin	$ 755,363,233	$ 604,290,586	$ 151,072,647	$ (37,768,162)	$ 717,595,071	$ 1,362,765,254	$ (607,402,021)	$ (645,170,182)
PQRI	$ 13,922,873	$ 13,922,873	$ -	$ -	$ 13,922,873	$ -	$ 13,922,873	$ 13,922,873
Total	$ 5,858,101,197	$ 4,689,265,532	$ 1,168,835,665	$ (292,208,916)	$ 5,565,892,281	$ 6,310,618,991	$ (452,517,794)	$ (744,726,710)

Five Physician Practice

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 2,836,954	$ 2,269,563	$ 567,391	$ (141,848)	$ 2,695,107	$ 2,758,370	$ 78,584	$ (63,263)
Drug Admin	$ 421,106	$ 336,885	$ 84,221	$ (21,055)	$ 400,051	$ 759,726	$ (338,619)	$ (359,675)
PQRI	$ 7,761	$ 7,761	$ -	$ -	$ 7,761	$ -	$ 7,761	$ 7,761
Total	$ 3,265,821	$ 2,614,209	$ 651,612	$ (162,903)	$ 3,102,918	$ 3,518,096	$ (252,274)	$ (415,177)

Per Beneficiary

	Reimbursement					Cost	Difference	
	Allowable	Medicare Spend	Patient Portion	Bad Debt	Allowable Net of Bad Debt		@ Allowable	@ Allowable Net of Bad Debt
Drugs	$ 7,565	$ 6,052	$ 1,513	$ (378)	$ 7,187	$ 7,356	$ 210	$ (169)
Drug Admin	$ 1,123	$ 898	$ 225	$ (56)	$ 1,067	$ 2,026	$ (903)	$ (959)
PQRI	$ 20	$ 20	$ -	$ -	$ 20	$ -	$ 20	$ 20
Total	$ 8,708	$ 6,971	$ 1,738	$ (434)	$ 8,274	$ 9,382	$ (673)	$ (1,108)

1/ Utilization based on 2005 Utilization Data from 2007 NPRM published at website www.cms.hhs.gov

2/ Specialties include Hematology (82), Hematology/Oncology (83) and Medical Oncology (90), Facility and Non Facility.

3/ Relative Value Units based on Addendum B published in ths FR Published in the December 1, 2006 Vol.71, No.231. Medicare Allowables based on unadjusted GPCI Medicare Allowables, including both Medicare and Patient Portion.

4/ Drug Cost based on Average Sales Price (ASP) published by CMS quarterly without Prompt Pay Discount (2%) including the six month lag from cost to reimbursment.

5/ Estimated Five Physician Practice is based on CMS Physician Directory Updated in July 2006 for the three Oncology Specialties Only; Hematology (82), Hematology/Oncology (83) and Medical Oncology (90).

6/ PQRI Payment for 2007 is based on the Physician Fee Schedule Services for Oncologist for July 2007 - December 2007 paid at 1.5%.

élan

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August 31, 2007

HAND DELIVERED

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Kuhn:

Elan Pharmaceuticals, Inc. (Elan) would like to thank you for the opportunity to comment on Proposed Rule CMS-1385-P, "Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007.[1] As requested, we have keyed our comments to the relevant issue identifiers in the Proposed Rule.

Background

Elan is a neuroscience-based biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies to treat neurological disorders, autoimmune diseases, and severe pain. Elan currently markets two products in the United States that are covered under Medicare Part B.

PRIALT® (ziconotide **intrathecal infusion**), is indicated for management of severe chronic pain in patients for whom intrathecal ("IT") therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine. PRIALT is intended only for IT delivery using a programmable implanted variable-rate microinfusion device or an external microinfusion device and catheter. Depending on the site of the service, PRIALT may be billed as a hospital outpatient service or physician office service.

TYSABRI®[2] (natalizumab) is a biological administered by intravenous ("IV") infusion for the treatment of patients with relapsing forms of multiple sclerosis ("MS") to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. Additionally, a supplemental biologics license agreement is currently under review by the FDA for the use of TYSABRI to treat moderate-to-severe Crohn's disease in patients who have failed or cannot tolerate available therapies. Elan, in conjunction with our partner Biogen Idec, is also evaluating other potential indications for TYSABRI including its use in the area of oncology.

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[1] 72 *Fed. Reg. 38120* (July 12, 2007)

[2] Elan is partnered with Biogen Idec on all aspects of research, development, and marketing of TYSABRI for current and future indications.

We are writing primarily to urge CMS to adopt DrugPoints as a successor to the United States Pharmacopoeia-Drug Information (USP-DI) and to announce that decision without delay or application of any new process for assessing compendia when it publishes the 2008 Physician Fee Schedule (PFS) Final Rule. Secondarily, we have provided our thoughts on appropriate processes for adding and deleting compendia to the list of approved compendia in Social Security Act § 1861(t)(2) in case Congress decides to authorize CMS to apply whatever processes it develops in that context to compendia lists that affect the Elan product line.

DRUG COMPENDIA

Compendia Listings Currently Governing Coverage under Federal Healthcare Programs

Social Security Act § 1861 (t)(1) defines "drugs" or "biologicals" (hereafter referred to as "drugs" for simplicity) with respect to their inclusion in specified compendia.[3] Social Security Act § 1861(t)(2) sets forth coverage rules under Part B for anticancer drugs, including a requirement for automatic coverage of unlabeled uses of anti-cancer chemotherapeutics listed in three different compendia,[4] and permits CMS to revise the list of authoritative compendia related to anticancer drugs as appropriate. In the Proposed Rule, CMS has outlined a process for considering both additions and deletions to the list of compendia that governs coverage of unlabeled indications of drugs used in an anti-cancer chemotherapeutic regimen.

CMS provides sub-regulatory guidance on the implications of both § 1861(t)(1) and § 1861(t)(2) for Part B drug coverage in Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15. Section 50.4.2 of the Manual interprets § 1861(t)(1) as permitting Part B to cover all FDA-approved indications as well as those unlabeled indications the local contractor deems medically acceptable in light of information in the "major drug compendia." Section 50.4.5 of the Manual addresses the coverage rules in § 1861(t)(2), primarily by providing guidance on how to interpret medical acceptability in the context of the drug rating systems used by the listed compendia, including USP-DI. Although the Manual does not identify what major drug compendia the contractors should consult, we understand that in recent years carriers have relied heavily on the USP-DI.

Despite the importance of the various compendia that define the scope of Medicare and Medicaid coverage when prescription drugs are prescribed or administered for unlabeled uses, at least one of the statutorily named compendia – the American Medical Association-Drug Evaluations – is no longer published. Furthermore, USP-DI has been purchased by Thomson Micromedex and will be renamed.

CMS' Authority to Adopt "Successor" Publications to USP-DI

In July 2007, Micromedex will begin publishing what it is describing as a "successor" product to USP-DI under the trademark of DrugPoints®. Congress anticipated the changes resulting from Thomson's acquisition of USP-DI and included a provision in the Deficit Reduction Act of 2005 (DRA)[5] that amended both Social Security Act § 1861(t)(2)(B)(ii)(I) and § 1927(g)(1)(B)(i)(II)[6] by inserting "(or its successor publications)" after "United States Pharmacopoeia-Drug

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[3] § 1861(t)(1) lists the United States Pharmacopoeia, the National Drug Formulary, The United States Homeopathic Pharmacopoeia, New Drugs, and Accepted Dental Remedies.

[4] § 1862(t)(2) lists the American Hospital Formulary Service Drug Information (AHF-DI), the American Medical Association Drug Evaluations (AMA-DE), and the USP-DI.

[5] § 6001(f) of Pub. L. 109071 (Feb. 8, 2006).

[6] § 1927(g)(1)(B)(i)(II) defines the list of compendia used by Medicaid, Medicare Part D, and Medicare Advantage-Prescription Drug Plans (compendia are: AHFS-DI, USP-DI, and DRUGDEX).

Information." In addition, Social Security Act § 1873 has long anticipated name changes more generally. It provides that:

> Designation in this title, by name, of any nongovernmental organization or publication shall not be affected by change of name of such organization or publication, and shall apply to any successor organization or publication which the Secretary finds serves the purpose for which such designation is made.

CMS has interpreted the DRA provisions as explicitly authorizing it, state Medicaid programs, and Part D and MA-PD plan sponsors "to continue recognition of the compendium currently know as USP-DI after its name change if the Secretary determines that it is in fact a successor publication rather than a substitute publication."[7] The name-change provision in § 1873 offers CMS the same authority with respect to other Medicare Part B drugs that are not used to treat cancer but are subject to the provisions in § 1861(t)(1).

DrugPoints Qualifies as a USP-DI "Successor" that CMS Should Adopt Immediately

Elan reads § 1873 as providing CMS the discretionary authority to instruct its contractors to look to DrugPoints as one of the "major compendia" that may be used, pursuant to § 50.4.2 of the *Medicare Benefit Policy Manual*, to inform local coverage decisions about unlabeled uses of Part B drugs that are *not* part of an anti-cancer chemotherapy regimen. We feel similarly about CMS' authority to turn to DrugPoints when decisions about unlabeled uses of cancer drugs must be made. Accordingly, we urge CMS to formally recognize DrugPoints as a successor to USP-DI when it publishes the 2008 Physician Fee Schedule Final Rule.

DrugPoints clearly qualifies as a "successor" to USP-DI because Micromedex reports reviewing each entry in USP-DI to develop DrugPoints. Although not every indication that was listed in USP-DI will appear in DrugPoints, the omitted indications are only those unlabeled uses where the Micromedex review team[8] judged the drug ineffective or found only weak evidence in support of a conclusion that the drug might be effective. In other words, the omitted unlabeled indications are all ones that would not qualify for coverage under Parts A or B pursuant to Medicare statute because, if they were listed in the compendium, they would be "unfavorably evaluated therein"[9] or considered "not indicated."[10] Micromedex' decision to cull out these indications should simplify CMS and contractor decision-making about drug coverage since, for any indication listed in DrugPoints, regardless of whether it is a labeled indication or an unlabeled one, the drug should be efficacious enough to warrant coverage provided it meets other applicable coverage requirements (e.g., for Part B, not usually self-administered, furnished in accordance with incident-to requirements).

We see no basis for concluding the enhancements Micromedex made when it migrated indications from USP-DI to DrugPoints means that the renamed and revamped compendium is a "substitute" rather that the statutorily required "successor." All compendia are supposed to be routinely updated so the fact that DrugPoints will contains listings that each reflect a coordinated, updated review of the available literature cannot be said to make it a substitute rather than a successor.

Micromedex also elected to replace the simple rating system used by USP-DI with the more complex approach that is used in other Micromedex products such as DRUGDEX. Rejecting

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[7] 72 *Fed. Reg.* at 38177.

[8] Editorial review committee is comprised of over 100 physicians, clinical pharmacists, nurses and other healthcare professionals employed by Micromedex.

[9] The rule out criterion in § 1861(t)(1).

[10] The rule out criterion in § 1861(t)(2).

DrugPoints as a "successor" reference source because the new tier-rating system is more robust that the old USP-DI acceptance ranking system does not make any sense. After all, if Micromedex had chosen to incorporate the new ranking system into USP-DI without changing the compendium's name, CMS would remain obligated by statute to use the compendium to make coverage decisions about cancer drugs under Part B and about outpatient drugs under Medicaid and Part D. That would, in our view, also make the compendium a "major compendium" eligible for use when local contractors must make a Part B coverage determination about non-cancer drugs.

The ranking system used in DrugPoints is the very system that Congress found acceptable when it chose to designate DRUGDEX Information Systems as an acceptable compendium for Medicaid and Part D purposes. It is also consistent with many medical societies' data ranking methodologies. We believe that these facts would make it difficult for CMS to conclude that DrugPoints is not suitable to serve the same purposes for which USP-DI was previously designated.

Finding fault with a compendium because it presents physicians and other healthcare professional with more information to inform their clinical decision-making – or in CMS' case, its coverage decision-making – would be inconsistent with CMS' work to improve quality of care for Medicare beneficiaries by driving the program towards more evidence-based care.

Processes for Deleting and Adding Compendia

Elan feels strongly that deleting compendia from any approved list of reference sources could be quite disruptive, not just to payment policy but also to clinical decision-making. We, therefore, suggest CMS adopt a removal process that differs significantly from the process it has proposed for adding compendia under § 1862(t)(2). Further, we would argue that CMS does not have the authority to remove compendia (or their successors) from use if Congress has chosen to identify them in a statute as a reference source for particular coverage determinations.

From an operational perspective, compendia should only be removed from an approved list of reference materials after the public has had a meaningful opportunity to comment on the removal. We are concerned about requests for removal of compendia that may originate with other compendia companies for purely competitive reasons. Because of this potential, we believe it would be a mistake to remove any approved compendium from a previously adopted reference list through a process short of notice and comment rulemaking. Further, the removal process should include an opportunity for compendia publishers to cure the perceived defects underlying a decision to commence or move forward with the removal process.

With regard to the addition of approved compendia, where CMS has the authority to augment an approved compendium list established by Congress, we think the process should be as streamlined as possible and we see no reason why a new compendium could not be approved for inclusion within six months of a request since CMS makes National Coverage Decisions within that timeframe. We agree that both CMS and the public should be able to generate requests to add compendia to the § 1862(t)(2) list or to any of the other compendia listings if Congress enacts a law allowing CMS that discretion. Since the number of compendia offered by the pharmaceutical reference industry is small, there would be no need for an annual approval cycle. Rather, CMS should adopt a rolling, first-come, first-serve process. Once CMS has received an outside request or generates an internal one to add a compendium, it should post a notice of review on its Web site that includes the identity of the requestor, the compendium, the reasons why the compendium should be added, and a link to the compendium itself. There should then be a 30-day public comment period. CMS should be able to make its decision within 90 days of the close of the

comment period. If the decision is a negative one, CMS should issue its denial in the form of a "proposed decision" that explains its rationale, allow another 30-day comment period with publication of a final decision 45 days after the reconsideration comment period closes. A compendium that was denied addition should be allowed to reapply after publication of the next edition if it can attest it has cured the deficiencies or shortcomings cited in a final denial decision.

Definition of a Compendium

In the Proposed Rule, CMS defines what a compendium is for purposes of the rule, lists the MedCAC desirable characteristics without requiring attainment of any, and lists additional characteristics that it "may" or "will" consider in its review. CMS notes that the MedCAC desirable characteristics of a compendium include the following:

- Detailed description of the evidence reviewed for every individual listing,
- Use of pre-specified published criteria for weighing evidence,
- Use of prescribed published process for making recommendations,
- Publicly transparent process for evaluating therapies,
- Explicit "Not Recommended" listing when validate evidence is appropriate,
- Explicit "Equivocal" listing when validated evidence is equivocal, and
- Process for public identification and notification of potential conflicts of interest of the compendium's parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

In our view, attainment of these desirable characteristics should be sufficient. We appreciate the fact that these characteristics are relatively objective standards, yet do not pre-specify how the standards should be attained. In other words the MedCAC standards implicitly recognize that there are many ways of, for example, evaluating and weighing evidence, handling conflicts of interest, and establishing a publicly transparent process. If this were not the case, there would be no need for multiple compendia. In our view, CMS should not add more characteristics, particularly the types of ill-defined, subjective ones it suggested in the Proposed Rule. For example, with regard to conflicts of interest, so long as the compendium has a process for addressing them, it would attain the standard. Similarly, the MedCAC standards for public transparency of the review process and evaluating evidence would allow compendia to look at evidence differently so long as the process is transparent and publicly available so that physicians and other healthcare providers may determine for themselves whether to follow the compendium's recommendations.

* * * * * * * * * * *

In closing, on behalf of Elan, thank you for the opportunity to provide comments on Proposed Rule CMS-1385-P. Please do not hesitate to contact us should you have any questions about the issues, concerns, and suggestions discussed above.

Sincerely,

Nick Poulios, PhD

Nick Poulios, PhD
Vice President
Pricing and Reimbursement Strategy
Elan Pharmaceuticals, Inc.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

SUBMITTED VIA HAND DELIVERY TO CMS WASHINGTON, DC OFFICE
(Hubert H. Humphrey Building, Room 445-G, 200 Independence Avenue, SW., Washington, DC 20201)

August 31, 2007

Re: CMS-1385-P: Section II.F.1. (ASP Issues) and Section II.S.3. (Proposed Elimination of the Exemption for Computer-Generated Facsimile Transmission From the NCPDP SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information for Part D Eligible Individuals)

Dear Acting Administrator Weems:

The National Community Pharmacists Association (NCPA)[1] provides the following comments to the sections of CMS' proposed Medicare rule regarding average sales price (ASP) issues and proposed elimination of the computer-generated fax exemption.

I. AVERAGE SALES PRICE (ASP) ISSUES

NCPA is very concerned with the provisions in the proposed rule that would not pay pharmacies less than their acquisition cost and not provide adequate reimbursement to cover administrative and overhead costs.

Not only does the proposed rule: (1) not increase supply or dispensing fees for Part B medications to help offset low reimbursements under ASP – which are often below acquisition costs for most independent pharmacists -- and administrative costs incurred in Medicare Part B claim submission; it also (2) reduces reimbursement to the lesser of the average manufacturer's price (AMP) or 103 percent of widely available market price (WAMP) if the ASP exceeds the AMP or the WAMP by five percent or more. Even outside of the unique economic and administrative challenges independent pharmacies face in serving Medicare Part B patients, CMS should address reimbursements below costs and not choose a reimbursement measure which would result in even lower payments.

A. Current WAC for Most Immunosuppressant Agents Below ASP

The ASP reimbursement schedule (Attachment 1) shows that the current wholesale acquisition costs (WAC) rates for seven of the 10 most commonly used immunosuppressant agents are substantially below July 2007 ASP rates. Approximately 60 percent of community pharmacies pay WAC for acquisition of immunosuppressant agents. This figure represents the most current ASP data and often this information changes on a quarterly basis. This loss is in addition to the unreimbursed extensive billing time and services

[1] The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies. These independents employ over 55,000 licensed pharmacists and over 300,000 additional employees across the United States.

100 Daingerfield Road
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associated with filling Medicare Part B prescriptions as well as the inadequate supply fee which results in an even greater financial loss for pharmacies.[2] Many of our members have advised us that they have already been forced to stop providing Part B medications which decreases access for patients. Others are only able to fill prescriptions for the least expensive Part B drugs as a costly courtesy to their patients. Some Part B medications, particularly cancer-battling drugs, are expensive, and thus pharmacists suffer significant loses when dispensing those medications. By way of example, two pharmacy invoices show that an independent pharmacist dispensed a month's supply of Xeloda at an ingredient cost of $1,291.99, yet was reimbursed only $1,210.29 by the plan – a loss of $81.70, not including the costs of operating the pharmacy. The pharmacist later dispensed the same prescription medication at an ingredient cost of $1,296.30 while being paid only $1,200.76 by the plan – $95.54 below acquisition costs (Attachment 2).[3]

B. AMP and WAMP +3% Pricing Will Result in Greater Reductions in Payment to Pharmacies for Immunosuppressant Agents

CMS' proposed use of the lower of AMP or WAMP plus 3 percent if ASP is found to be 5 percent above these figures would make the current situation even worse. Based on independent community pharmacy's experience with ASP since 2005, NCPA believes that a survey of pharmacy providers would not yield a WAMP that is lower than ASP. NCPA references the Transplant Pharmacy Coalition's testimony at page 16, in which it states that its trend analysis suggests that on balance ASP prices have been consistently lower than pharmacy acquisition costs over time. (See also Trend Analysis (Attachment 3), ASP reimbursement schedule, (Attachment 1) and CMS ASP schedules (Attachment 4)).

AMP is untested in the market as a reimbursement mechanism for pharmacy providers but is scheduled to be implemented in 2008. The GAO has found that if pharmacists are reimbursed at the maximum ceiling federal upper limit (FUL) of 250 percent above AMP, they will still be reimbursed at 36 percent below acquisition costs. The HHS OIG has similarly found that a completely funded FUL would still fall below pharmacy acquisition cost for 19 of the 25 high-expenditure generic medications studied. For five of the other six medications in the study, the pharmacy would only cover the cost of the drug, but would still realize a loss once the cost of dispensing is considered.

In addition to this straight comparison of purchasing costs to reimbursements, there is the added consideration of heightened administrative costs for Part B claim processing, despite some recent streamlining in the billing process. It is still more expensive for the retail pharmacy to bill Medicare Part B than any other third party. Administrative errors caused by the Medicare billing procedures accounts for numerous denials in coverage and often results in additional costs that pharmacies are forced to absorb without reimbursement.

For these reasons, the agency should not implement further restrictions by paying the lower of the AMP or WAMP where the ASP is higher by five percent or more.

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[2] Part B immunosuppressants and anticancer agents receive a supply fee only. Inhalant drugs receive a dispensing fee only.

[3] The $24 supply fee (which is labeled as the generic term "dispensing fee" in the attachment) is included in the reimbursement figures.

C. Proposed Part B Rule Does Not Increase Supply or Dispensing Fees for Part B Medications

NCPA strongly urges that Part B drug supply and dispensing fees be increased for CY2008 to help offset low reimbursement amounts realized under the ASP method, and administrative costs associated with Part B claims. NCPA supports and refers CMS to the $30.73 supply fee for each Medicare Part B immunosuppressant prescription recommended by the Transplant Pharmacy Coalition in its comments on pages 10-12. CMS' failure to increase supply and dispensing fees results in community pharmacies' reimbursement falling below the actual cost to dispense Part B prescriptions.

II. FAX EXEMPTION ISSUES

NCPA believes that widespread marketplace adoption of e-prescribing will have many benefits and efficiencies for prescribers, pharmacists and pharmacies, and patients. The proposed rule, however, would implement a lock-step approach for e-prescribing that will cause great disruption, expense and actually discourage e-prescribing. NCPA agrees with eRx's statement that a complete elimination of the fax exemption will have more adverse impacts then benefits. NCPA believes that at this time, the least disruption to safe and effective prescription transmission and dispensing and the smallest amount of prescription transmission error will be accomplished through allowing prescribers and pharmacists to use computer-generated faxes to send and receive prescriptions. Therefore NCPA recommends the adoption of language to allow the use of computer-generated prescriptions in the following situations:

1) When the destination does not yet support e-prescribing, or as a backup when the electronic communication is unavailable;
2) Where a prescriber or dispenser is prohibited from complying with the NCPDP SCRIPT standard for reasons beyond their control, such as DEA regulations prohibiting the e-prescribing of a prescription for a controlled substance;
3) When there is not an agreement between the prescribing and pharmacy vendor to allow sending transactions electronically, even though both are capable of communicating using the SCRIPT standard; and
4) Where prescribers/dispensers use software (such as a word processing program) that creates and faxes the prescription document, but does not have true e-prescribing capabilities.

NCPA also asks CMS to:

- Allow those who adopt NCPDP SCRIPT-compliant functionality one year after the effective date to comply with the SCRIPT standard;
- Exempt pharmacies from penalties for prescriber non-compliance;
- Address pharmacist liability concerns: prescriptions transmitted before the compliance deadline but filled or refilled after that deadline should be exempt, and dispensing a prescription transmitted in a noncompliant manner should not be considered a violation of either the federal or state false claims acts; and

- Establish April 1, 2009 as the rule's effective date consistent with the effective date of MMA-mandated e-prescribing standards.

Faced with having to either comply completely with the NCPDP SCRIPT standard if it chooses to e-prescribe, or revert to receiving and sending paper faxes, many pharmacies – particularly independent pharmacies -- will likely revert to the latter. Indeed, in the original rule published in November, 2004, CMS stated that "absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. This would cause computer-generated faxes to revert to paper prescribing." CMS does not offer data that shows that this conclusion should now change. In fact, CMS concedes that independent pharmacies are not prepared to implement e-prescribing, finding that SureScripts reports that only 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions.[4]

We support a modified lifting of the exemption as outlined above and in the proposed language provided in the e-prescribing section on pages 5-6. This approach will lead to more electronic prescribing, which will create an environment and practice/culture that will encourage prescribers and dispensers who do not currently have e-prescribing capabilities to adjust their prescription communication practices.

Pharmacies should not be penalized for prescriber non-compliance

- It is very difficult, if not impossible, for a pharmacy to tell the difference between a facsimile that originated for a facsimile machine and one that originated electronically. Independent pharmacists should not be penalized for prescriber non-compliance by being forced to return reimbursements when pharmacists have filled these non-compliant prescriptions in good faith.
- Similarly, any NCPDP SCRIPT enabled sending entity, such as a pharmacy, should be able to send a computer generated facsimile if the receiving entity is not capable of receiving an NCPDP SCRIPT message, and the pharmacy believes that a computer generated facsimile is the best and most efficient way to send the prescription message.
- If both the pharmacy and the prescriber have NCPDP SCRIPT standard communication capability, then they should do so -- unless another exemption applies.

Pharmacist Liability

CMS should clarify that:

- In order to avoid the inefficiency of obtaining new prescriptions, prescriptions transmitted before the compliance deadline but filled or refilled after the compliance deadline should not be subject to the rule.
- The dispensing of a prescription transmitted in a noncompliant manner should not be considered a violation of either the federal or state false claims acts. Failure to do so would increase Medicare program participation costs for pharmacies and could potentially discourage pharmacy participation in the program.

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[4] Federal Register, Vol. 72, no. 133, July 12, 2007 at 38195.

E-prescribing capability

NCPA endorses the following proposed language, which should be read narrowly so as to not require prescribers and dispensers to purchase different software systems in order to become NCPDP SCRIPT Standard compliant.

§ 423.160(a)(3(i) Entities transmitting prescriptions or prescription related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information in the following circumstances:

1. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) does not own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, whether on the version that the prescriber/dispenser is currently using or another version of such software.*

    a. *This exemption shall not apply to prescribers/dispensers sending a transaction listed at Section 423.160(b)(1)(i) through (xii) who own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, but who has not upgraded to the version that is compliant with the NCPDP SCRIPT Standard and/or has not activated that functionality.*

    b. *In addition, in the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) owns, licenses, or otherwise uses software that does not have or did not have the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated] to send and receive transactions compliant with the NCPDP SCRIPT Standard, but such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard at any time after [insert date rule promulgated], then this exemption shall not apply with respect to such software twelve months after such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard.*

2. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) is sending the transaction to a dispenser/prescriber who does not own, license, or otherwise use software that has the capability to receive transactions compliant with the NCPDP SCRIPT Standard.*

3. *In the event any applicable law or regulation would prohibit the electronic transmission of the prescription and prescription related information using the NCPDP SCRIPT Standard.*

4. *In the event there is a temporary communications failure, whether technological or otherwise, that would prohibit the electronic transmission of the transactions listed at Section 423.160(b)(1)(i) through (xii) using the NCPDP SCRIPT Standard. Such temporary communications failures include, by way of example and not limitation, power outages, connectivity failures, or temporary outages of the either the prescriber's or dispenser's computer or management systems.*

5. *Information transmitted in a manner that is compliant with this rule at the time of its transmission shall remain compliant with this rule for the purposes of this rule even if such information or transmission would otherwise become noncompliant at a future date.*

We appreciate the opportunity to submit the comments on behalf of our membership. If you have any questions, please do not hesitate to contact NCPA via telephone at 703-683-8200 or via email at: Charlie.Sewell@ncpanet.org.

Sincerely,

Charles B. Sewell

Charles B. Sewell
Senior Vice President, Government Affairs

ATTACHMENT 1

CURRENT ASP REIMBURSMENT SCHEDULE WITH WAC

CURRENT ASP REIMBURSEMENT SCHEDULE

NOTE: There are currently 10 Jcodes that are billed to CMS for immunosuppression. Seven of these ten are currently reimbursed at or below the acquisition cost of the pharmacy.

Jcode	Item	ASP	WAC	#Units	Loss
J7502	Cyclosporine 100 mg*	3.536	5.089	180	279.54
J7507	Tacrolimus 1 mg	3.738	3.812	240	17.76
J7509	Methylprednisolone 4 mg	0.086	0.287	60	12.06
J7510	Prednisolone 5 mg	0.029	0.079	60	3.00
J7515	Cyclosporine 25 mg*	0.916	1.274	180	64.44
J9517	Mycophenolate 250 mg	2.629	2.909	240	67.20
J7518	Mycophenolic 180 mg	2.269	2.452	240	43.92

* If brand name Neoral is dispensed. Currently about 50% of cyclosporine prescriptions are designated "DAW" (dispense as written).

WAC = Wholesale Acquisition Cost. This is the price that approximately 60% of retail pharmacies pay for their drugs.

ATTACHMENT 2

PHARMACIST INVOICES – ONE MONTH OF XELODA

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**********************************************************************************
* RPh LLB  Tech              NH Prescription Edit/Label          Fri Mar 23, 2007
**********************************************************************************
 Patient                                  Room 209    DOB [redacted]  Rx # [redacted]
 NH 002                                                                Rf # 4
  Doctor [redacted]                        Phone [redacted]    DEA [redacted]

    Drug XELODA 500 MG TABLET          Qty 89    Issued 90     Remaining 999999
NDC 00004-1101-50 BRAND PS 120.00      Onhand -598       LstQty 90    On 03/05/0
P A                                    Unit Dose? N   Refills 99   Remaining 99

**Plan*****Submitted*Adjudicated**PlanPay*****Copay*Last Copay********Drug U&C*
* T18A      $1,586.99  $1,210.29 $1,210.29 $      .00                  $1,586.99
* CHARGE    $      .00  $      .00 $      .00 $      .00 DAW             Drug Cost
*                                                      Subst Ok,Gen N/A $1,291.99
*            IngrdCost     DispFee  Incentive   SalesTax       Price       Margin
* Submitted $1,582.69  $    4.30  $      .00  $      .00  Difference   $  295.00
* T18A      $1,186.29  $   24.00  $      .00  $      .00   $ 376.70   $  -81.70
**********************************************************************************
```

RPh LLB Tech | Prescription Edit/Label | Mon Aug 27, 2007

Patient [redacted] Phone [redacted] Rx # [redacted]
DOB [redacted] Rf # 4
Doctor [redacted] Phone [redacted] DEA [redacted]
SN 5610020

Drug XELODA 500 MG TABLET Qty 84 Dispensed 84 QtyLeft 168
DC 00004-1101-50 BRAND PS 120.00 Onhand -1277 LstQty 84 On 08/10/07
A Unit Dose? N Refills 6 Remaining 2

*Plan*****	Submitted*	Adjudicated**	PlanPay*****	Copay*	Last Copay********	Drug U&C**
T18A	$1,592.27	$1,200.76	$1,200.76	$ .00		$1,592.27 *
					DAW	Drug Cost *
					Subst Ok,Gen N/A	$1,296.30 *

	IngrdCost	DispFee	Incentive	SalesTax	Price	Margin *
Submitted	$1,587.97	$ 4.30	$ .00	$ .00	Difference $ 391.51	$ 295.97 *
T18A	$1,176.76	$ 24.00	$ .00	$ .00		$ -95.54 *

ATTACHMENT 3

REPORT PREPARED FOR THE TRANSPLANT PHAMACY COALITION-

"ASSESSING THE COST OF DISPENSING IMMUNOSUPPRESSIVE DRUGS TO MEDICARE TRANSPLANT RECIPIENTS – AN UPDATE"

The LEWIN GROUP

Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients – An Update

Report Prepared for:

Transplant Pharmacy Coalition

Prepared by:

The Lewin Group, Inc.

April 15, 2007

Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients – An Update

Report Prepared for:

Transplant Pharmacy Coalition

Prepared by:

Joan E. DaVanzo, Ph.D., M.S.W.
Allen Dobson, Ph.D.
Ted Kirby

April 15, 2007

Table of Contents

EXECUTIVE SUMMARY

The Medicare Prescription Drug, Improvement and Modernization Act (MMA) was implemented in January 2005. The MMA requires CMS to pay specialty pharmacy providers a "pharmacy supply fee" to cover the administrative and other costs associated with dispensing immunosuppressive drugs and providing associated professional services to Medicare transplant patients. Professional services include focused therapeutic management, patient counseling, and assistance with the paperwork associated with insurance reimbursement. MMA also mandated a change to an average sales price (ASP) based payment system for Medicare Part B drugs.

Successful immunosuppressant therapy has two requirements: first, that the treatment be fine-tuned to each individual patient in terms of drugs selected, dosages, and side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. The second requirement is that transplant recipients take their medications as prescribed, and promptly report any complications or adverse reactions to their doctors in order that dosages can be corrected over time. These two aspects make immunosuppressant therapy a challenge, especially in the initial months after the transplant, and require sustained and careful attention from the specialty pharmacy staff.

The literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug regimens. [1,2,3] Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.[4]

This finding underscores the importance of the specialty pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.[5] A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages vs. a 65% adherence rate found in the literature.[6] Using decision analysis methods, the

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[1] Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

[2] Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.

[3] Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. Transplant International 18: 1121-1133.

[4] Vlaminck H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

[5] Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. Jour Transplant Coordination 9(1): 13-16.

[6] Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence.* Virginia Commonwealth University School of Pharmacy.

authors estimated a potential cost savings of $4,150 per patient per year associated with increased adherence. Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, there is a compelling need for public policy to support providers' efforts to help these patients adhere to their medication regimens.

The Transplant Pharmacy Coalition commissioned The Lewin Group to update its 2004 analysis of the pharmacy costs associated with providing immunosuppressive drugs under Part B. Eight specialty pharmacies comprise the Transplant Pharmacy Coalition, whose members collectively fill more than 28,000 immunosuppressive prescriptions monthly and hold about 40% of the Medicare Part B market share in immunosuppressive drug dispensing.

As in 2004, The Lewin Group surveyed Coalition members for costs associated with providing immunosuppressive drugs and related pharmacy services in general and also to Medicare beneficiaries. The purpose of this report is to present our findings, comparing them to our 2004 findings where appropriate. We found that:

- Transplant pharmacies' average supply cost per immunosuppressive drug prescription has remained relatively stable between 2004 and 2007. In 2007, it is $30.73, down slightly from $32.62 in 2004. (These results are for those six pharmacies that participated both in 2004 and 2007.) The stability of our results suggests that our surveys have been working as intended and show a high level of reliability.

- Unlike retail chain pharmacies, transplant pharmacies routinely provide immunosuppressive drugs covered under Medicare Part B, as well as other direct services to encourage patient adherence to their drug regimen. Together with additional labor-intensive Medicare Part B requirements for documentation, pharmacies' personnel requirements are sizeable. We found that personnel costs have risen from 21.6% to 28.1% of supply costs (excluding the cost of goods sold) between 2004 and 2007. Personnel costs rose from $7.04 in 2004 to $8.65 in 2007.

- Although Centers for Medicare and Medicaid Services (CMS) eliminated the requirement for the submission of the Durable Medical Equipment Regional Centers Information Forms (DIFs) to receive reimbursement for immunosuppressive drugs, administrative costs for filing Medicare claims still account for a sizeable amount of the pharmacies' supply cost. We found these administrative costs to be approximately 23.2%, up from 19.7% in 2004, from $6.43 to $7.13. This is contrary to CMS' expectation.

- Unlike other prescription drug payers, Medicare does not provide real-time online adjudication of claims, making coordination of benefits with secondary insurers costly and sometimes impossible. Several pharmacies noted that Medicare denials have increased since 2004, resulting in additional work and expense for the pharmacy to resubmit the claim and file an appeal. This observation was confirmed by the survey

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Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

which found that administrative overhead has increased to 13.4% from 9.0% in 2004. Administrative overhead increased from $2.93 in 2004 to $4.13 in 2007.

- In contrast, other non-labor costs declined from 6.4% in 2004 to 1.2% in 2007, or from $2.08 to $0.37. Shipping declined from 14.8% in 2004 to 11.5% in 2007, or from $4.82 to $3.55. Inventory cost declined from 11.8% in 2004 to 1.7% in 2007, or from $3.84 to $0.52.

Exhibit 1 below presents a summary of the 2007 survey results, as compared to the results from 2004. The ratio of average pharmacy supply costs to average total costs decreased from 8.0% to 7.0%, reflecting both a higher cost of goods and somewhat lower supply costs. The average per prescription cost declined from $32.62 in 2004 to $30.73 in 2007. The amount of the supply costs devoted to filing Medicare claims rose from $8.86 in 2004 to $9.40 in 2007.

Exhibit 1
Summary Results

	2004 Survey [a/]	2007 Survey
Ratio of Average Supply Costs to Average Total Costs	8.0%	7.0%
Average per-Prescription Supply Cost	$32.62	$30.73
Amount Attributable to Additional Cost for Filing Medicare Claims	$8.86	$9.40

a/ Reanalysis of 2004 survey using data from the six pharmacies that responded to the 2007 survey and 2007 data categories. The 2007 survey collected FY 2006 data.

Source: Lewin Group analysis of survey data.

INTRODUCTION

The Transplant Pharmacy Coalition is comprised of eight specialty pharmacies who serve approximately 40% of the Medicare immunosuppressive market. The remainder of the market is served by retail pharmacy chains, hospital outpatient pharmacies at transplant centers, and Pharmacy Benefit Managers (PBMs) [which do not typically serve Medicare patients due to the high cost of filing Medicare claims].

The Transplant Pharmacy Coalition commissioned the Lewin Group to update its 2004 study of transplant pharmacy costs for providing immunosuppressive drugs to Medicare beneficiaries. We collected FY 2006 cost data from coalition members, and also conducted a focused review of the research literature on transplant patient adherence to immunosuppressive therapy. Because transplantation is the preferred treatment for end-stage renal disease (ESRD) and is less expensive than dialysis, the preservation of functioning kidney transplants has been considered to be a national priority. [7] Medication non-adherence is a leading barrier to continued transplant function, so we conducted a focused review of what is currently known about the topic.

In this introduction, we present the study purpose, study rationale, and a discussion of the services provided by specialty transplant pharmacies.

Study Purpose

The study purpose was threefold:

- To identify the supply costs associated with providing pharmacy services to Medicare Part B transplant recipients;
- To approximate average total and component clinical administrative costs of providing these services; and
- To develop average per prescription pharmacy supply cost estimates under the payment methodology outlined by the *Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).*

Study Rationale

Transplantation represents a solution to many kinds of end-stage disease. However, without immunosuppressive drug therapy, transplant recipients experience organ rejection, meaning that the body's immune system attacks the donor organ's cells, reacting to them as if they were harmful.[8] Medications that curb the immune system (called immunosuppressant drugs) are

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[7] Dobson A, DaVanzo J, Kerns J. (2000). Appendix E. Cost estimates for expanded Medicare benefits: skin cancer screening, Medically necessary dental services, and immunosuppressive therapy for transplant recipients. In: Field MJ, Lawrence RL, Zwanziger L (eds). *Extending Medicare Coverage for Preventive and Other Services.* Institute of Medicine. Washington D.C.: National Academy Press:347-362.

[8] Kreis HA, Ponticelli C. (2001). Causes of late renal allograft loss: chronic allograft dysfunction, death, and other factors. Transplantation 71: SS5.

essential for transplant recipients. The discovery of immunosuppressant drugs – and the advances still being made – allow many transplant recipients to live longer, healthier lives.[9]

Nevertheless, immunosuppression creates a new set of problems. People with suppressed immune systems are less likely to reject their transplanted organs, but also less able to fight off harmful "invaders." This leaves them vulnerable to infections and some types of cancer. Immunosuppressive drugs (also called "anti-rejection drugs") can also cause other side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. Finally, immunosuppressant medications can be costly.[10]

The rapidly increasing growth of organ transplantation has resulted in a dramatic increase in the number of immunosuppressive agents and other medications used in transplantation, resulting in more complex medication regimens and greater potential for interactions, adverse effects and increased costs. However, despite advances in immunosuppressive therapy, a major weakness in the "therapeutic chain" remains the patient's behavior.[11]

Pharmacists and other staff at specialty transplant pharmacies often work closely with each patient to provide specialized therapeutic management, medication distribution, and counseling. An early study demonstrated that patients' knowledge about anti-rejection medications increased from 53% to 75% after counseling by pharmacists. Their knowledge level about other drugs such as antimicrobial and antihypertensive agents was 15% before pharmacist counseling and increased to 50% to 60% following counseling.[12]

Transplant centers typically have outpatient pharmacies that provide many of these services to patients. However, a large percentage of patients live too far from transplant centers to use them on a regular basis.

Retail chain pharmacies typically do not supply immunosuppressive drugs due to:

- The small number of transplant patients relative to population;
- The high cost of inventory and high risk of waste from drug expiration (due to the high cost of drugs and small number of patients); and
- Lack of business desire to deal with complex Medicare claims procedures.

Mail-order PBM pharmacies typically do not serve Medicare Part B transplant patients, as most mail-order pharmacies do not have processes in place to file Medicare claims.
Therefore, specialty transplant pharmacies are the only practical option for many patients, especially Medicare Part B patients.

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[9] Pascual M, Theruvath T, Kawai T et al. (2002). Strategies to improve long term outcomes after renal transplantation. *N Eng J Med* 346:580.

[10] Yen EF, Hardinger K, Brennan D et al. (2004). Cost-effectiveness of extending Medicare coverage of immunosuppressive medications to the life of a kidney transplant. Am J Transplant 4: 1703-1708.

[11] Michelon TF, Piovesan F, Castilho C et al. (2002). Noncompliance as a cause of renal graft loss. *Transplant Proc* 34:2768-2770.

[12] De Geest S, Borgermans L, Gemoets H, et al.(1995) Incidence, determinants, and consequences of subclinical non compliance with immunosuppressive therapy in renal transplant recipients. *Transplantation* 59:340-347.

Transplant Pharmacy Practices that Increase Supply Costs of Dispensing

Transplant pharmacy practice differs from that of retail pharmacies in several ways, all of which increase costs. The transplant pharmacy service model involves the provision of many specialized services. For example, the initial prescriptions are often hand-delivered to the hospital on the day of discharge. Until the correct dosage for the patient is determined (approximately four months), the pharmacist works closely with the prescribing doctor to determine the correct dosage, and with the patient to monitor for symptoms of incorrect dosage or side effects.

Transplant pharmacies not only accept Medicare patients, they file Medicare claims. The filing of Medicare claims is more difficult and more costly than filing other types of claims.

Non-Medicare payers - both private insurers and Medicaid - offer and require instant online adjudication of claims at the time a prescription is filled. Pharmacies know before delivering the product how much they will be paid and how much of a co-payment to collect. Medicare Part B does not utilize the online adjudication system. This increases billing errors and makes coordination of benefits with secondary insurers difficult and sometimes impossible. Medicare often errs in identifying patients as having "primary" or "secondary" Medicare coverage. Prior to filing a claim, pharmacies can call Medicare to determine this status, but the answers are often incorrect.

Medicare claims add substantial costs due to a complicated filing process and the increased cost of coordinating benefits without the presence of an instant adjudication process. In addition, Medicare often provides inaccurate information about patient coverage status (primary vs. secondary), and secondary reimbursement is often lost due to Medicare errors discovered after date of service.

Successful immunosuppressant therapy has two requirements: first, that the treatment be fine-tuned to each individual patient in terms of drugs selected, dosages, and side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. The second requirement is that transplant recipients take their medications as prescribed, and promptly report any complications or adverse reactions to their doctors. These two aspects make immunosuppressant therapy a challenge, especially in the initial months after the transplant, and require sustained and careful attention from the specialty pharmacy staff.

The literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug regimens. [13],[14],[15] Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.[16]

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[13] Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

This finding underscores the importance of the transplant pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.[17]

A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages, vs. a 65% adherence rate obtained from the literature. [18] Using decision analysis methods, the authors estimated a potential cost savings of $4,150 per patient per year associated with increased adherence. The study also presented the annual cost of functioning grafts of $15,537 vs. $70,930 for failed grafts.[19] Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, it seems sensible for public policy to support providers' efforts to help these patients adhere to their medication regimens.

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[14] Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation 77*: 769-789.

[15] Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. Transplant International 18: 1121-1133.

[16] Vlaminck H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

[17] Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. Jour Transplant Coordination 9(1): 13-16.

[18] Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence.* Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

[19] USRDS, 2005.

METHODOLOGY

In this section, we present an overview of our study process, and a discussion of our data analytic methods.

In 2004, Lewin developed a study process that was comprised of the following five steps. In this update study, we followed the same five steps, and performed a targeted review of the literature on non-adherence with immunosuppressive medications. As in 2004, we worked closely with the Transplant Pharmacy Coalition to verify study objectives.

1. In the earlier study, we worked with the Transplant Pharmacy Coalition to identify pharmacy supply cost categories and to develop a survey instrument. In this study, we verified the 2004 cost categories with the pharmacies, updating our instrument where needed.

2. We collected cost accounting data from participating transplant pharmacies using the updated instrument. Cost data were allocated to the Medicare Part B transplant line of business using the same top-down approach that was used in 2004.

3. We reviewed data with each participant to ensure their accuracy.

4. We analyzed the survey data, and presented draft study results for review.

5. We then drafted and finalized the report.

Data Collection

Data were collected from six of the eight specialty pharmacies of various sizes providing wide geographic coverage. As part of the earlier survey development, The Lewin Group and the Transplant Pharmacy Coalition identified and defined cost categories. The prior survey was used for this update study. For this study, we verified that the cost categories were still being created in the same way as in 2004. Where categories had changed for one company, we asked that costs in the new category be allocated to the original 2004 categories. Six transplant pharmacies completed the survey, providing FY2006 cost information. As before, to ensure consistency of reporting and accuracy of cost data, we worked individually with each company.

The current survey collected cost data on:

- Number of Medicare and non-Medicare prescriptions filled
- Cost of goods sold
- Clinical and administrative costs
- Inventory and overhead costs
- Cost of processing Medicare claims
- Medicare bad debt and collection costs

The 2007 survey instrument can be found in **Appendix A.**

Analytic Methods

Cost estimates were made with the intent of accurately representing the transplant pharmacy industry as a whole, given our sample of six specialty pharmacies. **Average cost per prescription** was calculated for each company and then a weighted average was calculated according to the number of prescriptions (not by dollar volume).

Data were used to analyze the major cost components associated with providing immunosuppressive drugs to patients. The **percent of total cost** for each component was also calculated. Cost components include:

- Cost of Goods Sold
- Pharmacy Supply Costs
  - Pharmacy personnel
  - Medicare Part B claims processing
  - Inventory cost and inventory shrinkage*
  - Shipping
  - Rent
  - Sales and marketing
  - Administrative overhead
- Medicare Bad Debt
  - Co-payments never made
  - Collection costs

Exhibit 2 contains the key summary variables and how they were calculated.

Exhibit 2
Key Summary Variables

Statistic	Numerator	Denominator
Ratio of Average Supply Costs to Average Total Costs	Aggregate pharmacy costs, except cost of goods sold (COGS)	Aggregate pharmacy total costs (includes COGS)
Average per-Prescription Supply Cost	Aggregate pharmacy costs, except cost of goods sold (COGS)	Number of prescriptions supplied to Medicare patients
Amount Attributable to Additional Cost for Filing Medicare Claims	Aggregate cost of submitting Medicare claims plus Medicare bad debt and collection costs	Number of prescriptions supplied to Medicare patients

(Provider data reflect CY 2006)

RESULTS

In this section, we present the key summary variables for both 2007 and 2004. This is followed by a presentation of the component cost structures, also from both 2007 and 2004.

Exhibit 3 contains the results of our analyses, as well as a comparison to our 2004 results, which have been adjusted to include the same six pharmacies that participated in the study in 2007. The ratio of average pharmacy supply costs to average total costs decreased from 8.0% to 7.0%, reflecting a higher cost of goods and somewhat lower supply costs. The average per prescription cost declined from $32.62 in 2004 to $30.73 in 2007. The amount of the supply costs devoted to filing Medicare claims rose from $8.86 in 2004 to $9.40 in 2007.

Exhibit 3
Summary Results

	2004 Survey [a/]	2007 Survey
Ratio of Average Supply Costs to Average Total Costs	8.0%	7.0%
Average per-Prescription Supply Cost	$32.62	$30.73
Amount Attributable to Additional Cost for Filing Medicare Claims	$8.86	$9.40

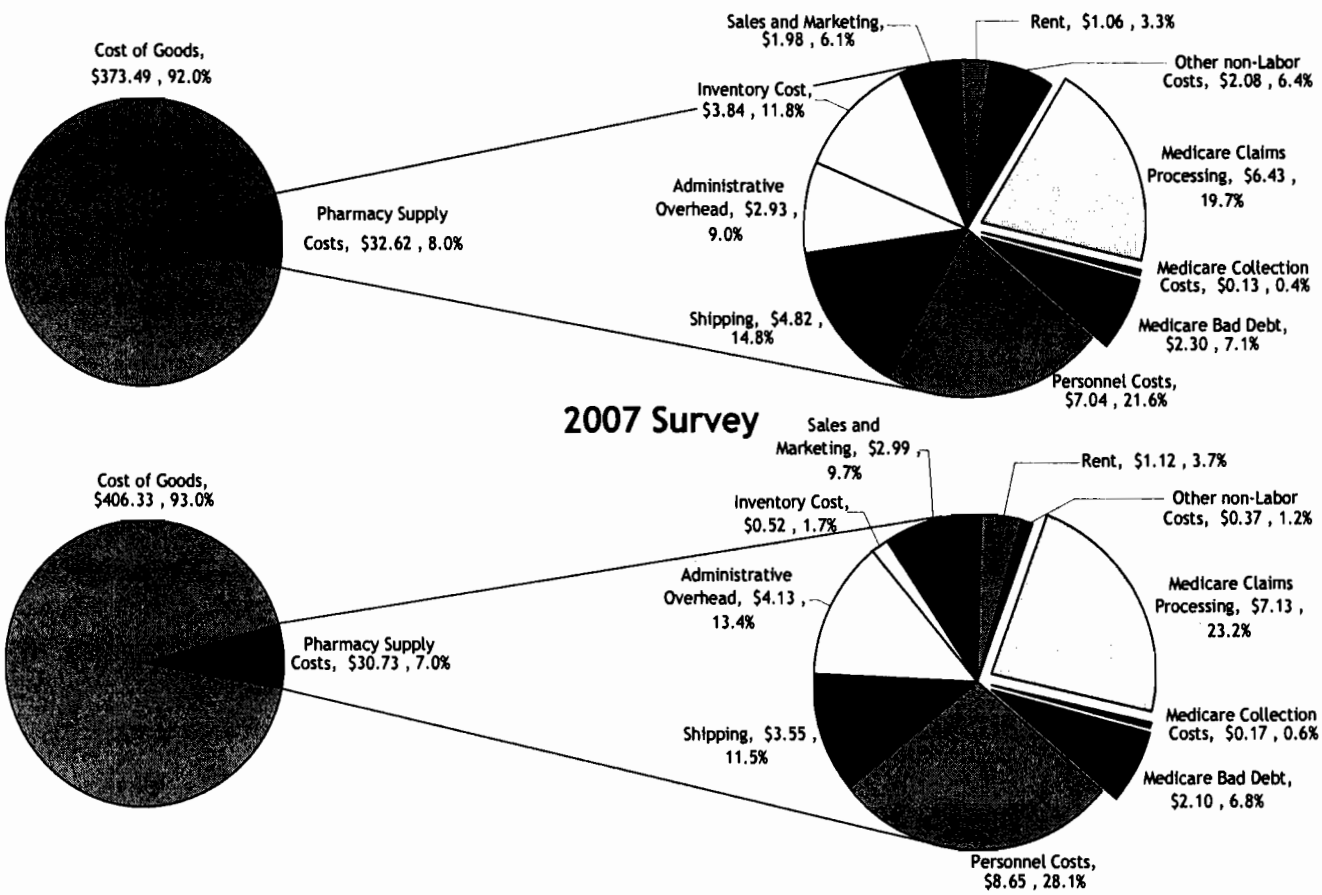
a/ Reanalysis of 2004 survey using data from the six pharmacies that responded to the 2007 survey and 2007 data categories. The 2007 survey collected 2006 data.

Source: Lewin Group analysis of survey data.

Exhibit 4 below contains a side by side comparison of the components of the supply cost for both 2007 and 2004.

- Transplant pharmacies' average supply cost per immunosuppressive drug prescription has remained relatively stable between 2004 and 2007. In 2007, it is $30.73, down slightly from $32.62 in 2004. (These results are for those six pharmacies that participated both in 2004 and 2007.) The stability of our results suggests that our surveys have been working as intended and show a high level of reliability.
- Unlike retail chain pharmacies, transplant pharmacies routinely provide immunosuppressive drugs covered under Medicare Part B, as well as other direct services to encourage patient adherence to their drug regimen. Together with additional labor-intensive Medicare Part B requirements for documentation, pharmacies' personnel requirements are sizeable. We found that personnel costs have risen from 21.6% to 28.1% of supply costs (excluding the cost of goods sold) between 2004 and 2007. Personnel costs rose from $7.04 in 2004 to $8.65 in 2007.
- Although Centers for Medicare and Medicaid Services (CMS) eliminated the requirement for the submission of the Durable Medical Equipment Regional Centers Information Forms (DIFs) to receive reimbursement for immunosuppressive drugs, administrative costs for filing Medicare claims still account for a sizeable amount of the pharmacies' supply cost. We found these administrative costs for Medicare claims processing to be approximately 23.2%, up from 19.7% in 2004, from $6.43 to $7.13. This is contrary to CMS' expectation.

Exhibit 4
Comparison of 2004 and 2007 Surveys
Using 2007 Cost Category Data from Respondents to Both Surveys



- Unlike other prescription drug payers, Medicare does not provide real-time online adjudication of claims, making coordination of benefits with secondary insurers costly and sometimes impossible. Several pharmacies noted that Medicare denials have increased since 2004, resulting in additional work and expense for the pharmacy to resubmit the claim and file an appeal. This observation was confirmed by the survey which found that administrative overhead has increased to 13.4% from 9.0% in 2004. Administrative overhead increased from $2.93 in 2004 to $4.13 in 2007.

- In contrast, other non-labor costs declined from 6.4% in 2004 to 1.2% in 2007 or from $2.08 to $0.37. Shipping declined from 14.8% in 2004 to 11.5% in 2007 or from $4.82 to $3.55. Inventory cost declined from 11.8% in 2004 to 1.7% in 2007 or from $3.84 to $0.52.

- We found that the literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug

regimens. [20,21,22] Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.[23]

- A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages vs. a 65% adherence rate found in the literature.[24] Using decision analysis methods, the authors estimated a potential cost savings of $4,150 per patient per year associated with increased adherence.

[20] Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.
[21] Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.
[22] Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. Transplant International 18: 1121-1133.
[23] Vlaminck H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.
[24] Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence.* Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

CONCLUSIONS

Organ transplant is the most effective, and sometimes the only, treatment for patients with a non-functioning heart, lung, kidney, liver, pancreas, or intestine. The most common organ transplanted is the kidney (61%) for treatment of End Stage Renal Disease (ESRD). Transplanted organs are rarely an exact match for the patient, and are therefore "rejected" by the patients immune system.

Lifetime treatment with immunosuppressive drugs is required to suppress the patient's immune system to prevent organ rejection. Without immunosuppressive drugs supplied at the proper dosage, the patient will reject the organ and require a return to dialysis, re-transplantation or die. Successful transplantation has become inseparably linked to pharmacological immunosuppression that must be maintained for the life of the graft.[25]

Specialty pharmacies are a dominant supplier of immunosuppressive drugs to Medicare Part B transplant patients. Together they serve about 40% of Medicare transplant patients. The Coalition's average cost of supplying a prescription to a Medicare Part B transplant patient is $30.73, down from $32.62 in 2004, exclusive of the cost of the drug itself (when comparing pharmacies that completed both surveys). The supply cost attributable to filing Medicare claims rose to $9.40 from $8.86 in 2004.

Many patients do not have reasonable access to alternative sources for these essential drugs. Continued assurance that Medicare transplant patients have access to quality service and life-sustaining drugs is an important policy objective as payment changes are considered for Medicare Part B drugs. As the cost of goods increases and supply cost pressures mount, Medicare payment policies will become ever more important to ensuring access to transplant recipients.

Our findings underscore the importance of the specialty pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.[26] Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, there is a compelling need for public policy to support providers' efforts to help these patients adhere to their medication regimens.

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[25] Gaston RS. (2000). Immunosuppressive Therapy: The Scientific Basis and Clinical Practice of Immunosuppressive Therapy in the Management of Transplant Recipients. In Extending Medicare Coverage for Preventive and Other Services (2000). National Academy of Science, Institute of Medicine.

[26] Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. Jour Transplant Coordination 9(1): 13-16.

Appendix A: Survey Instrument

The Lewin Group
Transplant Pharmacy Coalition survey

Company Name: _____

Is your business exclusively for transplant patients?
☐ Yes ☐ No
(If Yes, columns A and B should be the same.)

Data for:
☐ Calendar year 2006
☐ Calendar year 2005
☐ Other period _____

	Total Pharmacy (A)	Transplant Patients (B)	Medicare Transplant Patients (C)
Number of Prescriptions			
New Presciptions			
Refills			
Cost of Goods Sold			
Clinical Administration Costs (Personnel)			
Personnel costs, including benefits, payroll taxes, etc.			
Total cost of receiving and processing prescription orders			
Toal cost of preparing orders for shipping			
Total cost of maintaining inventory (ordering, stocking, etc.)			
Total cost of processing claims			
Total cost of patient education & counseling			
Sub-total: Direct labor costs			
Clinical Administration Costs (Other)			
Total cost of shipping (UPS/FedEx/USPS/etc. bill)			
Inventory cost (Average inventory times cost of capital)			
Sub-total: Non-labor clinical administrative costs			
Administrative Overhead			
Accreditation, licensing, and permits			
Supervision			
Office supplies and other administrative expenses.			
Sales and Marketing			
Rent			
Utilities (electric, gas, heating oil, etc.)			
Insurance			
Computer hardware/software			
Telephone/Internet			
Bank charges, legal and accounting expenses			
Sub-total: Unallocated Overhead			
Medicare Bad Debt			
Include ***only*** Medicare copayments that were never paid. ***Do not*** include denied claims or non-Medicare bad debt.			
Collections costs			
TOTAL COSTS:			

If you have any questions, please contact Joan DaVanzo, (703) 269-5724.

Please return survey by e-mail or fax to:
Joan DaVanzo, E-mail: joan.davanzo@lewin.com, Fax: (703) 269-5501

ATTACHMENT 4

CMS ASP+6% RATES FOR IMMUNOSUPPRESSANT AGENTS Q3 2007

ASP+6% Rates for Immunosuppressant Agents Q3 2007

		ASP Prices				
J Code	**Generic Name**	**Q3 2007***	**Q2 2007**	**Q1 2007**	**Q4 2006**	**Q3 2006**
J7500	Azathioprine Oral 50 mg	**$0.192**	$0.182	$0.274	$0.186	$0.174
J7502	Cyclosporine Oral 100 mg	**($3.536)**	$3.599	$3.541	$3.664	$3.968
J7515	Cyclosporine Oral 25 mg	**($0.916)**	$0.949	$0.952	$0.962	$1.003
J7506	Prednisone oral 5 mg	**($0.159)**	$0.192	$0.191	$0.185	$0.200
J7507	Tacrolimus 1 mg	**$3.738**	$3.662	$3.540	$3.549	$3.541
J7517	Mycophenolate mofetil oral 250 mg	**$2.629**	$2.624	$2.547	$2.504	$2.517
J7518	Mycophenolic acid 180 mg	**$2.269**	$2.267	$2.140	$2.148	$2.161
J7520	Sirolimus oral 1 mg	**$7.563**	$7.222	$7.224	$7.247	$7.151

***( ) means a decrease in price for Q3 2007 versus Q2 2007**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, 411, 413, 414, 415, 418, 423, 424, 482, 484, 485, and 491

[CMS–1385–P]

RIN 0938–AO65

Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address certain provisions of the Tax Relief and Health Care Act of 2006, as well as make other proposed changes to Medicare Part B payment policy.

We are proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This proposed rule also discusses refinements to resource-based practice expense (PE) relative value units (RVUs); geographic practice cost indices (GPCI) changes; malpractice RVUs; requests for additions to the list of telehealth services; several coding issues including additional codes from the 5-Year Review; payment for covered outpatient drugs and biologicals; the competitive acquisition program (CAP); clinical lab fee schedule issues; payment for renal dialysis services; performance standards for independent diagnostic testing facilities; expiration of the physician scarcity area (PSA) bonus payment authorized by section 413 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA); conforming and clarifying changes for comprehensive outpatient rehabilitation facilities (CORFs); a process for updating the drug compendia at section 1861(t)(2)(B) of the Social Security Act (the Act); physician self-referral issues; beneficiary signature for ambulance transport services; durable medical equipment (DME) update; the chiropractic services demonstration; a Medicare economic index (MEI) data change; technical corrections; issues related to therapy services; revisions to the ambulance fee schedule; the ambulance inflation factor for CY 2008; and the proposal to eliminate the exemption for computer-generated facsimile transmissions from the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for transmitting prescription and certain prescription-related information for Part D eligible individuals.

DATES: To be assured consideration, except for comments on section II.M.10 of the preamble, comments must be received at one of the adresses provided below, no later than 5 p.m. on Friday, August 31, 2007.

Comments on section II.M.10 "Alternative Criteria for Satisfying Certain Exceptions", of the preamble must be received by no later than 5 p.m. on Friday, September 7, 2007.

ADDRESSES: In commenting, please refer to file code CMS–1385–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1385–P, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1385–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Pam West (410) 786–2302 for issues related to practice expense and changes to the comprehensive outpatient rehabilitation facility.

Rick Ensor (410) 786–5617 for issues related to practice expense methodology.

Stephanie Monroe (410) 786–6864 for issues related to the geographic practice cost index and malpractice RVUs.

Craig Dobyski (410) 786–4584 for issues related to list of telehealth services.

Ken Marsalek (410) 786–4502 for issues related to the DRA imaging cap.

Catherine Jansto (410) 786–7762 for issues related to payment for covered outpatient drugs and biologicals.

Edmund Kasaitis (410) 786–0477 for issues related to the Competitive Acquisition Program (CAP) for part B drugs.

Anita Greenberg (410) 786–4601 for issues related to the clinical laboratory fee schedule.

Henry Richter (410) 786–4562 for issues related to payments for end-stage renal disease facilities.

August Nemec (410) 786–0612 for issues related to independent diagnostic testing facilities.

Karen Rinker (410) 786–0189 for issues related to the drug compendia.

David Walczak (410) 786–4475 for issues related to reassignment and

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

DRAFT DRAFT DRAFT DRAFT

SUBMITTED VIA CMS WEBSITE / HAND DELIVERED TO CMS WASHINGTON, DC OFFICE (Hubert H. Humphrey Building, Room 445-G, 200 Independence Avenue, SW., Washington, DC 20201)

August 31, 2007

(Mailing address)
Centers for Medicare and Medicaid Services
Department of Health and Human Services (HHS)
Attention: CMS-6006-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: CMS-1385-P: Section II.F.1. (ASP Issues) and Section II.S.3. (Proposed Elimination of the Exemption for Computer-Generated Facsimile Transmission From the NCPDP SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information for Part D Eligible Individuals)

Dear Acting Administrator Weems:

The National Community Pharmacists Association (NCPA)[1] provides the following comments to the sections of CMS' proposed Medicare rule regarding average sales price (ASP) issues and proposed elimination of the computer-generated fax exemption.

I. AVERAGE SALES PRICE (ASP) ISSUES

NCPA is very concerned with the provisions in the proposed rule that would not pay pharmacies less than their acquisition cost and not provide adequate reimbursement to cover administrative and overhead costs.

Not only does the proposed rule: (1) not increase supply or dispensing fees for Part B medications to help offset low reimbursements under ASP – which are often under acquisition costs for most independent pharmacists -- and administrative costs incurred in Medicare Part B claim submission; it also (2) reduces reimbursement to the lesser of the average manufacturer's price (AMP) or 103 percent of widely available market price (WAMP) if the ASP exceeds the AMP or the WAMP by five percent or more. Even outside of the unique

[1] The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies. These independents employ over 55,000 licensed pharmacists and over 300,000 additional employees across the United States.

Deleted:

THE VOICE OF THE COMMUNITY PHARMACIST

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

economic and administrative challenges independent pharmacies face in serving Medicare Part B patients, CMS should address reimbursements below costs and not choose a reimbursement measure which would result in even lower payments.

A. Current WAC for Most Immunosuppressant Agents Below ASP

The ASP reimbursement schedule (Attachment 1) shows that the current wholesale acquisition costs (WAC) rates for seven of the 10 most commonly used immunosuppressant agents are substantially below July 2007 ASP rates. Approximately 60 percent of community pharmacies pay WAC for acquisition of immunosuppressant agents. This figure represents the most current ASP data and often this information changes on a quarterly basis. This loss is in addition to the unreimbursed extensive billing time and services associated with filling Medicare Part B prescriptions as well as the inadequate supply fee which results in an even greater financial loss for pharmacies.[2] Many of our members have advised us that they have already been forced to stop providing Part B medications which decreases access for patients. Others are only able to fill prescriptions for the least expensive Part B drugs as a costly courtesy to their patients. Some Part B medications, particularly cancer-battling drugs, are expensive, and thus pharmacists suffer significant loses when dispensing those medications. By way of example, two pharmacy invoices show that an independent pharmacist dispensed a month's supply of Xeloda at an ingredient cost of $1,291.99, yet was reimbursed only $1,210.29 by the plan ($1,186.29 plus the $24 dispensing fee) – a loss of $81.70, not including the costs of operating the pharmacy. The pharmacist later dispensed the same prescription medication at an ingredient cost of $1,296.30 while being paid only $1,200.76 by the plan – $95.54 below acquisition costs (Attachment 2).

B. AMP and WAMP +3% Pricing Will Result in Greater Reductions in Payment to Pharmacies for Immunosuppressant Agents

CMS' proposed use of the lower of AMP or WAMP plus 3 percent if ASP is found to be 5 percent above these figures would make the current situation even worse. Based on independent community pharmacy's experience with ASP since 2005, NCPA believes that a survey of pharmacy providers would not yield a WAMP that is lower than ASP. NCPA references the Transplant Pharmacy Coalition's trend analysis, which suggests that on balance ASP prices have been consistently lower than pharmacy acquisition costs (Attachment 3).

AMP is untested in the market as a reimbursement mechanism for pharmacy providers but is scheduled to be implemented in 2008. The GAO has found that if pharmacists are reimbursed at the maximum ceiling federal upper limit (FUL) of 250 percent above AMP, they will still be reimbursed at 36 percent below acquisition costs. The HHS OIG has similarly found that a completely funded FUL would still fall below pharmacy acquisition cost for 19 of the 25 high-expenditure generic medications studied. For five of the other six medications in the study, the pharmacy would only cover the cost of the drug, but would still realize a loss once the cost of dispensing is considered.

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In addition to this straight comparison of purchasing costs to reimbursements, there is the added consideration of heightened administrative costs for Part B claim processing, despite some recent streamlining in the billing process. It is still more expensive for the retail pharmacy to bill Medicare Part B than any other third party. Administrative errors caused by the Medicare billing procedures accounts for numerous denials in coverage and often results in additional costs that pharmacies are forced to absorb without reimbursement.

For these reasons, the agency should not implement further restrictions by paying the lower of the AMP or WAMP where the ASP is higher by five percent or more. (this is covered below)

C. Proposed Part B Rule Does Not Increase Supply or Dispensing Fees for Part B Medications

NCPA strongly urges that Part B drug supply and dispensing fees be increased for CY2008 to help offset low reimbursement amounts realized under the ASP method, and administrative costs associated with Part B claims. NCPA supports and refers CMS to the $30.73 supply fee for each Medicare Part B immunosuppressant prescription recommended by the Transplant Pharmacy Coalition in its comments (the current monthly reimbursement is $24 for the first immunosuppressant and $16 for each prescription provided in a 30-day period). CMS' failure to increase supply and dispensing fees results in community pharmacies' reimbursement falling below the actual cost to dispense Part B prescriptions.

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II. FAX EXEMPTION ISSUES

NCPA believes that widespread marketplace adoption of e-prescribing will have many benefits and efficiencies for prescribers, pharmacists and pharmacies, and patients. The proposed rule, however, would implement a lock-step approach for e-prescribing that will cause great disruption, expense and actually discourage e-prescribing. NCPA agrees with eRx's statement that a complete elimination of the fax exemption will have more adverse impacts then benefits. NCPA believes that at this time, the least disruption to safe and effective prescription transmission and dispensing and the smallest amount of prescription transmission error will be accomplished through allowing prescribers and pharmacists to use computer-generated faxes to send and receive prescriptions in the following situations

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1) When the destination does not yet support e-prescribing, or as a backup when the electronic communication is unavailable;
2) Where a prescriber or dispenser is prohibited from complying with the NCPDP SCRIPT standard for reasons beyond their control, such as DEA regulations prohibiting the e-prescribing of a prescription for a controlled substance;
3) When there is not an agreement between the prescribing and pharmacy vendor to allow sending transactions electronically, even though both are capable of communicating using the SCRIPT standard; and
4) Where prescribers/dispensers use software (such as a word processing program) that creates and faxes the prescription document, but does not have true e-prescribing capabilities.

NCPA also asks CMS to:

- Allow those who adopt NCPDP SCRIPT-compliant functionality one year after the effective date to comply with the SCRIPT standard;
- Exempt pharmacies from penalties for prescriber non-compliance;
- Address pharmacist liability concerns: prescriptions transmitted before the compliance deadline but filled or refilled after that deadline should be exempt, and dispensing a prescription transmitted in a noncompliant manner should not be considered a violation of either the federal or state false claims acts; and
- Establish April 1, 2009 as the rule's effective date consistent with the effective date of MMA-mandated e-prescribing standards.

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Faced with having to either comply completely with the NCPDP SCRIPT standard if it chooses to e-prescribe, or revert to receiving and sending paper faxes, many pharmacies – particularly independent pharmacies -- will likely revert to the latter. Indeed, in the original rule published in November, 2004, CMS stated that "absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. This would cause computer-generated faxes to revert to paper prescribing." CMS does not offer data that shows that this conclusion should now change. In fact, CMS concedes that independent pharmacies are not prepared to implement e-prescribing, finding that SureScripts reports that only 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions.[3]

It would be better to have the modified lifting of the exemption as outlined above and in the concluding proposed language, thus leading to more electronic prescribing, which will create an environment and practice/culture that will encourage prescribers and dispensers who do not currently have e-prescribing capabilities to adjust their prescription communication practices.

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- Similarly, any NCPDP SCRIPT enabled sending entity, such as a pharmacy, should be able to send a computer generated facsimile if the receiving entity is not capable of receiving an NCPDP SCRIPT message, and the pharmacy believes that a computer generated facsimile is the best and most efficient way to send the prescription message.
- If both the pharmacy and the prescriber have NCPDP SCRIPT standard communication capability, then they should do so -- unless another exemption applies.

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Pharmacist Liability

CMS should clarify that:

[3] Federal Register, Vol. 72, no. 133, July 12, 2007 at 38195.

- In order to avoid the inefficiency of obtaining new prescriptions, prescriptions transmitted before the compliance deadline but filled or refilled after the compliance deadline should not be subject to the rule.
- The dispensing of a prescription transmitted in a noncompliant manner should not be considered a violation of either the federal or state false claims acts. Failure to do so would increase Medicare program participation costs for pharmacies and could potentially discourage pharmacy participation in the program.

E-prescribing capability

NCPA endorses the following proposed language, which should be read narrowly so as to not require prescribers and dispensers to purchase different software systems in order to become NCPDP SCRIPT Standard compliant.

§ 423.160(a)(3(i) Entities transmitting prescriptions or prescription related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information in the following circumstances:

1. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) does not own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, whether on the version that the prescriber/dispenser is currently using or another version of such software.*

    a. *This exemption shall not apply to prescribers/dispensers sending a transaction listed at Section 423.160(b)(1)(i) through (xii) who own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, but who has not upgraded to the version that is compliant with the NCPDP SCRIPT Standard and/or has not activated that functionality.*

    b. *In addition, in the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) owns, licenses, or otherwise uses software that does not have or did not have the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated] to send and receive transactions compliant with the NCPDP SCRIPT Standard, but such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard at any time after [insert date rule promulgated], then this exemption shall not apply with respect to such software twelve months after such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard.*

2. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) is sending the transaction to a dispenser/prescriber who does not own, license, or otherwise use software that has the capability to receive transactions compliant with the NCPDP SCRIPT Standard.*

3. *In the event any applicable law or regulation would prohibit the electronic transmission of the prescription and prescription related information using the NCPDP SCRIPT Standard.*

4. *In the event there is a temporary communications failure, whether technological or otherwise, that would prohibit the electronic transmission of the transactions listed at Section 423.160(b)(1)(i) through (xii) using the NCPDP SCRIPT Standard. Such temporary communications failures include, by way of example and not limitation, power outages, connectivity failures, or temporary outages of the either the prescriber's or dispenser's computer or management systems.*

5. *Information transmitted in a manner that is compliant with this rule at the time of its transmission shall remain compliant with this rule for the purposes of this rule even if such information or transmission would otherwise become noncompliant at a future date.*

We appreciate the opportunity to submit the comments on behalf of our membership. If you have any questions, please do not hesitate to contact NCPA via telephone at 703-683-8200 or via email at: Charlie.Sewell@ncpanet.org.

Sincerely,

Charles B. Sewell
Senior Vice President, Government Affairs

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

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SUBMITTED VIA CMS WEBSITE / HAND DELIVERED TO CMS WASHINGTON, DC OFFICE (Hubert H. Humphrey Building, Room 445-G, 200 Independence Avenue, SW., Washington, DC 20201)

August 31, 2007

(Mailing address)
Centers for Medicare and Medicaid Services
Department of Health and Human Services (HHS)
Attention: CMS-6006-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: CMS-1385-P: Section II.F.1. (ASP Issues) and Section II.S.3. (Proposed Elimination of the Exemption for Computer-Generated Facsimile Transmission From the NCPDP SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information for Part D Eligible Individuals)

Dear Acting Administrator Weems:

The National Community Pharmacists Association (NCPA)[1] provides the following comments to the sections of CMS' proposed Medicare rule regarding average sales price (ASP) issues and proposed elimination of the computer-generated fax exemption.

I. AVERAGE SALES PRICE (ASP) ISSUES

NCPA is very concerned with the provisions in the proposed rule that would not pay pharmacies less than their acquisition cost and not provide adequate reimbursement to cover administrative and overhead costs.

Not only does the proposed rule: (1) not increase supply or dispensing fees for Part B medications to help offset low reimbursements under ASP – which are often under acquisition costs for most independent pharmacists -- and administrative costs incurred in Medicare Part B claim submission; it also (2) reduces reimbursement to the lesser of the average manufacturer's price (AMP) or 103 percent of widely available market price (WAMP) if the ASP exceeds the AMP or the WAMP by five percent or more. Even outside of the unique

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economic and administrative challenges independent pharmacies face in serving Medicare Part B patients, CMS should address reimbursements below costs and not choose a reimbursement measure which would result in even lower payments.

A. Current WAC for Most Immunosuppressant Agents Below ASP

The ASP reimbursement schedule (Attachment 1) shows that the current wholesale acquisition costs (WAC) rates for seven of the 10 most commonly used immunosuppressant agents are substantially below July 2007 ASP rates. Approximately 60 percent of community pharmacies pay WAC for acquisition of immunosuppressant agents. This figure represents the most current ASP data and often this information changes on a quarterly basis. This loss is in addition to the unreimbursed extensive billing time and services associated with filling Medicare Part B prescriptions as well as the inadequate supply fee which results in an even greater financial loss for pharmacies.[2] Many of our members have advised us that they have already been forced to stop providing Part B medications which decreases access for patients. Others are only able to fill prescriptions for the least expensive Part B drugs as a costly courtesy to their patients. Some Part B medications, particularly cancer-battling drugs, are expensive, and thus pharmacists suffer significant loses when dispensing those medications. By way of example, two pharmacy invoices show that an independent pharmacist dispensed a month's supply of Xeloda at an ingredient cost of $1,291.99, yet was reimbursed only $1,210.29 by the plan ($1,186,29 plus the $24 dispensing fee) – a loss of $81.70, not including the costs of operating the pharmacy. The pharmacist later dispensed the same prescription medication at an ingredient cost of $1,296.30 while being paid only $1,200.76 by the plan – $95.54 below acquisition costs (Attachment 2).

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NCPA believes that widespread marketplace adoption of e-prescribing will have many benefits and efficiencies for prescribers, pharmacists and pharmacies, and patients. The proposed rule, however, would implement a lock-step approach for e-prescribing that will cause great disruption, expense and actually discourage e-prescribing. NCPA agrees with eRx's statement that a complete elimination of the fax exemption will have more adverse impacts then benefits. NCPA believes that at this time, the least disruption to safe and effective prescription transmission and dispensing and the smallest amount of prescription transmission error will be accomplished through allowing prescribers and pharmacists to use computer-generated faxes to send and receive prescriptions in the following situations

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NCPA also asks CMS to:

- Allow those who adopt NCPDP SCRIPT-compliant functionality one year after the effective date to comply with the SCRIPT standard;
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- Establish April 1, 2009 as the rule's effective date consistent with the effective date of MMA-mandated e-prescribing standards.

Faced with having to either comply completely with the NCPDP SCRIPT standard if it chooses to e-prescribe, or revert to receiving and sending paper faxes, many pharmacies – particularly independent pharmacies -- will likely revert to the latter. Indeed, in the original rule published in November, 2004, CMS stated that "absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. This would cause computer-generated faxes to revert to paper prescribing." CMS does not offer data that shows that this conclusion should now change. In fact, CMS concedes that independent pharmacies are not prepared to implement e-prescribing, finding that SureScripts reports that only 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions.[3]

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We appreciate the opportunity to submit the comments on behalf of our membership. If you have any questions, please do not hesitate to contact NCPA via telephone at 703-683-8200 or via email at: Charlie.Sewell@ncpanet.org.

Sincerely,

Charles B. Sewell
Senior Vice President, Government Affairs

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

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SUBMITTED VIA CMS WEBSITE / HAND DELIVERED TO CMS WASHINGTON, DC OFFICE (Hubert H. Humphrey Building, Room 445-G, 200 Independence Avenue, SW., Washington, DC 20201)

August 31, 2007

(Mailing address)
Centers for Medicare and Medicaid Services
Department of Health and Human Services (HHS)
Attention: CMS-6006-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: CMS-1385-P: Section II.F.1. (ASP Issues) and Section II.S.3. (Proposed Elimination of the Exemption for Computer-Generated Facsimile Transmission From the NCPDP SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information for Part D Eligible Individuals)

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THE VOICE OF THE COMMUNITY PHARMACIST

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C. Proposed Part B Rule Does Not Increase Supply or Dispensing Fees for Part B Medications

NCPA strongly urges that Part B drug supply and dispensing fees be increased for CY2008 to help offset low reimbursement amounts realized under the ASP method, and administrative costs associated with Part B claims. NCPA supports and refers CMS to the $30.73 supply fee for each Medicare Part B immunosuppressant prescription recommended by the Transplant Pharmacy Coalition in its comments (the current monthly reimbursement is $24 for the first immunosuppressant and $16 for each prescription provided in a 30-day period). CMS' failure to increase supply and dispensing fees results in community pharmacies' reimbursement falling below the actual cost to dispense Part B prescriptions.

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II. FAX EXEMPTION ISSUES

NCPA believes that widespread marketplace adoption of e-prescribing will have many benefits and efficiencies for prescribers, pharmacists and pharmacies, and patients. The proposed rule, however, would implement a lock-step approach for e-prescribing that will cause great disruption, expense and actually discourage e-prescribing. NCPA agrees with eRx's statement that a complete elimination of the fax exemption will have more adverse impacts then benefits. NCPA believes that at this time, the least disruption to safe and effective prescription transmission and dispensing and the smallest amount of prescription transmission error will be accomplished through allowing prescribers and pharmacists to use computer-generated faxes to send and receive prescriptions in the following situations

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1) When the destination does not yet support e-prescribing, or as a backup when the electronic communication is unavailable;
2) Where a prescriber or dispenser is prohibited from complying with the NCPDP SCRIPT standard for reasons beyond their control, such as DEA regulations prohibiting the e-prescribing of a prescription for a controlled substance;
3) When there is not an agreement between the prescribing and pharmacy vendor to allow sending transactions electronically, even though both are capable of communicating using the SCRIPT standard; and
4) Where prescribers/dispensers use software (such as a word processing program) that creates and faxes the prescription document, but does not have true e-prescribing capabilities.

NCPA also asks CMS to:

- Allow those who adopt NCPDP SCRIPT-compliant functionality one year after the effective date to comply with the SCRIPT standard;
- Exempt pharmacies from penalties for prescriber non-compliance;
- Address pharmacist liability concerns: prescriptions transmitted before the compliance deadline but filled or refilled after that deadline should be exempt, and dispensing a prescription transmitted in a noncompliant manner should not be considered a violation of either the federal or state false claims acts; and
- Establish April 1, 2009 as the rule's effective date consistent with the effective date of MMA-mandated e-prescribing standards.

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Faced with having to either comply completely with the NCPDP SCRIPT standard if it chooses to e-prescribe, or revert to receiving and sending paper faxes, many pharmacies – particularly independent pharmacies -- will likely revert to the latter. Indeed, in the original rule published in November, 2004, CMS stated that "absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. This would cause computer-generated faxes to revert to paper prescribing." CMS does not offer data that shows that this conclusion should now change. In fact, CMS concedes that independent pharmacies are not prepared to implement e-prescribing, finding that SureScripts reports that only 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions.[3]

It would be better to have the modified lifting of the exemption as outlined above and in the concluding proposed language, thus leading to more electronic prescribing, which will create an environment and practice/culture that will encourage prescribers and dispensers who do not currently have e-prescribing capabilities to adjust their prescription communication practices.

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Pharmacies should not be penalized for prescriber non-compliance

- It is very difficult, if not impossible, for a pharmacy to tell the difference between a facsimile that originated for a facsimile machine and one that originated electronically. Independent pharmacists should not be penalized for prescriber non-compliance by being forced to return reimbursements when pharmacists have filled these non-compliant prescriptions in good faith.
- Similarly, any NCPDP SCRIPT enabled sending entity, such as a pharmacy, should be able to send a computer generated facsimile if the receiving entity is not capable of receiving an NCPDP SCRIPT message, and the pharmacy believes that a computer generated facsimile is the best and most efficient way to send the prescription message.
- If both the pharmacy and the prescriber have NCPDP SCRIPT standard communication capability, then they should do so -- unless another exemption applies.

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Pharmacist Liability

CMS should clarify that:

[3] Federal Register, Vol. 72, no. 133, July 12, 2007 at 38195.

- In order to avoid the inefficiency of obtaining new prescriptions, prescriptions transmitted before the compliance deadline but filled or refilled after the compliance deadline should not be subject to the rule.
- The dispensing of a prescription transmitted in a noncompliant manner should not be considered a violation of either the federal or state false claims acts. Failure to do so would increase Medicare program participation costs for pharmacies and could potentially discourage pharmacy participation in the program.

E-prescribing capability

NCPA endorses the following proposed language, which should be read narrowly so as to not require prescribers and dispensers to purchase different software systems in order to become NCPDP SCRIPT Standard compliant.

§ 423.160(a)(3(i) Entities transmitting prescriptions or prescription related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information in the following circumstances:

1. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) does not own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, whether on the version that the prescriber/dispenser is currently using or another version of such software.*

    a. *This exemption shall not apply to prescribers/dispensers sending a transaction listed at Section 423.160(b)(1)(i) through (xii) who own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, but who has not upgraded to the version that is compliant with the NCPDP SCRIPT Standard and/or has not activated that functionality.*

    b. *In addition, in the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) owns, licenses, or otherwise uses software that does not have or did not have the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated] to send and receive transactions compliant with the NCPDP SCRIPT Standard, but such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard at any time after [insert date rule promulgated], then this exemption shall not apply with respect to such software twelve months after such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard.*

2. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) is sending the transaction to a dispenser/prescriber who does not own, license, or otherwise use software that has the capability to receive transactions compliant with the NCPDP SCRIPT Standard.*

3. *In the event any applicable law or regulation would prohibit the electronic transmission of the prescription and prescription related information using the NCPDP SCRIPT Standard.*

4. *In the event there is a temporary communications failure, whether technological or otherwise, that would prohibit the electronic transmission of the transactions listed at Section 423.160(b)(1)(i) through (xii) using the NCPDP SCRIPT Standard. Such temporary communications failures include, by way of example and not limitation, power outages, connectivity failures, or temporary outages of the either the prescriber's or dispenser's computer or management systems.*

5. *Information transmitted in a manner that is compliant with this rule at the time of its transmission shall remain compliant with this rule for the purposes of this rule even if such information or transmission would otherwise become noncompliant at a future date.*

We appreciate the opportunity to submit the comments on behalf of our membership. If you have any questions, please do not hesitate to contact NCPA via telephone at 703-683-8200 or via email at: Charlie.Sewell@ncpanet.org.

Sincerely,

Charles B. Sewell

Charles B. Sewell
Senior Vice President, Government Affairs

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National Committee for Quality Assurance Comments on Medicare's Physician Quality Reporting Initiative (PQRI):

CMS Rulemaking (CMS-1385-P)

August 30, 2007

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

The National Committee for Quality Assurance (NCQA) supports the goals of the Medicare Physician Quality Reporting Initiative (PQRI). Measuring physician performance using recognized, standardized, evidence-based measures will result in more meaningful information needed for quality improvement and increased accountability among the nation's physicians. While the PQRI is limited to physicians treating Medicare beneficiaries, it has the potential to improve care for all patients. As the private sector explores ways to encourage physicians to improve care and make better use of health care services through programs such as pay for performance, the common challenge is how to align these efforts to produce the best results. The Centers for Medicare & Medicaid Services (CMS) has the opportunity to help define the acceptable approaches for physician-level measurement and reporting that will likely impact the direction of future private initiatives.

NCQA places a high value on collaborating with others to identify best practices and minimize burden associated with measurement and data collection. One example of this has been our work with the American Medical Association (AMA) convened Physician Consortium for Performance Improvement® (PCPI) on developing a common set of physician level measures that are part of the 2007 PQRI measure set. NCQA and PCPI continue to work on a number of significant new physician-level measures. We have also been working with the American Board of Internal Medicine (ABIM) on a common set of principles for our respective work in the development and adoption of physician level measures. We have worked together to develop a streamlined process for the use of NCQA's Physician Recognition programs as part of ABIM's maintenance of certification (MOC) programs. The value of this partnership is to allow physicians to meet their board certification requirements while pursuing recognition for clinical excellence through one process.

We believe that the proposed rule takes too narrow an approach regarding measures eligible for inclusion in the 2008 PQRI measurement set. The current emphasis on the reporting of measures versus the actual performance of physicians themselves is also

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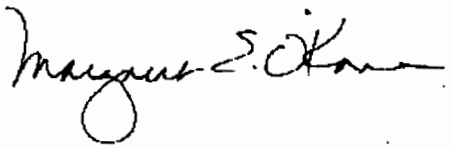
reason for concern. We believe that CMS will have greater flexibility to improve the quality of physician care for Medicare beneficiaries by utilizing existing data collection approaches beyond those included in the proposed rule. Our attached comments spell out a number of ways that we believe the proposed rule can be strengthened to achieve these critical goals. NCQA stands ready to work with CMS to make these changes and to advance our common goal of higher quality care for all Americans.

Sincerely,



Margaret E. O'Kane
President

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NCQA Comments and Recommendations

NCQA comments are specific to the PQRI program and the associated process for including physician measures in the 2008 program. We support a standardized and streamlined process for choosing measures. That requires the use of organizations such as the NQF and the AQA which, together, can serve as objective evaluators of reliable, appropriate and feasible measures for physician performance measurement and reporting.

Issue Identifier - TRHCA--SECTION 101(b): PQRI

P. 407: *Entities eligible for measure submission* - NCQA strongly supports the language in this section. We believe that measures should NOT be limited to those submitted by a single physician specialty. In fact, there is a strong argument that single physician specialty submissions may result in confusion and overlapping measures since in many instances multiple specialties provide the same procedures or care.

P. 419: *Entities eligible for measure submission* - We strongly endorse and agree with the formulation that "we (CMS) do not interpret the MIEA-TRHCA to place special restrictions on the type or make up of the organizations carrying out this basic development of physician measures, such as restricting the initial development to physician-controlled organizations." For example, NCQA's process of measure development and approval includes a broader and more balanced representation of clinical and scientific expertise, as well as input from users of measurement such as consumer, purchaser and plans, than is the case with single physician specialty organizations.

P. 424-427: *Measure approval process* - We take strong issue with the proposed language regarding inclusion of new PQRI measures for 2008. The proposed rule appears to establish two separate but unequal processes for inclusion in this important list. It is contrary to the careful assessment of the relative roles and capabilities of NQF and AQA to propose including yet unendorsed measures from the AMA/PCPI, or Quality Insight of Pennsylvania, in the 2008 PQRI, even with the caveat that they *" achieve NQF endorsement* **OR** *AQA adoption by November 15, 2007"* while proposing a different standard for other organizations. On page 428 it appears as if measures from other sources, including NCQA, would be subject to a higher standard, namely that "*We propose to include in the final 2008 PQRI measures other measures endorsed by NQF that were not included in the 2007 PQRI quality measures but that are relevant to Medicare beneficiaries ... Specifications necessary for reporting of these measures will be completed by November 15, 2007 and posted on the CMS web site.*" It appears as if the intent of this is to include measures, both structural and "non physician", from QIP, or the AMA/PCPI, that *may achieve* NQF endorsement, while others would need full NQF

endorsement by the November 15 cut off date. Further, we take strong issue with CMS if the intent of the citation of QIP is intended to limit the consideration by NQF of structural measures or "non physician" measures to those produced by QIP.

P. 424: *Structural measures* - It is unclear why it is necessary to have separate measures for "non physicians" such as those listed in Table 18. If they are different from existing NQF endorsed measures, it would seem undesirable to set different parameters based on the type of clinician. If they are essentially identical, it is unlikely they would be endorsed by either NQF (which is on record as striving for measure concordance) or by AQA which to our knowledge, does not include most "non physician" clinicians. Moreover, to allow these measures, which have not gone through any phase of NQF review, to be short circuited into the 2008 PQRI program would seem to set a very harmful precedent. Finally, and most importantly, CMS is aware of the existence of NCQA structural measures which have undergone extensive testing, are in broad use, and have been submitted to AQA for approval, and which NQF is awaiting funding to review. To exclude consideration of these measures if they are AQA approved, while allowing the inclusion of measures from QIP, would seem highly questionable.

P. 430-432: *Data collection approaches* - The description of the sampling procedure for programs as "information about a defined population of individual persons or events, collected using an observational study design in a systematic way, in order to serve a predetermined scientific, clinical, or policy purpose" is too narrow. There does not appear to be any provision for sampling, or even for inclusion of non Medicare patients in the data submitted. In order to avoid redundant data collection we urge a broader definition of allowable sampling. Any methodology should be sound and produce results that are representative of the physician's practice including Medicare beneficiaries but not necessarily limited to Medicare beneficiaries. We believe CMS has the opportunity to explore options other than registries that can yield a better end result through the evaluation of performance, not just reporting. Efficient, reliable measurement means that the physician does not measure every patient or episode, but uses a rigorous, validated sampling approach. The use of sampling, validation, and assessment against comparison thresholds is actually a higher bar than what is proposed in PQRI. CMS should not hold back progress by forcing the physician community to use older less efficient data collection methods when better methods are available.

P. 433: *Data collection approaches* - The five registry options outlined in the proposed rule do not take into consideration the availability of existing physician measurement programs such as the NCQA physician and practice recognition programs. These long-standing programs use a sampling methodology that allows NCQA to make a sound judgment about a physician's performance while minimizing the data collection burden.

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CMS should amend the definition of registries to allow physicians and practices recognized under these programs to be considered as meeting the PQRI requirements.

Measure Tables 16-22: *NCQA recommended measures* - We are encouraged that CMS is committed to using measures that have been endorsed by AQA or NQF, across a broad array of specialties and clinical topics. Success for PQRI will depend on measures being available for the broadest array of physicians and other clinicians as possible. To that end, we request that CMS include the measures listed below in Table 1 in the PQRI program for 2008. The NCQA Back Pain measures are undergoing NQF review, and have been submitted to the NQF membership for member comment. The PPC Structural measures have been submitted for AQA review. We also support CMS's inclusion of the measures in Table 2 as additional measures for consideration for use in PQRI 2008. These measures have been developed by nationally recognized measure developers, including NCQA and the AMA-PCPI, and all have been submitted for AQA review.

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Table 1: NCQA MEASURES Recommended for the PQRI 2008

Back Pain (Back Pain Recognition Program)
Measure #1: Back Pain Measurement Set (Aggregate Measure) Measure #2: Initial Visit Measure #3: Physical Exam Measure #4: Mental Health Assessment Measure #5: Appropriate Imaging for Acute Back Pain Measure #6: Repeat Imaging Studies Measure #7: Medical Assistance with Smoking Cessation Measure #8: Advice for Normal Activities Measure #9: Advice Against Bed Rest Measure #10: Recommendation for Exercise Measure #11: Appropriate Use of Epidural Steroid Injections Measure #12: Surgical Timing Measure #13: Patient Reassessment Measure #14: Shared Decision Making Measure #15: Patient Education Measure #16: Post-Surgical Outcomes Measure #17: Evaluation of Patient Experience
Physician Practice Systems (Physician Practice Connections Program)
Measure #1: Physician Practice Connections (Aggregate measure) Measure #2: Use of E-Prescribing Systems Measure #3: Alerts for Drug-Drug Interactions Measure #4: Use of Patient Registries Measure #5: Use of Electronic Health Records Measure #6: Reminders for Preventive Care at Point of Service Measure #7: Lab Test Tracking Measure #8: Staff Assigned to Execute Standing Orders Measure #9: Patient Reminders Measure #10: Patient Self-Monitoring Measure #11: Use of Feedback Reports for Quality Improvement

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Table 2: Additional Measures for Consideration for PQRI 2008

Dermatology *(AAD/AMA PCPI/NCQA)*
Measure #1: Process of care measures for Melanoma – Bundled Measure #2: Continuity of Care – Recall System Measure #3: Coordination of Care – communication with primary care physician Measure #4: Overuse measure – Imaging for patients with stage 0 or 1A Melanoma
HIV/AIDS *(NCQA/AMA PCPI/IDSA/HRSA)*
Measure #1: Medical visit in an HIV care setting Measure #2: CD4+ cell count and HIV Viral Load Measure #3: PCP prophylaxis (as an indicator of OI prophylaxis) Measure #4: Adolescent and adult clients with AIDS who are prescribed HAART Measure #5: Pregnant women with HIV infection who are on antiretroviral therapy Measure #6: TB (PPD) Screening Measure #7: STD Screening Measure #8: Vaccinations Measure #9: High Risk Behavior Measure #10: Appropriate Periodic Health Examinations
Nuclear Medicine (SNM/AMA PCPI/NCQA)
Measure #1: Radionuclide bone imaging; metastatic disease to the bone Measure #2: Radionuclide bone imaging; osteomeyelitis Measure #3: Radionuclide bone imaging; occult trauma
Eye Care *(AAO/AMA PCPI/NCQA)*
Measure #1: Primary Open-Angle Glaucoma: Reduction of Intraocular Pressure by 15% or Documentation of a Plan of Care Measure #2: Primary Open-Angle Glaucoma: Counseling on Glaucoma Measure #3: Cataracts: Postoperative Complications within 30 Days Following Cataract Surgery Measure #4: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery Measure #5: Cataracts: Comprehensive Pre-operative Package for Cataract Surgery with IOL Placement Measure #6: Cataracts: Counseling on Cataract Prevention Revised Measure #7: Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplements

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Geriatrics *(AGS/AMA PCPI/NCQA)*
Revised Measure #1: Advance Care Plan Measure #2: Falls: Risk Assessment Measure #3: Falls: Plan of Care
Radiology *(ACR/AMA PCPI/NCQA)*
Measure #1: Classification of risk for nephrotoxicity in contrast media administration Measure #2: Monitoring patients at risk for nephrotoxicity: Measurement of serum creatinine Measure #3: Nephropathy prophylaxis for patients receiving contrast enhanced imaging procedures Measure #4: Use of acetylcysteine for patients receiving contrast enhanced imaging procedures Measure #5: CT radiation dose reduction Measure #6: Report of exposure time for fluoroscopic procedures Measure #7: Mammography screening – additional assessment Measure #8: Mammography screening - use of BIRADS codes Measure #9: Mammography screening - Communication with the physician managing ongoing care Measure #10: Stenosis measurement in carotid imaging reports - Broadening of clinical indications
Chronic Kidney Disease *(RPA/AMA PCPI)*
Measure #1: Blood Pressure Measurement Measure #2: Plan of Care for Elevated Blood Pressure Measure #3: ACE Inhibitor (ACE) or Angiotensin Receptor Blocker (ARB) Therapy Measure #4: Laboratory Testing (Calcium, Phosphorus, PTH and Lipid Profile) Measure #5: Plan of Care – Anemia Measure #6: Influenza Vaccination Measure #7: Referral for Permanent Vascular Access
Oncology *(ASTRO/ASCO/AMA PCPI)*
Measure #1: Cancer stage documented Measure #2: Hormonal therapy for stage IC-III, ER/PR positive breast cancer Measure #3: Chemotherapy for Stage III colon cancer patients Measure #4: Plan for chemotherapy documented before chemotherapy administered Measure #6: Treatment summary communicated – Radiation Oncology Measure #7: Normal tissue dose constraints specified Measure #8: Pain Intensity Quantified Measure #9: Plan of Care for Pain

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Measure #10: Pathology report – Medical Oncology Measure #11: Pathology report – Radiation Oncology
Anesthesiology and Critical Care *(ASA/AMA PCPI)*
Measure #1: Stress ulcer disease (SUD) prophylaxis considered in ventilated patients Measure #2: Perioperative temperature management for surgical procedures under general anesthesia
Atrial Fibrillation *(ACC/AHA/AMA PCPI)*
Measure #1: Assessment of thromboembolic risk factors Measure #2: Chronic anticoagulation therapy Measure #3: Monthly INR measurement
Perioperative Care *(AMA PCPI)*
Measure #1: Perioperative cardiac risk assessment (History) Measure #2: Perioperative cardiac risk assessment (Current symptoms) Measure #3: Perioperative cardiac risk assessment (Physical examination) Measure #4: Avoidance of electrocardiogram overuse Measure #5: Perioperative continuation of beta-blockers

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HOWARD UNIVERSITY

College of Pharmacy, Nursing and
Allied Health Sciences
Division of Allied Health Sciences
Department of Physical Therapy

Department of Health and Human Services
Attention CSM 1385-P
P.O. Box 8018
Baltimore, MD 21244-1850
Re: CSM 1385 **Therapy Standards and Requirements**

Dear Sir or Madam:

As student physical therapists at Howard University, we strongly disapprove of the proposed rules changing the definition of "physical therapist" in Section 484, Title 42 Of the Code of Federal Regulations. The proposed rules are part of the 2008 Proposed Revisions to Payment Policies under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008, found in Volume 72 of the Federal Register, published on July 12, 2007.

CMS would be doing a great disservice to licensed physical therapists by subjecting them to the undue burden of having to sit for another exam, confusing the examination process and usurping the authority of the Licensure Boards. Currently, CMS respects states' rights and state licensure for other health care professions, and it should continue to do so with respect to physical therapists. For example, CMS' regulations define a physician as a "doctor of medicine ... legally authorized to practice medicine and surgery by the State in which such function or action is performed." 42 C.F.R. § 484.4 (2006). Likewise, a registered nurse is defined as "[a] graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing." 42 C.F.R. § 484.4. Establishing requirements that are different than what the states require for licensing Physical Therapists would be inconsistent with not only the rights of the states, but also CMS' own standards.

We have already adopted a national qualifying exam for physical therapists, the National Physical Therapy Examination ("NPTE"). The Federation of State Boards of Physical Therapy ("FSBPT") develops and administers the NPTE in close collaboration with the state boards. Working together, we have developed a national passing score. The FSBPT has done an outstanding job of meeting our needs. Likewise, the NPTE has been a valuable tool in screening physical therapist applicants. Through the NPTE, we have been able to successfully filter applicants. In turn, we, as a policing body, have been able to protect the public by ensuring that only qualified therapists are licensed to care for our citizens.

6th & Bryant Streets, NW
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www.howard.edu

We strongly disagree with the proposed rule changes and urge you to remove the requirements. We appreciate the opportunity to comment on the proposed rules regarding physical therapist and physical therapy assistant qualification requirements.

Respectfully yours,

Herman Green, SPT

Herman Green SPT

Lauren D Palmer, SPT

Lauren Palmer SPT

Nicole Sergeant SPT

Nicole Sergeant SPT

Xiaoyun Ling SPT

Xiaoyun Ling, SPT

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MEDICAL DIRECTORS COUNCIL

August 31, 2007

HAND DELIVERED

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

Re: CMS-1385-P

Dear Mr. Kuhn:

As radiologists and the medical directors for the Center for Diagnostic Imaging ("CDI"), we are writing to urge the Centers for Medicare and Medicaid Services ("CMS") to take steps to ensure that we and our radiologist colleagues are able to continue our radiology practice in an independent diagnostic testing facility ("IDTF") setting.

CMS' proposed prohibition on IDTFs from sharing space, equipment or staff will fundamentally change how we practice radiology with no benefit to the patients whom we serve. We and our radiologist colleagues practice radiology in an IDTF-based setting and we do not maintain separate radiology office locations outside of CDI's centers, with the exception of limited space some of our radiologist practices have at the hospitals we serve. For the vast majority of us, the IDTF centers are our radiology offices. *The legitimate purpose of sharing space, equipment and staff in the center is to ensure the efficient delivery of safe, sophisticated diagnostic imaging services to patients.* If we are not allowed to share space, we will have to move our offices to a different location. This means that we will not be on-site every day at the centers like we are currently but only when required to provide supervision. Because our radiology office will be in a different location, we will not be as readily available to consult with referring physicians about the appropriateness of certain diagnostic imaging tests for a particular patient or answer patient questions and concerns, or be able to work closely with the technologists to prepare imaging protocols for specific patients and generally monitor the quality and safety of the diagnostic imaging services provided at the centers on a daily basis.

In addition to our diagnostic imaging services, many of us also perform interventional radiology and therapeutic procedures at the same IDTF locations but bill for them under our physician NPI (not under the IDTF number). This gives the attending physician and his or her patient the option of having a biopsy of a potentially malignant tumor (if ordered by the patient's attending physician) at the same location the diagnostic mammogram was performed. These biopsies are performed under imaging guidance using imaging equipment located in the IDTF.

c/o CDI Institute ● 5775 Wayzata Blvd., Suite 400, St. Louis Park, MN 55416 ● *tel:*952-543-6500 *fax:* 952-847-1152

Should the sharing prohibition go into effect, we would have to purchase duplicate imaging equipment in a separate medical office to perform these biopsies (or other urgent interventional procedures as ordered by the referring physician). The patient would have to schedule another appointment at another location on a different day. This would be a disservice to Medicare beneficiaries who want the procedure performed at the same location on the same day as the diagnostic imaging service. The benefits to the patient include reduced anxiety, less time off work for themselves or their escort and no need to arrange transportation.

We also use CDI's sophisticated Picture Archiving and Communication Solutions ("PACS") and Radiology Information Systems ("RIS") located in the centers to interpret diagnostic imaging services. The proposed sharing prohibition appears to only permit us to supervise a diagnostic imaging test but not perform the professional interpretation of the test. This would be a significant waste of our professional time and greatly reduce our efficiency.

In our radiology practice, we frequently consult with each other. For example, a radiologist interpreting a difficult MRI scan of the brain at our Douglas County, Minnesota location may want to consult with his/her fellowship trained, board-certified neuroradiologist who is practicing or providing supervision at our St. Louis Park, Minnesota location. (These consultations are performed among our practice as a professional courtesy and we only bill Medicare once for the interpretation.) The integrated RIS allows us to simultaneously view the same images even when we are consulting with our colleague who may be located 80 miles or more away. We believe that this sharing improves patient care because it reduces the risk that a patient's condition could go undetected and improves our turn-around time on interpretative reports. Without any prolonged delay, we can provide a high quality interpretative report to the patient's attending physician (and even have the images in the operating room) which is critically important to that physician's evaluation of the patient's condition and is needed before starting the patient's course of treatment.

Should CMS adopt its proposed prohibition, it would be extremely difficult for radiology practices to offer sub-specialized imaging services in rural locations or other underserved locations without collaborating with CDI. We simply could not bear the financial commitment to purchase high field/cutting edge diagnostic imaging equipment, invest in an interconnected information technology system, hire certified, sub-specialized technologists to staff a location, and provide a sub-specialist radiologist to perform the supervision and interpretation of the tests. The productivity and quality losses associated with having a radiologist supervise and interpret tests in a rural community, without the connectivity to a company such as CDI, is easily assessed in terms of equipment strength and accreditation, level of technologist training and radiologist specialization. Should the proposed prohibition go into effect, we would have to disband our collaborative arrangements with CDI and would be forced to make painful choices about not serving Medicare beneficiaries in rural and other underserved locations. As a result, many Medicare beneficiaries will have fewer provider options and reduced access to high quality imaging services.

This proposal unfairly limits our ability to provide radiology services in an IDTF setting. This constitutes a Federal restriction on the practice of medicine, which is an area that is historically regulated by the states under state licensing laws. This restriction would appear to require us to establish two different offices—one to receive Medicare patients and the other to see non-Medicare patients—with no identifiable public policy rationale or benefit to patients.

We believe that no other medical specialty is as dramatically affected by the proposed prohibition. This proposal, if finalized, would make it impossible for us and our radiologist colleagues to continue our practices as we currently operate and to provide safe, sub-specialized, high strength imaging services and care to patients.

We urge you to address this issue by specifically excluding radiologists and radiology groups, who are not self-referring, from the proposed ban on sharing arrangements in IDTFs.

Thank you for your consideration of our concerns.

Sincerely yours,

Kenneth B. Heithoff, M.D.
National Medical Director

Steven Pollei, M.D.
Medical Director
CDI Northwest (Seattle, WA)

Kurt P. Schellhas, M.D.
Medical Director
Twin Cities, MN

C. Todd Cunningham, M.D.
Medical Director
Central Minnesota

Scott Swenson, M.D.
Medical Director
Douglas County Hospital, MN

James Youker, M.D.
Medical Director
Milwaukee CDI

Kim Roys, M.D.
Medical Director
Kansas City CDI

Elizabeth McFarland, M.D.
Medical Director
St. Luke's CDI

Michael Hayt, M.D., DMD
Medical Director
CDI Central Florida

Robert Breit, M.D.
Medical Director
Corporate Woods CDI and Central States CDI, ILL

Michael Sullivan, M.D.
Medical Director
CDI Provena, Geneva, ILL

Aaron Guajardo, M.D.
Medical Director
CDI Provena, Bourbannais, ILL

Thomas Vahey, M.D.
Medical Director
CDI Indiana

astellas
Leading Light for Life

August 31, 2007

BY HAND DELIVERY AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

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

Re: CMS 1385-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Mr. Kuhn:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to comment on the Medicare Physician Fee Schedule Proposed Rule for 2008 published by the Centers for Medicare and Medicaid Services (CMS).[1] Astellas is among the top 20 global research-based pharmaceutical companies, with global sales of approximately $8 billion, and the number two Japan-based pharmaceutical company. Our fundamental goal is to use our expertise in key therapeutic areas to improve the health of Americans by developing and marketing cures for unmet medical needs. Our North American product lines, which focus on the therapeutic areas of infectious disease, immunology, cardiology, dermatology, and urology, are used by Medicare beneficiaries in a variety of settings, including physician offices and other outpatient settings.

Our detailed comments are set forth below, and focus on three important goals: developing clear ground rules that produce consistency and accuracy in manufacturers' Average Sales Price (ASP) calculations; refining the Part B Competitive Acquisition (CAP) so that it can better serve the needs of physicians and patients; and ensuring patient access to important diagnostic procedures.

* * *

[1] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed rule, 72 Fed. Reg. 38122 (July 12, 2007).

Astellas Pharma US, Inc.
Three Parkway North Deerfield, IL 60015-2537
Tel 847-405-1640 www.us.astellas.com

I. ASP Calculations and Bundling

Because of its importance in setting providers' payment rates for Medicare Part B drugs, Average Sales Price (ASP) should be calculated by rules that are clear, free of unnecessary complexity, and designed to produce accurate figures. Clear ground rules are essential for allowing manufacturers to calculate ASPs in a consistent manner that accords with CMS' expectations.

Given these principles, we have concerns about CMS' proposal to extend to ASP calculations the new bundling provisions in the Medicaid prescription drug rule.[2] These provisions define a "bundled" sale and require that manufacturers proportionately allocate discounts on bundled sales across the drugs in the bundle. The definition of a "bundled sale" in the Medicaid rule (which is substantially similar to the "bundled arrangement" definition CMS proposes to adopt in the ASP context) is confusing and potentially overbroad.[3] Both definitions define bundling to include arrangements that involve unspecified "performance requirements," even if such requirements relate to the "same drug." We are concerned that without additional clarifying guidance from CMS, this language will apply too broadly. Specifically, CMS should avoid a construction of "bundled sale" that sweeps in arrangements that do not involve attempts to use the discount on one drug to reduce the effective price of another. For example, CMS

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[2] 72 Fed. Reg. 39142 (July 17, 2007). More specifically, CMS proposed to extend to ASP the approach to bundling that it had adopted in the proposed Medicaid rule (which is substantially identical to the language adopted in the final Medicaid rule), and stated that it intended to "remain consistent with the final policy in the Medicaid final rule on this issue, as appropriate." 72 Fed. Reg. 38122 at 38151.

[3] The Medicaid rule defines a "bundled sale" as "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle." 42 C.F.R. § 447.502. In the ASP context, CMS proposes to define a "bundled arrangement" as "an arrangement, regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement." 72 Fed. Reg. at 38151. CMS also proposes to require that "all price concessions on drugs sold under a bundled arrangement must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement." Id.

should clarify that a "bundled sale" only occurs where there is a purchase or market share requirement in exchange for the discount, and not in an arrangement that merely conditions the discount for one drug on the formulary inclusion or placement of another drug. Avoiding such an overbroad construction of "bundled sale" is appropriate both to reduce the confusion faced by manufacturers, and because such a definition would require the reallocation of discounts on a larger set of sales that would tend to undermine, rather than improve, the accuracy of ASP calculations.

We agree with CMS that, other things being equal, adopting consistent rules for ASP calculations and Medicaid rebate calculations is a desirable step that should increase the efficiency of manufacturers' pricing calculations. As noted above, however, extending the Medicaid rule's bundling provisions to ASP calculations could potentially produce greater confusion and complexity, more errors, and reduced consistency between manufacturers. If CMS wishes to adopt this approach in the ASP context, the Agency should provide manufacturers with clear guidance on the many questions that remain unanswered regarding how to apply the Medicaid bundling definition and the related allocation procedures. Among other things, CMS should explain how the bundled discount allocation procedure intersects with the 12-month rolling average methodology for estimating lagged price concessions, and how manufacturers should handle any cases where the information needed to reallocate discounts was unavailable before the deadline for ASP submissions. CMS also should specify how manufacturers should allocate discounts for bundled sales involving a combination of drugs that are ASP-eligible and drugs that are not.

We strongly encourage CMS to study these kinds of issues carefully and, if CMS ultimately decides to require allocation of bundled discounts, to commit itself to giving manufacturers the clear guidance that they would need to understand and implement these requirements.

II. Competitive Acquisition Program Issues

CAP has significant potential to improve Medicare beneficiaries' access to Part B drugs as the program attains higher levels of physician participation. Consequently, Astellas encourages CMS to adopt refinements to CAP that will help make the program more "user friendly" for physicians and increase their CAP participation rate.

Along these lines, Astellas supports the effort by CMS to explore "narrowing the restriction on [the physician] transporting CAP drugs where this is permitted by State law and other applicable laws and regulations."[4] Allowing physicians to transport CAP drugs to a

[4] 72 Fed. Reg. 38122 at 38158.

satellite office or to the patient's home, when this can be done safely and in accordance with other applicable laws and regulations, could give physicians participating in CAP a degree of increased flexibility that would make CAP participation more attractive, and increase patients' access to needed medicines.

Astellas also supports the proposal by CMS to define additional exigent circumstances in which physicians could withdraw from CAP,[5] since we believe that this could ease physician concerns about enrolling in CAP in the first instance and thus ultimately boost participation in CAP. To that end, CMS may wish to consider liberalizing the proposed procedures for physicians to withdraw from CAP due to "significant burden," by giving physicians a period longer than 30 days in which to submit a written request to withdraw from the program.

Finally, CMS should also consider encouraging physicians to participate in CAP by eliminating the current requirement that CAP-participating physicians submit claims for drug administration services for CAP drugs within 14 days of administering the drug. There may be many physician practices that do not customarily submit claims within this window, and eliminating the 14-day claims submission requirement could therefore make CAP participation a more attractive prospect for those practices. CMS initially adopted the 14-day claims submission requirement because, at that time, it was necessary to match the physician's drug administration claim with the CAP vendor's drug claim before the CAP vendor could be paid; imposing the 14-day claims submission requirement on CAP-participating physicians was therefore the only mechanism to enable the CAP vendor to be paid relatively promptly. However, due to recent statutory changes the claims matching requirement (and the related 14-day physician billing requirement) are no longer necessary for this purpose; under Section 108 of the Medicare Improvements and Extension Act (Division B of the Tax Relief and Health Care Act of 2006) payment for drugs and biologicals supplied by the CAP vendor must be made upon receipt of the vendor's claim, and a separate post-payment review process confirms that the drugs have in fact been administered to beneficiaries. CMS therefore has the opportunity to remove an administrative requirement now imposed on CAP-participating physicians that likely has been an impediment to CAP participation for some physician practices. We encourage CMS to take this step, and any other steps it identifies that can make it simpler and more convenient for physicians to participate in CAP.

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[5] Currently physicians can withdraw from CAP early (before their one-year commitment expires) in certain "exigent circumstances," i.e.: (1) if the physician's CAP vendor ceases to participate in CAP; (2) if the physician leaves the group practice that selected the CAP vendor; (3) if the physician moves to another competitive acquisition area (if multiple CAP areas are created); or (4) for other exigent circumstances defined by CMS. CMS now proposes to define an additional exigent circumstance in which a physician could opt out of CAP if he or she submitted a written request to do so within 30 days of entering the CAP physician election agreement and if CMS granted the request due to remaining in CAP being a "significant burden" on the physician.

III. Payment for Certain Diagnostic Imaging Services

In the Proposed Rule, CMS proposes no longer to provide separate payment for Doppler echocardiography color flow velocity mapping (CPT code 93325) when performed in conjunction with several echocardiography codes. We urge CMS carefully to consider comments submitted in response to this proposal by interested physician specialty societies, and to ensure that the issue has been fully considered by the CPT Editorial Panel and all relevant stakeholders who participate in the CPT process before CMS finalizes any proposal in this area.

* * *

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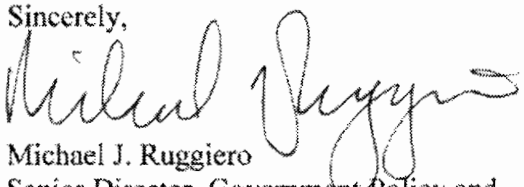
Astellas appreciates the opportunity to provide these comments. If you have any questions or would like additional information, please contact me at 202-812-6162 or via e-mail (michael.ruggiero@us.astellas.com).

Sincerely,



Michael J. Ruggiero
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By Hand-Delivery

August 31, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
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200 Independence Avenue, S.W.
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CMS File Code: CMS-1385-P

RE: Comments Regarding Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

The Centers for Medicare and Medicaid Services ("CMS" or "the Agency") recently published its proposed Physician Fee Schedule for CY 2008 ("Proposed Rule"). See 72 Fed. Reg. 38121 (July 12, 2007). In this Proposed Rule, CMS solicited comments on a process for authorizing additional drug compendia for anticancer therapeutic regimens under Medicare Part B. Celgene Corporation ("Celgene") is appreciative of CMS' efforts to develop a thoughtful process and welcomes the opportunity to comment on this issue.

As CMS finalizes this rulemaking, Celgene urges the Agency to exercise its discretion to authorize additional Medicare Part D compendia and to establish a level playing field for the coverage of Part B and Part D drugs. Authorizing additional compendia is important for maintaining beneficiary access to Part D drugs and for addressing the current delays in reviews of applications for additions to the existing compendia. In our comments, Celgene will discuss the importance of expanding the compendia process to Part D and specific ways that the proposed process may be enhanced.

About Celgene

As a global biopharmaceutical company, Celgene is engaged in the discovery, development, and commercialization of innovative therapies designed to treat cancer and

immune-inflammatory related diseases. Celgene's research also includes several scientific areas that may deliver proprietary next-generation therapies, such as intracellular signaling, immunomodulation and placental stem cell research. The therapies (drugs and cell therapies) we develop are designed to treat life-threatening diseases or chronic debilitating conditions where patients are poorly served by current therapies.

I. CMS' Authority to Authorize Additional Drug Compendia Under Medicare Part D

While Celgene supports modifying the current compendia process, we are concerned that the Agency has effectively decided to limit the scope of its compendia proposal to Medicare Part B. Many of the same reasons cited by CMS for modifying the process impacting Part B drugs also apply to other federal healthcare programs that rely upon drug compendia for coverage determinations. For example, Medicare Part D relies upon certain statutorily enumerated compendia to determine coverage of off-label uses. Most of these designated compendia are the same as those listed in § 1861(t)(2). Yet the proposed rule would not effect the Part D compendia process even though the same problems of delayed review also plague these compendia.

Celgene encourages the Agency to take the opportunity to correct this problem by applying the same proposed process for authorizing additional compendia under § 1861(t)(2) to Medicare Part D. In this section of our comments, we explain the legal provisions that authorize CMS to take such an action. Exercising this discretion will allow the Agency to establish a more level playing field between Part B and Part D drugs and enable the Agency to address long-standing problems in the review of applications by a wider number of compendia publishers.

A. CMS Has the Legal Discretion to Authorize Additional Compendia Under Medicare Part D

As the Agency is aware, § 1860D-2(e)(1) of the Social Security Act defines a covered Part D drug as "any use of a covered part D drug for a medically accepted indication (as defined in section 1927(k)(6))." 42 U.S.C. § 1395w-102(e)(1). Section 1927(k)(6) defines a "medically accepted indication," in relevant part, as any use supported by one or more citations in compendia enumerated in § 1927(g)(1)(B)(i), including the American Hospital Formulary Service Drug Information, the United States Pharmacopeia – Drug Information ("USP-DI"), and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(k)(6) (referencing 42 U.S.C. § 1396r-8(g)(1)(B)(i)).

Unlike § 1861(t)(2), the statutory provisions governing Medicare Part D do not list "other authoritative compendia as identified by the Secretary." 42 U.S.C. § 1395x(t)(2). But, as the Agency is aware, § 6001(f)(1) of the Deficit Reduction Act of 2005 ("DRA") added language to the relevant statutory provisions that provided for "successor publications" to the USP-DI. Pub. L. No. 109-171, 120 Stat. 4, 58 (2006) (codified at 42 U.S.C. § 1396r-8(g)(1)(B)(i)). This language clearly provides CMS with the discretion to authorize additional compendia for Medicare Part D.

As CMS references in the Proposed Rule, the name "USP-DI" may not be used after 2007. In fact, Thomson Healthcare Inc. has announced that another publication,

DrugPoints®, has replaced USP-DI.[1] This announcement represents the predicate event for CMS to determine what "successor publications" it will authorize. The DRA amendments neither specify the process for determining the "successor publications," nor dictate that the successor be published by the same entity that publishes USP-DI. In fact, the statutory language suggests that Congress envisioned that CMS would authorize multiple compendia because the language discusses successor publications (plural) rather than a single publication or compendium.

Thus, the Agency's interpretation of this DRA provision as "explicitly authorizing the Secretary to continue recognition of the compendium currently known as USP-DI" is too narrow. 72 Fed. Reg. at 38177. CMS possesses the discretion to select "successor" compendia beyond DrugPoints®. Accordingly, we encourage the Agency to exercise this discretion to authorize additional Part D compendia to address significant delays in the current compendia review process.[2]

B. Authorizing Additional Part D Compendia Promotes Appropriate Beneficiary Access and Would Be an Efficient Use of CMS' Administrative Resources

In recent years, CMS has taken many positive steps to enhance the attractiveness of the Part D benefit in a manner that facilitates beneficiary access to prescription drugs. Unfortunately, in the Proposed Rule, the decision to authorize additional Part B compendia alone will likely limit patient access to therapies available under Medicare Part D, particularly given the significant delays currently experienced in the Part D compendia review process.

As you know, Congress has long sought to avoid having the site of service dictate cancer treatment. In the Omnibus Budget Reconciliation Act of 1993, Congress extended coverage to certain self-administered anticancer drugs to ensure that the site of service did not impede beneficiary access to products that were equally effective but easier to administer. Pub. L. No. 103-66, § 13553, 107 Stat. 312, 591. Failure by CMS to use its discretion to authorize additional Part D compendia will hinder beneficiary access and may lead to treatment decisions based potentially upon site of service and not the physician's determination of what is in the patient's best interest. It would also be inconsistent for the Agency to adopt a coverage policy at one site of service (Part B) that it could, in its discretion, adopt at another site of service (Part D).

Reviewing compendia for both Parts B and D at the same time also promotes efficient use of Agency resources. The MedCAC criteria for evaluating compendia are applicable regardless of the site of service, and CMS' consideration of the compendia under both parts of the Medicare program is likely to be substantially the same. As a result, we encourage

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[1] See Thomson Healthcare Website, Important Notice, available at, http://www.micromedex.com/products/uspdi/v1/ (last visited Aug. 22, 2007) ("USP DI® Drug information for the Health Care Professional has been succeeded by DrugPoints®.").

[2] Beyond the discretion authorized by the DRA amendments, CMS also has discretion under § 1873 of the Social Security Act. Section 1873 states that designation of any "nongovernmental ... publication shall not be affected by change of name of such ... publication, and shall apply to any successor publication which the Secretary finds serves the purpose for which such designation is made." 42 U.S.C. § 1396jj. The same plain reading as that applied to the DRA amendments suggests that CMS has the authority to designate any successor publication and not merely ratify a replacement publication from an entity that published the former authorized publication.

the Agency to open the process for adding compendia to applications for additional Part D compendia.

II. Recommendations Regarding Authorizing Drug Compendia

If the process is expanded to Medicare Part D, Celgene believes that the Agency's approach will represent a thoughtful and transparent method of authorizing additional compendia. At this time, we would like to suggest a few ways to further refine the proposed process. These suggestions include reducing the overall time for authorizing a new compendium, prioritizing among the criteria for evaluating compendia and expanding the definition of a "compendium." We believe that these suggestions will result in an even more efficient and effective process.

A. Reducing the Overall Timetable for Authorizing Compendia

We appreciate that the Agency recognizes in the preamble to the Proposed Rule that changes in the publishing industry have resulted in fewer statutorily-named compendia being available for reference. This, in addition to other factors, has led to significant delays in the review of applications for additions or modifications to existing compendia. These delays, sometimes numerous months in duration, have resulted in a system that no longer answers the needs of the Agency or the beneficiaries it serves. It can no longer be said that the "[t]he compendium process for making decision is ... continuously updated." Medicare Benefit Policy Manual, Ch. 15, § 50.4.5.D. Delays in the review of applications translate into compendia that are not up-to-date and may interfere with beneficiary access to effective treatments. Compendia that are updated with current information is particularly important for beneficiaries with cancer because months of delay to access an effective treatment can be deadly to those with life-threatening diseases.

We applaud CMS for proposing a process to authorize additional compendia that will, hopefully, reduce the current delays in compendia applications. We are concerned, however, that the proposed process may be too long and will create an unnecessary delay of its own. The Proposed Rule currently describes a process that calls for as much as 225 days between the initial notice of solicitation for changes and CMS' final decision.

Although the process should permit an opportunity for careful evaluation and public input, we suggest that the process could be streamlined from the approximately eight month cycle currently proposed. For example, CMS could begin accepting requests immediately upon publication of the notice and stop accepting requests forty-five days later. In addition, because the relatively small universe of drug compendia will likely lead to a few consolidated requests, we are hopeful that the review time by the Agency could be reduced from the 120 days suggested in the preamble of the Proposed Rule. Reducing the overall timeline for authorizing compendia will help facilitate beneficiary access.

B. Prioritizing Compendia Evaluation Criteria

In the Proposed Rule, CMS explains that it will evaluate compendia based upon the desirable characteristics recommended by the Medicare Evidence Development and Coverage Advisory Committee ("MedCAC"), in addition to other reasonable factors. These factors encompass a variety of important issues, including transparency and breadth. But one factor, the quick throughput from application for inclusion to listing, is particularly important in light of recent delays in processing applications to revise compendia. We urge CMS to make this factor a high priority, particularly in the first few rounds of this process, to ensure resolution of this issue. We believe it would be appropriate for compendia publishers to establish a general time table for reviewing applications. Establishing such a standard would promote accountability and help ensure quick throughput.

We also encourage CMS to make transparency of process a high priority in reviewing requests for additional compendia. Currently patient groups and manufacturers have experienced great difficulty in obtaining information about the status of applications to amend the authorized compendia – often months or even years after the application's submission. This process should be more open so that patients, physicians, and manufacturers understand the status of all pending treatment options.

Timely review and transparent consideration of compendia applications is essential to maintain beneficiary access to the most effective treatments. Failure to timely review such applications results in a loss of beneficiary access to a potentially life-saving or life-extending therapy.

C. Expanding the Definition of "Compendium"

The proposed rule defines a "compendium" as a "comprehensive listing of FDA-approved drugs and biologicals" (or subset thereof) that includes a summary of the products' pharmacologic characteristics and "is indexed by drug or biological." 72 Fed. Reg. at 38227 (emphasis added). Unfortunately, this definition is too narrow to capture important compendia frequently used by physicians that may be indexed by disease. For example, the National Comprehensive Cancer Network ("NCCN") Drugs and Biologics Compendium™ is frequently used by oncologists in treating patients with a variety of cancers, but this compendium would not fit under the proposed definition because it indexes information by type of cancer rather than by drug or biological and may not always include a summary of pharmacologic characteristics.

Indexing by drug or biological understandably promotes some efficiency in CMS' review and use of a compendium, but we believe that such advantages should not exclude important compendia used by practitioners in the treatment of life-threatening diseases. CMS suggests in the Proposed Rule that compendia organized by disease are really "treatment guidelines" rather than "compendia" but making this distinction would, under CMS' own observations, negate the effort to establish a process for authorizing additional compendia. CMS notes in the Proposed Rule that participants in the March 30, 2006 MedCAC meeting reported that oncologists generally rely on published treatment guidelines rather than compendia when making treatment decisions. 72 Fed. Reg. at 38178. This observation suggests that it makes little sense for CMS to propose a process that would authorize additional "compendia" under the

Agency's narrow definition because the physicians for whom the compendia would be targeted, i.e., those administering anticancer therapeutic regimens, generally rely upon other publications or resources.

Notably, § 1861(t)(2) of the Social Security Act extends coverage for certain off-label uses of "drugs or biologicals used in an anticancer chemotherapeutic regimen." 42 U.S.C. § 1395x(t)(2). CMS itself has recognized that "[a] regimen is a combination of anti-cancer agents which has been clinically recognized for the treatment of a specific type of cancer." Medicare Benefit Policy Manual, Ch. 15, § 50.4.5. The Agency has also recognized that these combinations may be outlined in "protocol[s]." Id. Recognizing this, it is appropriate to expand the definition of "compendium" to include those publications that have such protocols and regimens that are specifically described in and are the focus of the statute.

Using a broader definition of "compendia" is also consistent with Congress' goals when it passed the legislation that was codified as § 1861(t)(2) of the Social Security Act. See Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66, § 13553, 107 Stat. 312, 591 (1993). The legislative history indicates that this provision was intended to "establish a uniform national coverage policy for the 'off-label' use of drugs in anti-cancer therapy by providing guidance to Medicare carriers to assist them in making coverage determinations." H.R. Rep. No. 103-111, at 537 (1993), as reprinted in 1993 U.S.C.C.A.N. at 769. Congress recognized the importance of off-label cancer treatments and sought to standardize coverage in this area by referencing what it believed to be reputable, frequently-used resources. Defining "compendium" so narrowly so as to exclude compendia publications frequently used by oncologists undermines Congress' intentions when it enacted this provision.

D. Treatment Continuity for Beneficiaries

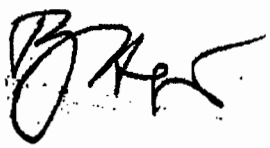
The Proposed Rule does not indicate how CMS plans to address the issue of treatment continuity. Anti-cancer therapeutic regimens often involve multiple treatment cycles. For treatment purposes, it is important that a patient complete the entire cycle. In the event this process is used to remove a compendium from the authorized list, however, beneficiaries should not be left struggling to pay for this treatment. CMS should ensure that some grandfathering mechanism is used to guarantee continued access for these patients. In addition, in cases where compendia are added to the authorized list, beneficiaries should receive the benefit of that addition even if they are in the middle of a course of treatment.

CMS recently acknowledged how important continuity is in oncology treatment as demonstrated by the approach the Agency has taken in Medicare Part D for antineoplastic agents. Guidance from CMS requires Part D plan formularies to include "all or substantially all drugs" in this class. Prescription Drug Benefit Manual, Ch. 6, § 30.2.5, available at, http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp (last visited Aug. 23, 2007). CMS notes that this policy was adopted "to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations." Id. The same rationale would apply in the context of any change in the list of authorized compendia.

III. Conclusion

We appreciate this opportunity to comment on the Proposed Rule and recognize that a great deal of thought and attention have gone into its development. We hope that CMS will carefully consider our comments and not place Medicare Part D at a disadvantage to the Part B program.

Sincerely yours,



Robert J. Hugin
President & Chief Operating Officer
Celgene Corporation

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The Specialty Biotech Distributors Association
1501 K Street, NW
Washington, DC 20005

August 31, 2007

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

Re: Comments on CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CAP ISSUES & ASP ISSUES)

Dear Mr. Kuhn:

The Specialty Biotech Distributors Association ("SBDA") submits the following comments regarding the issues relating to the Competitive Acquisition Program ("CAP") and the Average Sales Price ("ASP") methodology in the Proposed Rule: "CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008." SBDA commends the Centers for Medicare and Medicaid Services ("CMS" or "the Agency") for proposing to make changes that enhance the attractiveness of CAP to physicians and vendors, but urges the Agency to refrain from substantially modifying the program midstream during performance of the current vendor contract. We ask CMS to delay implementation of any changes until all interested entities are provided an opportunity to compete for a vendor contract.

SBDA also requests that the Agency proceed only with widely available market price ("WAMP") determinations in a manner that provides adequate notice and comment opportunities to stakeholders. Finally, we urge CMS to finalize a rulemaking that ensures consistent treatment of customary prompt pay discounts between the Medicare and Medicaid programs by excluding customary prompt pay discounts extended to wholesalers from the ASP calculation for Medicare Part B Drugs.

Background on SBDA

SBDA is comprised of companies dedicated to maintaining the integrity of the specialty distribution system in physician offices and other settings. Our members include

AmerisourceBergen Specialty Group, Cardinal Health, Inc., Curascript, Health Coalition, Inc., Oncology Therapeutics Network, McKesson Specialty, and U.S. Oncology. Together, we represent over eighty percent of the physician office specialty distribution volume in the United States. We are committed to the safe, timely, and cost-effective distribution of Part B drugs to Medicare beneficiaries.

Specialty distributors provide tremendous value and efficiency to the Medicare Program. While often not visible to the public, specialty distributors manage the increasingly complex handling and delivery requirements of drugs and costly new biologics for virtually all physician offices in the country. These distributors perform important services, such as warehousing products, providing specialty handling and shipping services (such as packaging, refrigeration, or customized dosing), and ensuring the timely delivery of drugs and biologics to physicians and providers.

Competitive Acquisition Program Issues

The Proposed Rule implements changes to the CAP regulations to mirror the provisions set forth in Section 108 of the Medicare Improvements and Extension Act of 2006 (Division B of the Tax Relief and Health Care Act of 2006) ("MIEA-TRHCA"). To that end, the Proposed Rule contemplates enacting substantial changes to CAP that will enhance the attractiveness of the program to potential vendors and physicians and reduce the level of risk borne by CAP vendors. CMS proposes, among other changes, to allow vendors to bill for cost sharing upon receipt of initial payment for the drug from the CAP carrier, to define a new exigent circumstance under which physicians may terminate CAP participation, and to consider processes that would permit physicians to transport drugs among office locations.

Although we applaud CMS for proposing changes that will significantly increase the likely success of CAP, we do not believe that the law governing CAP or government contracting principles permits CMS to implement these changes during the performance of the current CAP contract. If CMS adopts substantial revisions that impact the current vendor contract, CMS would be materially harming the bidders and others who relied on the previous language in the enabling statute and associated rulemaking. As you know, SBDA was very supportive of CAP and actively engaged with CMS and Congress in the development of the CAP regulations. Despite these efforts, a number of suggestions critical to the success of the program were not incorporated in the final rulemaking.

In light of the regulatory implications, we emphasize that it would be entirely inappropriate for CMS to alter CAP in midstream to make it more beneficial for the current CAP vendor, particularly considering that competition for the contract has ended. Substantially modifying CAP at this point in performance of the vendor contract amounts to a material change to the contract and would violate fundamental principles of promoting competition in government contracting. In essence, CMS would be providing one company with a "special deal" to the detriment of all others who previously submitted a CAP bid to the Agency.

Although the governing CAP statute permits the Secretary to waive provisions of the Federal Acquisition Regulation ("FAR") as needed to efficiently implement the program, the

waiver language specifically states that the purpose of allowing such a waiver is "to promote competition." Social Security Act, § 1847B(a)(1)(C) (2007) (emphasis added). Accordingly, any FAR waiver is expressly limited to situations in which promotion of competition is enhanced, rather than restricted. Modifying CAP during the contract performance is inequitable to those vendors that would have been interested in participating in the program if CMS had made these changes prior to the contract award. It also defeats the underlying purpose of "promoting competition" in the acquisition of Part B drugs.

As such, the proposed CAP changes should only be implemented to CAP if other interested entities are provided an opportunity to participate under the same ground rules at the same time. This goal may be accomplished by either publishing another request for proposals ("RFP") or delaying the effective date of the CAP changes until the beginning of the next contract period. This section of our comments discusses the more significant changes included in the Proposed Rule.

Proposed Changes to Claims Processing System

According to the Proposed Rule, Section 108(a) of the MIEA-TRHCA obligates the Secretary of HHS "to establish (by program instruction or otherwise) a post-payment review process (which may include the use of statistical sampling) to assure that payment is made for a drug or biological only if the drug or biological has been administered to a beneficiary." The MIEA-TRHCA further requires the Secretary to recoup, offset, or collect any overpayments that are identified through this process. It also provides that payment for a drug or biological may only be made upon receipt of a contractor's claim for administration to a beneficiary, rather than upon receipt of matching claims from the physician and vendor verifying administration of a drug. CMS emphasizes that Section 108(b) of the MIEA-TRHCA states that "nothing in this section shall be construed as requiring the conduct of any additional competition under section 1847B(b)(1) of the Act; or requiring an additional physician election."

Unfortunately, rather than merely proposing alterations to the claims processing system to facilitate implementation of a post-payment review process and to permit payment based upon claim receipt, the Proposed Rule contemplates substantial revisions to CAP that will take effect on January 1, 2008. One such significant change is CMS' proposal to permit a CAP vendor to bill a beneficiary's supplemental insurer immediately following initial claim payment by the designated CAP contractor. CMS rationalizes that this change is necessary due to the MIEA-TRHCA provision allowing vendor payment based upon receipt of a claim.

Currently, the vendor is only allowed to bill the supplemental insurer for cost sharing after the CAP claim is matched in the system with the physician's related drug administration claim, which often takes months. SBDA believes that this change will expedite payment to the CAP vendor and, as such, will reduce the financial risk borne by the vendor.

To be clear, SBDA supports the substantive change being proposed. However, making this change midstream during performance of the current CAP contract goes beyond the statutory changes to the claims processing system. As such, it is inequitable to those vendors that likely

would have submitted bids during the CAP vendor competition had these provisions been included in the program.

Proposed Exigent Circumstance for Physicians to Terminate Participation

CMS further proposes, among other changes, to establish an additional exigent circumstance to permit physicians to opt out of CAP outside of the annual election process. Under this proposal, CMS would establish a process through which physicians could request to end their CAP physician election agreement if they are able to prove that continuing participation would place a significant burden on them. The Proposed Rule provides the following as examples of significant burdens: "[a] demonstration of financial hardship due to participation in the CAP" or "the practice's inability to update its billing system despite its good faith effort[.]" SBDA believes this change will encourage greater numbers of physicians to participate in CAP because they will have enhanced options for terminating participation if it becomes burdensome, which in turn will increase the likely success and attractiveness of the program to vendors.

The change being proposed is positive, but it is also materially different than the regulation in place when the RFP was first put out for bid several years ago. Once again, SBDA urges CMS to refrain from making such a change unless it reopens the CAP vendor contract for rebidding. CMS should establish a level playing field for all entities engaged in the distribution of Medicare Part B drugs to physician offices.

Proposed Narrowing of Restriction on Transportation of Drugs

A significant drawback of CAP in terms of physician participation is the restriction on a physician's ability to transport CAP drugs to office locations beyond the site of delivery. The Proposed Rule indicates CMS is considering narrowing this restriction where permitted under State law and other applicable laws and regulations. CMS is seeking comments on methods for permitting transportation of drugs that would ensure that the integrity of the drugs is maintained and that the vendor is able to "retain control over how drugs it owns are handled." SBDA is pleased that CMS is considering narrowing the restriction on transportation of drugs while also being mindful of the importance of protecting the CAP vendor's control over the use of the drug and ensuring that the integrity of the product is not compromised. As stated throughout this section, however, it is inequitable to other interested vendors to make changes to CAP during contract performance.

Other Changes Under Consideration

CMS further proposes to revise the CAP vendor appeals process for denied drugs and to consider making changes in the future to the method used to track administration of doses of drugs. Additionally, the Proposed Rule indicates that CMS is considering reevaluating its policy relating to the use of prefilled syringes, although it does not intend to make a change at this time. Finally, based on the Agency's awareness that bevacizumab is being used off-label to treat exudative age-related macular degeneration (wet AMD) in small doses, CMS is planning to publish a program instruction notifying CAP physicians that they are permitted to "use the furnish as written option, as appropriate, and to obtain small doses of bevacizumab outside of the

CAP in prefilled syringes if their local carrier's coverage determinations allow such a practice and it is consistent with applicable laws and regulations." To the extent that these revisions to CAP enhance its attractiveness to vendors and physicians, SBDA commends the Agency for considering these changes. Even so, we reiterate that such modifications should only be undertaken if CMS provides another opportunity for entities to submit bids under the revised program.

Widely Available Market Price Issues

As the Proposed Rule explains, the ASP statute requires the Inspector General of the Department of Health and Human Services ("HHS") to conduct studies comparing a drug's ASP with its average manufacturer price ("AMP") and WAMP. Where a drug's ASP exceeds its AMP or WAMP by a set threshold percentage, which currently is five percent, the Secretary is permitted to reimburse for the drug based on the lesser of the drug's WAMP or 103 percent of the drug's AMP. For CY 2008, CMS proposes to continue to specify an applicable threshold percentage of five (5) percent for WAMP and AMP. CMS indicates that this decision is appropriate, in part, because limited information is available regarding the affect that recent modifications of the AMP calculation may have on comparisons of AMP to ASP. CMS also emphasizes that it will act cautiously in enacting any payment substitutions and give stakeholders adequate notice and an opportunity to provide input on processes for substitutions.

As CMS continues to evaluate the use of its WAMP authority, we urge the Agency to consider the impact any WAMP determinations may have on the specialty distribution industry. Specifically, in light of the fact that many distributors still earn prompt pay discounts from manufacturers, any WAMP determination must take into account such pricing terms when reviewing whether an acquisition cost represents the amount a product is acquired by a "prudent physician or supplier." Failure to consider prompt pay discounts and other pricing practices may unintentionally harm the way distributors realize a significant portion of their revenues. We reiterate comments we have submitted in the past on this topic in which we urged CMS to ensure that any WAMP guidance issued reflects the meaningful input of all interested stakeholders in the price-setting process, including beneficiaries, distributors, manufacturers, and physicians. As such, we once again ask the Agency to publish a proposed and final rule on the use of WAMP before any determinations are applied on Part B drugs.

Conclusion

SBDA appreciates the opportunity to submit comments to CMS on matters of critical importance to the specialty distribution industry. We urge the Agency to finalize this rulemaking in a manner that enhances the attractiveness of CAP to physicians and vendors without inequitably treating entities that would have been interested in participating in the program had the proposed changes been in place at the time of bidding. We also emphasize the importance of developing a final rule that takes into account the important role that specialty distributors serve in the pharmaceutical supply chain. To that end, we respectfully request that CMS once again consider excluding prompt pay discounts from the calculation of ASP. With the AMP rule now finalized, CMS has yet another compelling public policy reason to implement a consistent set of

rules between ASP and AMP. We ask that CMS once again review the legal arguments we have made to permit the exclusion of this pricing term from the calculation of ASP.

Respectfully Submitted,

John F. Akscin
President
Specialty Biotech Distributors Association

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SEPRACOR

August 31, 2007

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

Re: Comments on CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (ASP ISSUES)

Dear Mr. Kuhn:

Sepracor Inc. ("Sepracor") submits the following comments on the Widely Available Market Price ("WAMP") provisions in the "Average Sales Price (ASP) Issues" section of the Proposed Rule titled, "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS-1385-P)." Sepracor is pleased that the Centers for Medicare and Medicaid Services ("CMS") intends to afford stakeholders an opportunity to provide input regarding procedures for implementing payment substitutions, such as WAMP determinations. We also commend CMS for expressing an interest in understanding why the ASPs for certain drugs continually exceed their WAMPs or average manufacturer prices ("AMP").

Our comments on the proposed rule are narrowly focused. Specifically, we recommend that the Secretary substitute the ASP for a drug contained in a multiple source billing and payment code with its WAMP or 103 percent of its AMP in instances where substantial overpayments of a multiple source drug will occur by virtue of it receiving reimbursement based on the volume-weighted ASPs for all drugs in the code. Use of the Secretary's payment substitution authority in these circumstances will protect the Medicare Trust Fund and American taxpayers from making needlessly excessive reimbursements for these drugs.

Background Information on Sepracor

Sepracor is a research-based pharmaceutical company headquartered in Marlborough, Massachusetts. The company is dedicated to treating and preventing human disease through the discovery, development, and commercialization of innovative pharmaceutical products that are directed toward serving unmet medical needs. Sepracor is the exclusive manufacturer of several Part B innovator drugs, including Xopenex® Inhalation Solution and Brovana™ Inhalation Solution.

Sepracor Inc., 84 Waterford Drive, Marlborough MA 01752 Tel: (508) 481-6700 Fax: (508) 357-7894

WAMP Determinations In Instances When Significant Price Differences Exist Between Multiple Products Within the Same Billing and Payment Code

As CMS continues to review drugs having ASPs that are consistently higher than their WAMPs and AMPs, Sepracor emphasizes that CMS should pay particular attention to situations where a multiple source drug is combined with a single source drug in the same Healthcare Common Procedure Coding System ("HCPCS") code and paid based on the drugs' blended ASPs. In those instances, massive overpayment of the multiple source drug may occur for a long period of time to the detriment of the Medicare Trust Fund and American taxpayers.

The whole purpose of the WAMP authority is to eliminate excessive differentials that may exist between a specific product's acquisition cost and the product's reimbursement. As such, while we do not oppose the Agency's threshold of five percent for issuing a WAMP determination, we believe CMS may wish to establish an accelerated WAMP determination process for factual situations where the differences between a product's acquisition costs and reimbursement is far greater than five percent—*e.g.*, 500 percent or more. In those circumstances, the Secretary should take action to quickly substitute the ASP for that drug with its WAMP or 103 percent of its AMP. Failure to do so may cost taxpayers significant sums of money.

As CMS evaluates how it may wish to exercise its WAMP authority, we also urge the Agency to consider using coding modifiers to ensure that the two products within the same code are appropriately reimbursed. Thus, to facilitate a payment substitution for a drug contained in a multiple source code, CMS should issue a coding modifier to permit reimbursement of the drug at issue based upon its WAMP or 103 percent of its AMP while continuing to reimburse the drugs in the code not subject to the substitution based upon their ASPs. This use of the payment substitution authority will prevent Medicare from making inappropriate overpayments that otherwise might result as unintended consequences of coding decisions.

Conclusion

Thank you for your consideration of our comments. We urge the Agency to take immediate steps to eliminate egregious overpayments in the Medicare Program.

Sincerely,

Mark J. Wanda
Sr. Vice President, Legal Affairs
and Deputy General Counsel

P&G

August 31, 2007

VIA HAND DELIVERY AND E-MAIL
http://www.cms.hhs.gov/eRulemaking

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

Re: CMS-1385-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Acting Deputy Administrator Kuhn:

Procter & Gamble appreciates the opportunity to comment on physician payment and quality reporting provisions of the proposed physician fee schedule rule for 2008 (CMS-1385-P).[1] Our comments address provisions affecting the prevention and management of osteoporosis.

RE: PHYSICIAN FEE SCHEDULE

1. P&G respectfully requests that CMS reevaluate payment rates for two tests used in the diagnosis of osteoporosis: dual energy x-ray absorptiometry (DXA, CPT code 77080) and vertebral fracture Assessment (VFA, CPT code 77082). We recommend that CMS collaborate with outside experts to develop accurate estimates of the work and costs associated with axial DXA and VFA and to revise payment policies. Fair reimbursement to physicians will help ensure appropriate patient access to these preventive services.

We are concerned that current and planned cuts in Medicare payment for DXA and VFA will reduce patients' access to secondary and tertiary prevention, causing an increase in bone fractures and associated costs to the Medicare program. The Medicare population accounts for 87% of osteoporosis-related fracture costs in the U.S. (Burge et al. JBMR 2007). Both observational research and modeling studies suggest that increased osteoporosis testing and treatment will produce savings to the Medicare program (Newman et al. JCOM 2003; King et al. Ost Int 2005; The Lewin Group 2007). However, the January 2007 cuts in Medicare payment have already caused physician offices to curtail DXA use and professional development activities related to osteoporosis (survey of ISCD, AACE, ACR, and TES members, April-May 2007).

Restricting the availability of DXA and VFA to imaging centers and hospital outpatient departments may create significant access barriers, particularly among ethnic minorities and rural populations. These barriers include reduced service availability, lack of transportation, increased travel time, referral requirements, appointment scheduling, lengthy intake procedures and waiting (Scheppers et al. Fam Practice 2006; Okoro et al. Prev Med 2005). For mammography, delayed referral was found to be independently associated with patient age over 65 and the presence of more than one chronic illness, both of which are common in patients at risk for osteoporosis (Gimotti et al., HSR 2002). The perception that preventive services are "not needed" was also a powerful demotivator among lower-income, rural, blacks (Strickland et al. J Rural Health 1996). These challenges are compounded for asymptomatic conditions like osteoporosis.

[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule, 72 Fed. Reg. 38122 (July 12, 2007).

Reduced access to osteoporosis testing may exacerbate disparities in care. Late diagnosis of health conditions in minority populations often leads to more serious disease outcomes and poorer prognosis. For example, black hip fracture patients have a greater number of comorbid illnesses and longer hospital stays than white patients, and they are more likely than whites to be nonambulatory at discharge (Furstenberg & Mezey J Chron Dis 1987). Black women are also more likely than white women to die following a hip fracture (Jacobsen et al. AJPH 1992).

RE: TRHCA—SECTION 101(b): PQRI

2. We support the proposal to retain four of the 2007 osteoporosis measures (listed below and in Table 16 of the proposed rule, CMS-1385-P), **as well as screening for falls, in the final set of 2008 PQRI measures.**

- Osteoporosis Management Following Fracture.
- Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture
- Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older
- Osteoporosis: Pharmacologic Therapy

Incentives for reporting osteoporosis quality measures may help change care patterns, leading to improved screening, diagnosis, and management of osteoporosis.

A considerable body of evidence documents the underdiagnosis and undertreatment of osteoporosis in older women and men (US Surgeon General, Bone Health and Osteoporosis, 2004). Although the relationship between bone density and fracture is stronger than the relationship between cholesterol and heart attack (Marshall et al. BMJ 1996), screening for fracture risk lags. Modest growth in Medicare bone mass measurement followed the expansion of coverage in 1998 (King et al. Ost Int 2005), but growth has attenuated in recent years. In 2002, the US Preventive Services Task Force recommended routine osteoporosis screening in women aged 65 years and older (Ann Int Med, 2002). However, less than 10% of female Medicare beneficiaries received a Medicare-reimbursed DXA test in 2006 (BESS data, CMS ORDI, August 2007).

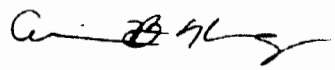
Separate quality measures for screening and therapy are needed because an osteoporosis diagnosis frequently does not result in treatment (King et al Osteoporosis Int 2005; Pressman et al. Ost Int 2001). Even for high-risk patients who have already fractured (Klotzbuecher et al. JBMR 2000, Johnell et al. Ost Int 2004), treatment is uncommon.

HEDIS data demonstrate the substantial need for improvement in care following fracture. In 2005, only 20% of women in Medicare Advantage plans were either tested or treated for osteoporosis in the six months following a fracture (NCQA, The state of health care quality, 2006, Washington, DC).

3. To promote primary, secondary, and tertiary prevention of fragility fractures, we recommend that CMS specifications for 2008 PQRI measures distinguish DXA testing from pharmacologic therapy. In the 2007 specifications for two of the osteoporosis measures (#40 osteoporosis management following fracture, and #39 screening or therapy in woman aged 65 years and older), the numerator includes both patients with a DXA test ordered and those for whom treatment was prescribed. Separate CPT II codes are used to report these subgroups. Thus, CMS is already collecting data that distinguish which patients are tested and which are treated. We recommend that CMS reporting of 2008 measures include the DXA and treatment subgroups, as well as the total. This will enable better feedback on quality of care in confidential reports to individual providers, as well as evaluation of whether CMS policies or medical interventions differentially affect testing and treatment rates at the aggregate level.

Thank you for considering these suggestions for strengthening Medicare payment policies and quality initiatives to improve preventive care for patients at risk for fragility fractures.

Sincerely,



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August 31, 2007

Mr. Herbert Kuhn
Acting Deputy Administrator
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Department of Health and Human Services
Room 445-G
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200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Changes to Payment Under Part B

Dear Mr. Kuhn:

Amgen Inc. (Amgen) is writing to comment on the Calendar Year (CY) 2008 Medicare Physician Fee Schedule Proposed Rule (the "Proposed Rule"), which the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* on July 12, 2007.[1] As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs" following the agency's convention) for Medicare beneficiaries. For this reason, our comments address the following issues:

- the agency's proposals related to the calculation of the average sales price (ASP) of drugs;
- other issues impacting access to drugs in the physician office setting, including proposals related to anemia quality indicators and drug compendia; and,
- the use of the ASP methodology as the basis for Medicare payment to dialysis facilities for certain separately billed drugs.

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

Below, we review our comments on each of these issues in detail.

COMMENTS ON ASP ISSUES

In this section, Amgen provides our comments on a series of ASP policy issues.

I. CMS Should Not Implement a Reallocation Methodology that Would Undermine the ASP System.

As Amgen has commented to the agency on a number of occasions, we believe that the adoption of the ASP methodology, as currently implemented and administered, has to date resulted in the following:

- adequate payment for Part B covered drugs,
- access to critical treatments by Medicare beneficiaries, and
- lower Medicare and beneficiary costs for Part B covered drugs.

The success of the ASP system in achieving Congressional objectives and in reducing Medicare expenditures continues to be well documented.[2] Given the importance of the ASP-based payment system, it is essential that the regulations governing calculation of ASP be clear and that the prices reported to CMS reflect those available in the marketplace.

CMS has proposed to adopt a definition and a reallocation methodology for bundled price concessions for ASP reporting purposes. These changes will not improve the accuracy of ASP reporting and may actually lead to ASP distortions.

Our comments on this Proposed Rule will provide our recommendations and raise questions about CMS proposals regarding the ASP calculation. As we did in comments last year to CMS, Amgen will focus particular attention on the proposed introduction of a new concept – specifically, the definition of "bundled arrangement"– and a new reallocation methodology that would impact the ASP calculations for products subject to this definition.

We continue to believe that the proposed reallocation methodology should not be applied when individual prices of Part B drugs in a multiproduct contract can be ascertained without reallocation of price concessions. Any reallocation can distort the actual market prices of all affected products.

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2 Medicare Payment Advisory Commission (MedPAC), "Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs" (January 2007)

Multiproduct contracts are common, pro-competitive mechanisms for price competition.

It is our understanding that arrangements which provide buyers the opportunity to obtain larger discounts when purchasing multiple products that remain separately available are common and provide recognized benefits to producers and consumers.[3] Bundled discounts, which are distinct from tying arrangements because they do not require a consumer to purchase one product in order to purchase a second product in the bundle, often promote price competition and efficiency. The Supreme Court recognized that the discounting of a package of multiple products or services can benefit consumers and the market when it said, "[t]here is nothing inherently anticompetitive about packaged sales."[4] Specifically addressing this form of discount for items and services paid for by Medicare or Medicaid, the US Department of Health and Human Services Office of Inspector General (OIG) said, "in certain circumstances, discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale. Such circumstances exist where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment."[5]

CMS did not identify any specific concerns about the "bundled arrangements" in the preamble to the Proposed Rule or point to any harm resulting from manufacturers' current treatment of them in their ASP calculations. Therefore, we are concerned that there is no compelling policy rationale that serves as the impetus to CMS to revise ASP reporting requirements for all Part B covered drugs at this time.

An accurate ASP reflects the prices available in the market for a specific product. Reallocation of discounts from one product to another is unnecessary and could result in inaccurate ASPs, impaired beneficiary access, and inappropriate financial incentives.

Given the lack of a compelling policy rationale, CMS should pay specific attention to the possible negative impacts of the definition and reallocation methodology. As we have

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3 *See* John Thorne, Discounted Bundling by Dominant Firms, 13 Geo. Mason L. Rev. 339 (2005)("Bundled discounts are in many ways akin to ordinary volume discounts, because in both cases the purchase of additional units leads to a lower overall price."); Michael A. Salinger, A Graphical Analysis of Bundling, 68 J. Bus. 85 (1995) ("Bundling can . . . increase consumer surplus when it results in lower prices.").

4 Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 25 (1984); *see also,* Daniel Crane, Multiproduct Discounting: A Myth of Nonprice Predation, 72 U. Chi. L. Rev 27, 48 (2005) ("Packaged discounting is a common phenomenon among firms that have no predatory ambition. It is a business strategy that often makes perfectly good sense without any need for injury to a rival. In the short run it cannot harm competitors any more than an equivalent discount on a single product and, in the long run, it increases consumer welfare by lowering the price of goods and services even if no competitor exits the market.")

5 *See* 64 *Fed. Reg.* 63518, 63530 (Nov. 19, 1999).

previously noted[6], it should not be necessary to reallocate price concessions among the products in a multiproduct contract in order to calculate an accurate ASP. In fact, where all products in a multiproduct contract are paid for by Medicare based on ASP (as Amgen's are), the discounts are appropriately disclosed in the quarterly ASP submissions discussed below (as is the case with Amgen's discounts), and all price concessions benefit Medicare and its beneficiaries (as Amgen's do).

Last year, a single manufacturer offered an unworkable proposal that would dramatically increase the agency's and manufacturers' regulatory burden and potentially increase costs for Medicare and its beneficiaries. CMS rejected that proposal and should do so again if it is raised this year.

One manufacturer proposed last year that CMS implement its recommendation requiring that "incentives granted on dominant drugs that are conditioned in whole or in part on purchases of a competitive drug should be allocated to the competitive drug (or drugs, based on the relative sales of the competitive drugs)". After carefully considering this issue, CMS concluded in last year's final Medicare Physician fee Schedule rule that this concept would be impossible to implement:

> *"[W]e note that we received a comment suggesting that Medicare adopt a special policy concerning the treatment of bundled price concessions in the ASP calculation for bundling arrangements that include dominant drugs without significant clinical alternatives. We do not believe it would be feasible for the Medicare program to establish a definition of a dominant drug without significant clinical alternatives that would be precise enough to clearly delineate when a product was or was not dominant, especially given the potential for great variation in the structure of bundling arrangements and the characteristics of drugs included in those arrangements."*[7]

CMS was right. Implementation of such a flawed concept would create a regulatory quagmire. Rather than ensure that the ASP system is an "accurate reflection of market prices," this recommendation would distort ASP and dissociate it from the actual transaction prices. The recommendation would undermine the integrity of the ASP reimbursement system while at the same time risking higher costs to Medicare and its beneficiaries.[8] If this concept is raised again, the agency should reject it once more for the same reasons expressed in last year's final rule.

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6 See Letter from Amgen to Leslie V. Norwalk, Esq., Administrator, CMS (March 21, 2007); Letter from Amgen to Mark B. McClellan, MD PhD, Administrator, CMS (Oct. 10, 2006).

7 71 *Fed. Reg.* 69675 (Dec. 1, 2006).

8 As Amgen explained in its October 10, 2006 comment letter to CMS, the reallocation of discounts from a so-called "dominant drug" to a "competitive drug" could have the effect intended by its sole proponent—the moving of market share to its more expensive product. *See* Letter from Amgen to Mark B. McClellan, MD PhD, Administrator, CMS, at 10-11 (Oct. 10, 2006)

In response to last year's Proposed Rule, which briefly discussed "bundled price concessions," stakeholders commented that CMS should not publish guidance on this issue without giving all affected parties a meaningful opportunity to comment on a specific definition and reallocation methodology through rulemaking.

Last year, CMS signaled in the preamble to the Proposed Rule that it might use its authority to provide guidance in this area through program instruction or other guidance. In response, stakeholders asked to have an opportunity to comment on the specifics of any possible proposal (in the form of a proposed rule), before it is effective.

For this reason, our comments this year reflect our appreciation for the care with which CMS has approached this proposed policy change. Soliciting comments in successive rulemakings is a responsible and appropriate practice where controversial regulatory changes are contemplated.

While there is no compelling need or rationale for CMS to change its policy on "bundled price concessions," if CMS chooses to implement a reallocation methodology, it should be explicit and clear, avoid greater computational complexity than necessary and minimize distortion to market based payment rates.

Amgen appreciates the agency's decision not to propose certain methodology options, outlined above, which raised the specter of major distortions in ASP and possible costs to the Medicare program and its beneficiaries. Instead, CMS has proposed to implement one of the options mentioned in the January 2007 MedPAC Report to Congress (MedPAC Report),[9] a methodology similar to one recently finalized under Medicaid.[10] In doing so, CMS appears to have proposed a methodology for allocating "bundled price concessions" that would distort ASP somewhat, but is less likely than the approach discussed above to move ASPs in a direction that could lead to a serious disconnect between the ASP-based payment rates and prices available to providers in the marketplace.

For these reasons, while we continue to see no need to issue a prescriptive definition and reallocation methodology, we note that the CMS proposal to align ASP reporting requirements with those used under the Medicaid program is likely to lead to less distortion in payment rates and market prices. In particular, given the variation in the structure of bundling arrangements, CMS' proposal to reallocate bundled discounts based on the relative sales volume of the drugs included in the bundle is a clear and objective method that is more likely to have a fair and consistent effect in all situations, because the percentage of sales will be the same across the bundle. Therefore, if CMS chooses to codify a "bundled arrangement" definition and reallocation methodology in the Final Rule, we recommend that the agency adopt the definition and reallocation methodology as proposed, with certain clarifications discussed below.

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9 MedPAC. "Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs" (January 2007)

10 72 Fed. Reg. 39,142 (July 17, 2007) ("Medicaid Final Rule"). http://www.cms.hhs.gov/MedicaidGenInfo/Downloads/CMS2238FC.pdf.

II. CMS Should Provide Additional Clarity on the Proposed Definition of a Bundled Arrangement and the Reallocation Methodology.

Amgen has technical questions on the proposed definition and reallocation methodology. Responses to these questions will help manufacturers report ASPs in the manner CMS is requesting. In comments below, Amgen raises questions and requests clarification about the "bundled arrangement" definition and provides some recommendations regarding how to implement the proposed new policy.

1. CMS Should Clarify Whether All Price Concessions Must Be Reallocated in "Bundled Arrangements."

As CMS notes in the preamble to the Proposed Rule, "there is a potential for great variation in the structure of bundled arrangements and in the characteristics of drugs included in those arrangements."[11] For example, some contracts may offer a customer both contingent and non-contingent discounts on the same products. In its Preamble to the Medicaid Final Rule, CMS responded to a comment asking for clarification about the reallocation of discounts when a bundled sale arrangement includes both contingent and non-contingent discounts and rebates. In reply, CMS noted that all such discounts are considered to be "within the bundled sale if any drug must be purchased in order to get a discount on any drug in the bundle regardless of whether any drug is purchased at full price."[12]

After careful consideration, Amgen is writing to support the same treatment of bundled arrangements in the Medicare ASP context. This position is based on the need for simplicity and consistency in these very complicated calculations. A different requirement for Medicare than for Medicaid could make quarterly reporting an even more time-consuming exercise. We are also concerned that if the decision to include or exclude a drug or a discount from the quarterly reallocation were based on facts and circumstances that changed from quarter to quarter, the complexity and possibility of error would be increased. For example, in some quarters, the customer might not meet some of the volume purchase or other performance requirements for the contingent discounts under the contract, while meeting others and also receiving non-contingent invoice discounts. Amgen requests that CMS provide specific guidance in its Final Rule regarding whether all discounts in a bundled arrangement should be allocated proportionally among the drugs in the arrangement. This additional clarity will help to ensure that manufacturers employ a uniform approach for reallocating discounts under a bundled arrangement.

2. CMS Should Limit Reallocation to Drugs Reimbursed Under the ASP Payment System.

Amgen urges CMS to clarify that only those drugs which are reimbursed by Medicare based on the ASP payment system are subject to the bundled arrangement reallocation under CMS' proposed methodology. The OIG has determined that in order for a contingent

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11 *Id.* at 38151.

12 72 Fed. Reg. at 39159.

discount to come within the discount safe harbor to the federal anti-kickback statute, "the goods and services [must be] reimbursed by the same Federal health care program using the same methodology."[13] As we noted above, in addressing this safe harbor, the OIG explained that contingent discounts do not pose a risk of program abuse and may benefit Federal health care programs through lower costs or charges "where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment."[14] A bundled arrangement that includes drugs that are not reimbursed by Medicare or reimbursed based on other payment systems would appear to be outside of the OIG's safe harbor for purposes of the anti-kickback rule. For example, a bundled arrangement that included both ASP-reimbursed Part B drugs and over-the-counter drugs could adversely affect Medicare, as some of the discounts on the Part B drugs would likely be allocated to the drugs or products not covered by Medicare or packaged into a payment for services. Accordingly, Amgen asks CMS to clarify in the Final Rule that only those drugs that are reimbursed under the ASP methodology be included in the "bundled arrangement" and subject to reallocation.

3. *CMS Should Permit Manufacturers to Use the Reallocation Methodology for Prior Quarters of the 12-Month Rolling Average Ratio for Lagged Price Concessions.*

In the preamble to the Proposed Rule, CMS invited comment on how the proposed approach for treatment of bundled price concessions may impact the estimation of lagged price concessions and whether additional guidance is needed on this topic. Amgen appreciates that CMS is cognizant of the potential impact of its reallocation methodology on the 12-month rolling average ratio used to calculate lagged price concessions. One important area where additional guidance is needed is on the question of whether manufacturers would reallocate bundled discounts for quarters prior to the first quarter of 2008 for purposes of calculating lagged price concessions. Amgen strongly recommends that CMS permit manufacturers to choose between reallocating discounts for all four quarters in the 12-month rolling average ratio or implementing the reallocation methodology only for the quarter being reported.

According to the Proposed Rule, if the proposed reallocation methodology is implemented it would apply to bundled arrangements beginning with the reporting period for the first calendar quarter of 2008.[15] If a manufacturer includes the first quarter 2008 reporting period in the 12-month rolling average ratio used to calculate lagged price concessions, the ratio will include all ASP-eligible rebates and other lagged price reductions for the second quarter of 2007 through the first quarter of 2008. Amgen asks CMS to specify in the Final Rule that manufacturers may choose to reallocate bundled discounts for the three quarters prior to the first quarter of 2008 that are included in the 12-month rolling average. Permitting manufacturers to immediately adopt the reallocation methodology at once for all four quarters, rather than proceeding piecemeal based on the quarter being reported, may reduce the computational complexity involved in updating current ASP systems and testing and validating the results of those modifications. Because discounts under a bundled

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13 42 C.F.R. § 1001.952(h)(5)(ii).
14 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999).
15 72 Fed. Reg. at 38,151.

arrangement will generally be treated as lagged, reallocating discounts for all four quarters in the 12-month rolling average ratio will also avoid a 12-month delay in reported ASPs reflecting CMS' reallocation policy. Amgen recommends, nonetheless, that manufacturers be permitted to choose between immediate adoption or a quarter-by-quarter implementation, to allow the flexibility needed to accommodate manufacturers' individual methodology systems.

4. CMS Should Clarify Whether the Reallocation Methodology is Based on Gross Sales in the Period to which the Discount or Rebate Relates.

The Proposed Rule directs manufacturers to allocate bundled discounts "proportionately according to the dollar value of the units of each drug sold under the bundled arrangement."[16] Amgen asks that CMS to specify in its Final Rule that the relative sales dollar volumes of products in the bundled arrangement should be valued based on gross sales (i.e., undiscounted sales) in the period to which the price concession relates. For example, annual rebates would be reallocated based on undiscounted sales during the 12-month period on which the rebate was based, even though it might be paid in a subsequent quarter. Similarly, if a rebate on first quarter sales is paid in the second quarter, the reallocation would be based on undiscounted first quarter sales. Finally, an invoice discount given in the first quarter as a reduction in a direct price would be reallocated based on undiscounted first quarter sales. Aside from an invoice discount to a direct customer, these discounts and rebates likely would be treated as "lagged" for both ASP and, beginning October 1, 2007, for average manufacturer price (AMP) purposes[17]. Therefore, the reallocated discounts would go into the discount equation when the amounts are known, usually when they are paid.

This approach is consistent with the bundled sale example set forth in the Medicaid Final Rule, in which the bundled discount is allocated proportionally, based on the undiscounted sales of each product in the bundle.[18] As CMS discusses in the preamble to the Proposed Rule, establishing an overall consistent methodology for the treatment of bundled discounts across both the ASP and AMP contexts will reduce the burden on manufacturers and lower the potential for error. For these reasons, Amgen urges CMS to make clear in the Medicare Final Rule that bundled discounts should be reallocated based on gross sales for the period during which the discount was earned, for purposes of ASP reporting.

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16 *Id.* at 38,226 (proposed 42 C.F.R. § 414.804(a)(2)(iii)).

17 Medicaid Final Rule, 72 Fed. Reg. at 39243 (42 C.F.R.§447.510(d)(2)).

18 *Id.* at 39158.

III. CMS Should Consider Policy Changes and Clarifications Affecting ASP.

In comments below, Amgen reviews our recommendations on other ASP policy issues.

1. CMS Should Revise Its Methodology for Calculating Volume-Weighted ASPs.

Amgen recommends that CMS adopt a revised methodology for calculating volume-weighted ASPs. Specifically, we recommend that CMS calculate the weighted ASP of the number of billing units sold rather than the number of National Drug Codes (NDCs) sold.

Under CMS' current methodology, the ASP per billing unit for each NDC is weighted equally regardless of package size, therefore not taking into account differences in strength or billing units per NDC. Said another way, there is no sales volume weighting to mirror the actual market based purchases and resulting average pricing. In the final rule on the physician fee schedule for calendar year 2006, CMS responded to comments from manufacturers and other commenters recommending that payment limits should be calculated based on the weighted ASP of the number of billing units sold rather than the number of NDCs sold. CMS did not revise its methodology at that time, but it advised that "[a]s we gain more experience with the ASP data and other sources of information become available about the purchasing patterns of providers and their acquisition costs, we may consider altering the methodology or establishing exceptions, if we find good reason to do so."[19]

In February 2006, the OIG issued a report entitled "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs."[20] The OIG found that CMS' method for calculating volume-weighted ASPs is "mathematically incorrect because CMS does not use billing units consistently throughout its equation" and that CMS' method "often results in reimbursement amounts that are either too high or too low."[21] The OIG recommended that CMS "adopt an alternate equation, which uses billing units consistently and produces a volume-weighted ASP that is both mathematically correct and consistent with the results of the calculation set forth in section 1847A(b)(3) of the [Social Security] Act."[22] CMS wrote in its comments on the OIG's report that "we continue to work toward refinements in the ASP payment methodology, and are already addressing the subject matter of this OIG report."[23] Importantly, we note that the OIG suggestion does not require any changes in the data submitted by manufacturers in the quarterly ASP submissions. Amgen urges CMS to adopt the OIG's recommendations and to implement a revised methodology for calculating the volume-weighted ASP.

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19 70 Fed. Reg. 70116, 70218 (Nov. 21, 2005). CMS stated further that "[i]f we decided such a change is warranted, we would implement the change at the next quarterly update." *Id.*

20 OIG, Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs (Feb. 2006).

21 *Id.* at 6-8.

22 *Id.* at 11.

23 Letter from Mark B. McClellan, M.D., PhD, Administrator, CMS, to Daniel R. Levinson, Inspector General, OIG (Dec. 22, 2005).

2. CMS Should Avoid Inappropriate Substitution of AMP for ASP.

When Congress set up the ASP methodology, it authorized the Secretary of Health and Human Services (the Secretary) to base payment on 103% of a drug's AMP, instead of 106% of its ASP, if the Inspector General determined that the ASP exceeded the AMP or the widely available market price (WAMP) by a threshold to be determined by the Secretary.[24] For 2006 and 2007, the threshold percentage has been 5%, and CMS proposed to continue that threshold for 2008, while expressing some concerns about this provision.

As CMS points out in the Proposed Rule preamble, "there are complicated operational issues associated with potential payment substitutions," and "information on how recent changes to the calculation of the AMP may affect the comparison of AMP to ASP is not available at this time."[25] The agency expressed its intention to move cautiously, giving adequate notice and an opportunity to comment, before imposing the authorized price substitutions.[26] We applaud the agency's caution in implementing this provision and are responding to the invitation to assist CMS in developing a better understanding of the issues that may be related to certain drugs for which the WAMP[27] and the AMP may be lower than the ASP over time.[28]

Even before the recent Medicaid Final Rule, the methodologies for calculating AMP and ASP were quite different, for understandable reasons. AMP is primarily used to calculate the rebates paid by manufacturers on utilization of their drugs under the Medicaid program. Because Medicaid has long included an optional outpatient pharmacy benefit, the vast majority of drugs paid for under that program are dispensed by retail pharmacies. Therefore, the definition of AMP is intended to capture the average price paid to a manufacturer for sales to wholesalers of drugs distributed to the retail pharmacy class of trade.[29] ASP, on the other hand, is mainly used to set payment for Medicare Part B drugs, the vast majority of which are administered incident to a physician's service, in a physician clinic, or a hospital or other provider setting.

Manufacturers have not been required to include hospital or clinic sales in their AMP calculations, but the ASP methodology does include sales to those and virtually all other classes of trade. However, the recent Medicaid Final Rule specifies that the AMP includes sales to physicians, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers, as well as to hospitals where the sales can be identified as for outpatient pharmacy use.[30] Although sales prices to these classes of trade might not dramatically impact the AMP of a drug sold predominantly through traditional retail

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24 Social Security Act §1847A(d)(3).

25 72 Fed. Reg. at 38152-53.

26 *Id.* at 38152.

27 The statutory provision gives the Inspector General the role of determining WAMP. See Social Security Act § 1847A(d)(5). We are not addressing that aspect of the price substitution authority in these comments.

28 72 Fed. Reg. at 38153.

29 Social Security Act §1927(k).

30 *See* 72 Fed. Reg. 39142, 39241 (July 17, 2007)(codified at 42 CFR §447.504(g)).

pharmacies, inclusion of those prices will predictably lower the AMPs of the typical drug paid for under Medicare Part B based on its ASP.

Implementation of the "bundled sale" definition in the Medicaid Final Rule could also affect the comparison of AMP and ASP. As discussed above, the comparison would be affected by any differences between the AMP and ASP reallocation methodologies (for example, if one requires non-contingent discounts to be reallocated while the other does not). Whether or not CMS finalizes its proposed requirement for reallocation of "bundled arrangements" in the calculation of ASP, such reallocations will be required for AMP purposes before the effective date of any ASP change. This timing difference could affect the relationship between the AMP and ASP reports for the same drug.

For the reasons set out above and in the interest of fairness and accuracy in price reporting and payment decisions, we encourage CMS to consider increasing the threshold percentage or otherwise preventing an inappropriate reduction in the payment rate to physicians and others that would occur if the Part B payment rate were based on a 103% of AMP, rather than 106% of ASP.

COMMENTS ON TRHCA – SECTION 110 (ANEMIA QUALITY INDICATORS)

I. CMS Should Provide Clear Instructions on the Scope and Reporting Requirements for Anemia Quality Indicators.

In the Proposed Rule, CMS discusses and requests comments on implementation of section 110 of the Tax Relief and Health Care Act of 2006 (TRHCA), which requires that each request for payment for a drug furnished on or after January 1, 2008, for the treatment of anemia in connection with the treatment of cancer include information on the hemoglobin or hematocrit levels of the individual, in a form and manner specified by the Secretary.[31] Additionally, the agency commented that "[a]nemia adversely impacts the quality of life for beneficiaries being treated for cancer" and noted that "[f]atigue and reduced performance capacity are the side effects of anemia that cancer patients report as the most disabling and contributing to poor quality of life."[32] Amgen applauds the agency's recognition of the debilitating effects of anemia in patients fighting cancer, and we fully support efforts to ensure that patients receive appropriate treatment for this condition.

Amgen understands that the next phase in implementing the TRHCA requirements will be to provide instruction to physicians, providers, and contractors on how this information should be reported, based on CMS' final rule. As the agency is aware, claims processing can be complicated both for CMS and for physicians. As CMS moves toward developing the claims reporting system, it will be important that physicians have clear guidance on the reporting process as well as a reasonable time frame for incorporating these new

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31 72 Fed. Reg. at 38204-05.

32 *Id.* at 38204.

requirements into their existing billing practices. Amgen would be happy to serve as a resource for CMS or the Medicare contractors in developing the reporting system.

CMS also requests public comment on the potential for expanding the reporting of anemia quality indicators beyond the TRHCA section 110 requirements to include all uses of anti-anemia therapies, noting that this expansion is not required by statute.[33] Amgen has a number of recommendations with regard to CMS' implementation of the TRHCA section 110 requirements, including the CMS proposal for expansion.

1. *CMS Should Clarify Whether the Reporting Requirement Applies to All Anemia Therapies.*

TRHCA Section 110 requires reporting of anemia quality indicators for each request for payment "for a drug furnished to an individual for the treatment of anemia." The statute references anti-anemia treatment, which include but are not limited to erythropoiesis-stimulating agents (ESAs). Therefore, we request that CMS clarify whether the reporting requirements apply to all anti-anemia treatments approved by the U.S. Food and Drug Administration (FDA). If so, CMS should provide a listing by Healthcare Common Procedure Coding System (HCPCS) code of all products affected by the TRHCA provision.

2. *CMS Should Consider the Minimal Dataset that Will Be Essential for Understanding or Correctly Interpreting How a Beneficiary Responded to a Particular Course of Anemia Management When Developing Requirements for Implementation.*

If CMS intends to use the anemia quality indicators reported by physicians to assess quality of care for patients treated for anemia, it may also need to collect additional data (e.g., information on co-morbidities, blood use, and hospitalizations). Before implementing any specific policies, and in order to avoid an undue burden on physicians and their staff, CMS may want to consider convening an expert advisory panel to assist in identifying the relevant data elements and whether those data elements are already captured in CMS data.

3. *CMS Should Be Cognizant of the Burden on Physicians When It Develops the New Claims Reporting System.*

Implementing and complying with CMS' new claims reporting policy may increase administrative burdens for physicians and their staff. CMS should provide clear instruction to physicians and providers to reduce the time and cost associated with implementing new billing requirements and should try to achieve consistency with reporting policies of other payers to further lessen the administrative burden.

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33 *Id.* at 38205.

4. *CMS Should Finalize Its Proposal that Physicians May Report Hemoglobin or Hematocrit Levels.*

The Proposed Rule would require reporting of "the beneficiary's most recent hemoglobin *or* hematocrit level."[34] Amgen supports this proposal. We believe that CMS should allow physicians to report either hemoglobin or hematocrit levels. As CMS is likely aware, there is no nationally recognized measurement unit (i.e., hematocrit or hemoglobin) for reporting or diagnosing anemia. Requiring that all physicians report using one indicator would increase the administrative burden for those physicians who would have to convert the actual test result to the methodology required for reporting.

5. *If CMS Proceeds with Broader Collection of Hematocrit and Hemoglobin Levels, CMS Should Consider Issues Raised by the Recent Changes in ESA Coverage and the Reporting Burden on Physicians.*

CMS has solicited comments on the potential for expanding the reporting requirements beyond the statute to include patients receiving anti-anemia treatments for other conditions. If CMS decides to move forward with an expanded hematocrit and hemoglobin reporting policy, we recommend that CMS assess the minimal dataset(s) that will be essential for understanding or correctly interpreting how beneficiaries with various underlying indications responded to a particular course of anemia management if proceeding with the proposed expansion.

Additionally, because the recently announced National Coverage Determination (NCD) on Medicare coverage for oncology uses of ESAs[35] severely restricts coverage, we recommend that CMS consider instructing its contractors to require hematocrit or hemoglobin levels on claims relating to conditions described in the NCD as ones for which ESA treatment would no longer be covered. Such an expansion of the reporting requiring could help the agency measure the impact of its new policy on patient access.

Lastly, we urge CMS to remain sensitive to the potential administrative burden for physicians and their staff when considering broader collection than required by the statute. Any expansion of the reporting requirement should be contemplated only with active input from clinicians and their specialty societies.

COMMENTS ON DRUG COMPENDIA

CMS Should Clarify the Timeline for Updating the List of Recognized Compendia.

CMS has proposed an annual process to solicit public comment on updating the list of accepted compendia used to determine medically-accepted indications for drugs and

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34 *Id.* (emphasis added).

35 Decision Memo for Erythropoiesis Stimulating Agents (ESAs) for non-renal disease indications (CAG-00383N), July 30, 2007.

biologicals used in anticancer chemotherapeutic regimens.[36] Amgen generally supports CMS' proposal but is concerned that the timeline for updating the list of compendia could unnecessarily delay the incorporation of stakeholder comment. The proposed process will provide 45 days notice that the agency will open a 30-day comment period during which it will accept completed requests to revise the list of compendia. We believe that a 30-day notice period is sufficient in light of CMS' specific guidance on the process for submitting a complete request. We also urge CMS to specifically address the time frame for publishing the list of complete requests as well as how quickly thereafter it will open the 30-day period for comment on the requests. Minimizing these time periods will avoid further delay in updating the compendia. Finally, we recommend that CMS consider shortening to 90 days the proposed 120-day time frame for publishing its decision after the close of the public comment period, similar to the timeline used for finalizing National Coverage Determinations after issuance of CMS' proposed decision.

COMMENTS ON ESRD PROVISIONS

Payment for Separately Billable Drugs Furnished in Connection with Renal Dialysis Services Should Continue To Be ASP+6%.

In the final physician fee schedule rule for CY 2006, CMS stated that payment for a separately billable dialysis-related drug furnished during 2006 by hospital-based and freestanding dialysis facilities would be based on 106% of ASP.[37] CMS clarified in the physician fee schedule rule for CY 2007 that this payment methodology applied to CY 2006 and subsequent years (until it specifies otherwise).[38] In the Proposed Rule, CMS has not proposed to change the ASP+6% reimbursement for separately billable dialysis-related drugs.

Amgen continues to support using the ASP+6% methodology for separately billable drugs, including ESAs, in ESRD. The Medicare statute clearly outlines that ASP+6% is a permissible method for payment for ESRD drugs.[39] ASP+6%, a market-based methodology, is used throughout the Medicare Part B system and has resulted in substantial savings, with almost a billion in savings in 2005 alone according to testimony by the HHS OIG before the Ways and Means Subcommittee on Health on July 13, 2006.[40]

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36 72 Fed. Reg. at 38178.

37 *See, e.g.,* 70 Fed. Reg. 70116, 70162, (Nov. 21, 2005).

38 *See, e.g.*, 71 Fed. Reg. 69624, 69680-81 (Dec. 1, 2006).

39 Section 1881(b)(13)(A)(iii) of the Social Security Act ("the Act") sets payment amounts for separately billed drugs and biologicals at the acquisition cost or the amount determined under section 1847A of the Act, as the Secretary may specify. The amount determined under section 1847A is ASP+6%, except in limited cases.

40 Testimony of Robert A. Vito, Regional Inspector General for Evaluation and Inspections Office of Inspector General, U.S. Department of Health and Human Services, House Committee on Ways & Means Subcommittee on Health: Hearing July 13, 2006.

ASP+6% also has resulted in lower drug payments in the ESRD setting according to MedPAC in its March 2007 report to Congress.[41]

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Amgen appreciates this opportunity to comment on the important issues raised in the Proposed Rule and we look forward to working with you to ensure that Medicare beneficiaries continue to have access to new and important drug and biological therapies. Please contact Sarah Wells Kocsis at (202) 585-9713 to arrange a meeting or if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Regards,

Joshua J. Ofman, MD, MSHS
Vice President
Global Coverage and Reimbursement
and Global Health Economics

cc: Elizabeth Richter, Acting Director, Center for Medicare Management, CMS
Deborah Taylor, Acting Deputy Director, Center for Medicare Management, CMS
Terrence Kay, Acting Director, Hospital and Ambulatory Policy Group, CMS
Donald Thompson, Acting Deputy Director, Hospital and Ambulatory Policy Group, CMS
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Louis Jacques, MD, Director, Division of Items & Devices, CMS
Maria Ciccanti, Coverage and Analysis Group, CMS
Karen Rinker, Coverage and Analysis Group, CMS

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41 MedPAC. "Report to the Congress: Medicare Payment Policy" (March 2007).

AMERICAN ACADEMY OF AUDIOLOGY

August 31, 2007

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

Subject: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Coding-additional codes from 5-year review

Dear Mr. Kuhn:

On behalf of the American Academy of Audiology, I appreciate the opportunity to provide comments regarding the proposed revisions to payment policies under the physician fee schedule and other part B payment policies for 2008. The American Academy of Audiology, with an active membership of more than 10,000 audiologists, is the world's largest professional organization of, by and for audiologists.

The Academy appreciates CMS' recognition that audiology services, which previously were included under the nonphysician work pool, are considered professional services and should be assigned work values. Because audiologists are health care professionals who enroll as providers independently under the Medicare program and directly bill Medicare for their services, clearly these services should have work values.

However, we are deeply concerned with the work values recommended by the American Medical Association Specialty Society RVS Update Committee (RUC) and proposed in the rule for CPT codes 92557 and 92579, which would significantly undervalue these services. CMS indicates in the proposed rule that changes to the work values and the practice expense values combined would result in a 17% decrease in payment for audiology services when fully implemented in 2010. When combined with the projected decreases that would occur due to the sustainable growth rate, audiologists would receive

a cut of approximately 37% in their reimbursement in 2010. Such a dramatic cut is disproportionate to reductions proposed for other specialties and creates an undue burden on audiologists.

The decrease in rates is compounded by the fact that as a specialty, the audiology services described above represent the majority of services billed. Unlike other specialties that bill a mix of services—including some services whose rates decrease and some whose rates increase—audiologists experience a disproportionately greater decrease in reimbursement as a specialty compared to others.

The Academy appreciates the importance of establishing codes that properly reflect the costs and resources associated with providing services and CMS's important role in this process. We believe it is especially important that CMS use its resources to ensure that the value inputs assigned to individual codes reflect the true resources and costs of furnishing the services. We strongly recommend the following:

1) **CMS should recognize that the work values for two audiology codes (CPT codes 92557 and 92579) recommended by the RUC in the 2008 final rule and times proposed significantly undervalue these services.**
2) **CMS and the RUC should revisit the work values for CPT codes 92557 and 92579 in order to determine appropriate values for these services. As CMS and the RUC reconsider values for these services, there should be an opportunity to obtain additional data and further input from all affected groups regarding the resources needed to furnish these services. As these values are revisited, the American Academy of Audiology, as well as other stakeholders, should be given a meaningful opportunity to participate in the process.**

I. CMS Payment Policies Should Permit Access to Audiology Services

Audiologists provide services to people who have hearing, balance, and related ear problems. They examine individuals of all ages and identify those with hearing loss and other auditory, balance, and related sensory and neural problems. Audiologists assess the nature and extent of the problems and help the individuals manage them. Audiologists utilize audiometers, computers, and other devices to diagnose hearing and balance dysfunction, and the impact of hearing loss on an individual's daily life. Audiologists share the results of their testing with physicians, who use this information to determine appropriate medical or surgical treatment of a hearing or balance deficit.

It is a well-known fact that hearing loss is strongly associated with aging and therefore audiology services are of critical importance to Medicare beneficiaries. Undiagnosed and untreated hearing loss will result in social isolation and depression, and may hasten dementia. In the near future, as the baby boomer generation approaches their sixties and will be prone to medical conditions that result in hearing problems, there will be an even

greater demand for the services of audiologists. The demand for these services is also increasing due to medical advances that are improving the survival rate of individuals who have had a stroke or other neurological disorder.

Audiologists are highly trained professionals, who have received a master's or doctoral degree from an accredited university graduate program. By combining a complete history with a variety of specialized auditory and vestibular assessments, audiologists determine appropriate patient treatment of hearing and balance problems. The services of an audiologist result in significant improvements in the quality of life for their patients. Thus, the Centers for Medicare and Medicaid Services must ensure that Medicare beneficiaries are able to access these important services.

II. The Values Proposed in This Rule Threaten Access to Audiology Services

On the individual CPT code level, the cuts are severe. For example, payment for CPT code 92557 (Comprehensive audiometry threshold evaluation and speech recognition) would drop from approximately $50.40 in 2007 to $35.96 in 2010 (a 29% reduction) if payment is calculated in 2010 using the 2007 conversion factor ($37.8975). These cuts will be far greater if the forecasted reductions in the conversion factor due to the flawed "sustainable growth rate" (SGR) formula become effective. For example, if the projected 9.9%, 5%, and 5% reductions to the conversion factor occur in 2008, 2009, and 2010, respectively, CPT code 92557 would be paid at approximately $29.26 compared to $50.40 in 2007. These cuts will occur while the practice costs faced by audiologists will continue to rise.

The work values proposed in this rule, combined with an anticipated cut in the SGR, and the fully implemented practice expense values, severely undervalue certain audiology services. According to estimates prepared by The Moran Company, audiologists will experience a decrease in reimbursement of 27% by 2010 -- jeopardizing access to these essential services for seniors. Table 1 below summarizes the percent change in reimbursement experienced by audiologists compared to other specialties; it holds 2006 volume constant across years and incorporates changes to work values over time, changes to practice expense values over time, and includes the proposed change in the conversion factor for 2008-2010.

Table 1. Percent Change in Reimbursement from 2006 for Audiology and Selected Specialties

Specialty	% Δ (2006 to 2007)	% Δ (2006 to 2008)	% Δ (2006 to 2009)	% Δ (2006 to 2010)
Audiologist	-1%	-7%	-17%	-27%
Optometry	-4%	-13%	-15%	-17%
Dieticians	42%	12%	-2%	-16%
Otolaryngology	-1%	-10%	-11%	-11%
Internal Medicine	4%	-6%	-6%	-5%

Source: The Moran Company
Uses 2006 "Utilization File", 2006 RVU file, 2007 RVU file, and 2008 Proposed Rule Appendix B

The Academy is alarmed by these cuts. The resources necessary to provide the services will be greater than the payment amount. These cuts will undermine the goal of Congress and CMS to create a Medicare payment system that preserves patient access and achieves greater quality care. If audiologists experience significant cuts in payment at a time of rising practice costs, access to care for the elderly and disabled will be jeopardized.

III. CMS and the RUC should reconsider the work values for CPT codes 92557 and 92579

The Academy strongly disagrees with the RUC determination regarding values for CPT codes 92557 and 92579, which would significantly undervalue these services. CMS and the RUC should revisit the work values for CPT codes 92557 and 92579. To determine appropriate values it is necessary to obtain further information regarding the resources and time necessary to provide these services.

There are several factors that show the values assigned by the RUC would undervalue these services. First, recent surveys conducted jointly by the Academy and the American Speech-Language-Hearing Association (ASHA) showed significantly higher values for these audiology services than the values recommended by the RUC. Specifically, in 2007, the Academy and ASHA conducted surveys to determine appropriate work values for the audiology CPT codes in order to transition these services from practice expense values to work values. These surveys yielded a high number of responses for CPT codes (i.e., 92557, 92567, 92568) billed frequently by audiologists. For example, there were 147 respondents to the survey of CPT code 92557 (comprehensive audiometry threshold evaluation and speech recognition), resulting in an Academy/ASHA recommended work value of 1.40.

Table 2 below shows the number of responses to the surveys and the recommended work RVUs that were based on these surveys. We believe that these services accurately reflect current clinical practice. These values are compared in the Table to the work values recommended by the RUC. The large discrepancy in these values indicates these codes were undervalued.

Table 2: Academy/ASHA recommended work values compared to RUC recommended work values

HCPCS Code	Descriptor	Academy/ASHA recommended work RVU based on survey data	RUC recommended work RVU	Academy/ ASHA survey respondents
92557	Comprehensive audiometry threshold evaluation and speech recognition	1.40	.60	147
92579	Visual reinforcement audiometry (VRA)	1.70	.70	91

The Academy/ASHA surveys conducted in 2007 showed times for furnishing these services that were significantly higher than the times recommended by the RUC. Table 3 below includes the results of the survey conducted in 2007 by the Academy and ASHA in comparison to the RUC recommended time. Clearly, there is a large difference between these recommendations, pointing to the fact that the work values proposed in this rule for these codes do not accurately reflect the audiologist time and therefore undervalue these services

Table 3: Comparison of Assigned Time

HCPCS Code	Descriptor	Academy/ASHA 2007 survey time (pre, intra, and post)	RUC recommended time (total)
92557	Comprehensive audiometry threshold evaluation and speech recognition	55 minutes	28 minutes
92579	Visual reinforcement audiometry (VRA)	55 minutes	34 minutes

As CMS is aware, the existing times adopted by the PEAC, RUC, and CMS in 2002 and 2004 would be removed from the clinical labor time used in valuing the practice expense component of these services and replaced with the new work values. Because this time will be removed from the practice expense component, it is critical that the correct amount of audiologist time be used to determine values for these services.

A comparison of the work values recommended for these audiology CPT codes with work values assigned to CPT codes for other services that could be considered comparable supports our contention that these CPT codes were undervalued. There are a number of instances when CMS and the RUC have relied on the Intra Work Per Unit of Time (IWPUT) in making determinations of whether a code is undervalued. In addition, the RUC has also used the IWPUT for comparable services to derive work values for codes that do not have values assigned to them. Although no particular service is entirely the same as audiology services, the Bureau of Labor Statistics has identified occupational therapy, physical therapy, optometry, and psychology as related occupations.

The Academy determined the IWPUT for certain services furnished by physical therapists, occupational therapists and psychologists, and physicians. Using the time survey data from the Academy/ASHA survey conducted in 2007, the Academy derived work values for these services. For instance, a physical therapy evaluation (CPT code 97001) has an IWPUT of .031. For CPT code 92557, the Academy/ASHA survey resulted in median times of 5 pre-service minutes, 35 intra-service minutes, and 15 post-service minutes. Applying the IWPUT to these survey times would result in a work value of 1.533 for CPT code 92557. This work value is significantly higher than the RUC recommended value of .60 and is close to the work value of 1.40 recommended based on the Academy/ASHA survey.

In another example, the code for psychological testing, interpretation and reporting, per hour by a psychologist (CPT code 96101) has an IWPUT of .028. As referenced above, for CPT code 92557, the Academy/ASHA survey resulted in median times of 5 pre-service minutes, 35 intra-service minutes, and 15 post-service minutes. Using the IWPUT of .028, the work value for CPT code 92557 would be 1.428, which is close to the work values recommended from the Academy/ASHA survey. By comparing these values to other comparable services, it is clear that these services would be undervalued.

IV. Assigning Work Values for Audiology Services Presents Unique Challenges

Over the years, the RUC has developed sophisticated rules and processes for recommending relative values. Because audiology services were previously included as part of the practice expense values, developing work values for audiology services presented unique challenges. One major challenge to developing work RVUs is that there is no well-established set of reference codes. Without a reference code that the

audiologists are familiar with performing, it is difficult for the audiologists to evaluate and value their services relative to others.

Another challenge is that there are different views among specialties regarding the pre-service, post-service and intra-service work involved in providing this service. When treating a patient, an independent audiologist assumes a comprehensive and global role, including history-taking, administering the procedures, interpreting the findings, counseling the patient, and coordinating care. An independent audiologist typically schedules approximately one hour for each patient who is scheduled to receive a comprehensive hearing test (CPT code 92557). Some physician specialties are of the opinion that the audiologist only administers the procedure with limited patient interaction because the physician in the practice manages the patient encounter. These differences of opinion are indicated by the descriptions of pre-service, intra-service and post-service work that were included in surveys conducted by the Academy/ASHA as compared to surveys conducted by a physician specialty during the RUC process.

Table 4 (below) shows a comparison of the descriptions of work included in two different surveys of CPT code 92557. It clearly shows that there is a difference of opinion and confusion over the work involved in providing this service. As a result, the amount of time and values recommended for services, such as 92557, were significantly different. When the results of these surveys were combined, the result was a work value for CPT code 92557 that is too low.

Table 4: Comparison of Description of Work included in surveys for CPT code 92557

CPT Descriptor: Comprehensive audiometry threshold evaluation and speech recognition (92557)

Clinical Vignette: A 49-year old female was referred for an audiologic evaluation with chief complaint of progressive tinnitus in her right ear. No episodes of vertigo or imbalance were reported.

Survey	ASHA/AAA Survey	Physician specialty survey
Description of Pre-Service Work	Review any prior records and referral documentation. Prepare the room for the patient. Enter demographics in computer.	The test is explained to the patient. The patient is then seated in a booth, headphones placed, computer set up and patient information entered.
Description of Intra-Service Work	The audiologist greets the patient and accompanies her to the audiometric test area. The audiologist confirms elements of the referring history and makes further inquiries regarding other medications and aspirin	The patient is presented sounds (different frequencies and sound levels). The patient indicates whether heard or not by pressing/not pressing a button. This is done with air/bone and

	ingestion earlier that same day. An otoscopic examination is performed and the patient is then seated in the audiometric test booth. The audiologist instructs the patient regarding what to listen for in establishing pure tone thresholds for air conduction stimulation. Earphones are then placed over her ears and appropriate comfort is ensured. The audiologist then moves to the control side of the audiometric test booth and presents an initial series of pulsed 1000 Hz tones at a level that is clearly audible to the patient. Based on the patient's responses, the audiologist decreases the intensity of each pulsed tone series by 10 dB until the patient no longer responds. He then increases the intensity in 5 dB steps until the patient indicates that the tones are once again audible. This minimum level is verified to ensure accuracy through a repeated presentation. Threshold is defined as the lowest intensity at which the patient consistently responds to a pulsed tone stimulus. This procedure is repeated for the frequencies 250 Hz, 500 Hz, 2000 Hz, 4000 Hz, and 8000 Hz for each ear. After the air conduction thresholds are completed, the audiologist enters into the patient side of the audiometric booth, removes the earphones, and places a bone conduction oscillator on the patient's right mastoid, securing the appropriate position with a head band. The patient is then instructed to listen for another series of pulsed tones and to respond in the same manner as before. She is also	masking if needed. Patient is then given words to repeat to test their discrimination.

	instructed that if she should hear a "noise" (e.g., 1/3 octave band masking noise) in the opposite ear, she should ignore the noise and respond only to the pulsed tones. An earphone is then placed over the ear contralateral to the bone conduction oscillator and secured in place with the earphone headband. The audiologist then proceeds to the control side of the audiometric test booth and begins the bone conduction threshold measurements by presenting a pulsed tone that is clearly audible to the patient. Thresholds are determined in the same manner as described above for the frequencies 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz. If a difference between the bone conduction threshold and the air conduction threshold exceeds 10 dB, masking noise is introduced into the earphone to remove the contralateral ear from possible participation in the test. The bone conduction threshold is then verified by increasing the masking noise levels and checking for shifts in the bone conduction threshold. After the bone conduction testing is completed, a speech reception threshold is then established by presenting bisyllabic words through the earphones and having the patient repeat them. Again, the audiologist begins the test by presenting the words at a level that is clearly audible. Upon a correct response from the patient, the audiologist decreases the intensity in 10 dB steps until the patient's responses are no longer accurate. At that intensity, the audiologist begins	

	to increase the intensity in 5 dB steps until the patient once again achieves accuracy. Speech reception threshold is defined as at least 50% accuracy in repeating the bisyllabic words at the lowest possible intensity. After the speech reception threshold has been established, the audiologist presents monosyllabic words to evaluate speech recognition. The patient is instructed for this new task, the audiologist then presents a recorded word list at a level approximately 40 dB louder than the speech reception threshold. The audiologist records errors and establishes a percent correct score for each ear.	
Description of Post-Service Work	The audiologist reviews, synthesizes and interprets the results of the functional diagnostic tests and discusses the results of the test outcomes with the patient. The audiologist summarizes the results and answers questions from the patient/family. A report is then written for the referring professional.	The results are recorded or saved in computer and/or printed out.
Median Pre-Service Time	5 minutes	1 minute
Median Intra-Service Time	35 minutes	15 minutes
Median Post-Service Time	15 minutes	3 minutes
Total Time	55 minutes	19 minutes
Surveys completed	147	21

The Academy along with ASHA had an informal discussion with the RUC about our concerns and was advised that we could request a review of the values assigned to CPT codes 92557 and 92579. We intend to request this review and plan to resurvey these two codes with our colleagues at ASHA assuming we are given that opportunity by the RUC.

We hope to work with the RUC and CMS in the future to address this unique situation and determine a methodology that will appropriately value these services.

Conclusion

We appreciate the opportunity to submit comments and look forward to working with CMS to address our concerns. The Academy understands the important role of the RUC in assisting CMS with the valuation of codes; however, there are times when it is appropriate for the Agency to address issues that may have been overlooked in the RUC process. If you have further questions, please contact Phil Bongiorno at (703-226-1032), email pbongiorno@audiology.org.

Sincerely,

Alison M. Grimes, AuD
President

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August 31, 2007

VIA HAND DELIVERY AND ELECTRONIC MAIL
www.cms.hhs.gov/regulations/eRulemaking

Mr. Herb Kuhn
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Centers for Medicare and Medicaid Services
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RE: [CMS-1385-P] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Dear Acting Deputy Administrator Kuhn:

The Medical Imaging and Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is pleased to submit comments regarding the proposed rule entitled "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008."[1] MITA is the leading trade association representing companies whose sales comprise over ninety percent of the global market for medical imaging. We are pleased to provide the Centers for Medicare and Medicaid Services (CMS) our perspective on ways to enhance the physician payment system to ensure continued access to the transformative medical imaging technologies that are improving diagnostic and therapeutic interventions for Medicare beneficiaries.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, and nuclear medical imaging, including positron emission tomography (PET) and magnetic resonance imaging (MRI). Imaging is used both to diagnose and treat patients with disease and offers physicians the ability to view soft tissue and organs, often reducing the need for costly and invasive medical and surgical procedures.[2] In addition, imaging equipment is used in some procedures to guide physicians as they carry out a medical or surgical intervention, such as device placement, to ensure high-quality clinical results for the patient.[3]

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

[2] Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., New England Journal of Medicine, Vol 352, No 17; pp1760-1768, April 28, 2005.

[3] Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731 - 737.

MITA appreciates the opportunity to detail our concerns with the proposed rule and looks forward to continuing to work with CMS in the upcoming year. We ask CMS to consider the following comments regarding:

- Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
  - Imaging Equipment Usage
  - Imaging Equipment Interest Rate
- RUC Recommendations for Direct PE Inputs and Other PE Input Issues For Specific Procedures
- Additional Codes for the 5-Year Review of Work RVUs
- Physician Quality Reporting Initiative
- Physician Self-Referral
  - Unit of Service Payments in Space and Equipment Leases

I. Resource Based PE RVUs

A. Equipment Usage

Currently, CMS utilizes a 50 percent utilization rate for all equipment. In the proposed rule, no proposals are made to revise the formula. As was cited in the CY 2007 Physician Fee Schedule Final Rule and the CY 2008 proposed rule, CMS determined that there were not sufficient empirical data to justify raising the equipment utilization rate.[4] We understand that a major oncology provider with over 80 sites of service in the United States recently conducted a utilization rate survey for PET and CT scanners in accordance with the CMS PE RVU calculations, and determined that its utilization rate for PET and CT was approximately 25 percent on average. The International Society for Clinical Densitometry also conducted a similar survey of utilization rate for DXA (dual energy x-ray absorptiometry) and VFA (vertebral fracture assessment) and found the utilization rate is 15 to 20 percent. As a result, MITA strongly agrees with CMS's decision to maintain the equipment utilization rate at 50 percent unless or until such time that CMS has conclusive data to substantiate an alternative rate.

In the June 2006 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) surveyed providers in six markets (Boston; Miami; Greenville, South Carolina; Minneapolis; Phoenix; and Orange County, California) that performed MRI and CT services on Medicare beneficiaries to examine whether certain imaging equipment is used more than 50 percent of the time.[5] MedPAC's survey indicated that providers in those six markets used MRI and CT machines significantly more than 50 percent of the time they were open for business.

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[4] 71 Fed. Reg. 69624 (December 1, 2006) and 71 Fed. Reg. 38122 (July 12, 2007).

[5] Report to Congress: Keeping physicians' practice expense payment rates up to date, Medicare Payment Advisory Commission, June 2006, page 92.

The trade association, AdvaMed, commissioned United Biosource Corporation (UBC) to analyze and provide a report evaluating the survey done by MedPAC.[6] UBC determined that, "...the methods and sampling frame used [by MedPAC] were insufficient to reach a level of validity needed to use the results as evidence for policy and/or reimbursement decision-making on a national level." Also, surveys that focus solely on MRI and CT services do not capture the full range of imaging utilization rates for all imaging modalities.[7]

As outlined above, many sources were used to attempt to assess accurate equipment utilization rates. Neither CMS nor UBC were able to establish an appropriate methodology to determine equipment utilization rates across all imaging modalities and relevant settings. The array of modalities, the array of potential uses to which they can be applied clinically, and the array of sites in which they are employed create a highly complex set of usage algorithms. Therefore, MITA agrees with CMS that the empirical data are insufficient to validate an alternative methodology to determine equipment utilization rates for all imaging modalities. We stress to CMS that it is important to move cautiously in this area, and if an alternative methodology is considered, that the Agency allow the public the opportunity to comment on any proposed changes to the formula in a future notice of public rulemaking prior to implementation.

B. Equipment Interest Rate

In the proposed rule, CMS makes reference to the possibility of revising the equipment interest rate used in determining payment rates for physicians. After reviewing the Small Business Administration (SBA) data on loans and applicable interest rates, CMS found that interest rates were comparable to the current equipment interest rate utilized in the payment rate-setting methodology.

MITA agrees with CMS's decision to not propose an alternative equipment interest rate and maintain the equipment interest rate at 11 percent.

II. Resource-based Practice Expense (PE) Relative Value Units (RVUs)

By submitting supplemental survey data to CMS, specialty societies play an important role in determining appropriate scaling factors used to calculate physicians' practice expenses. The primary purpose of these surveys is to ensure that Medicare payment for the indirect practice expenses of various specialties accurately reflect the indirect practice expenses of the various specialties.

In the proposed rule, CMS proposes to revise the practice expense per hour (PE/HR) values associated with radiology, based on an analysis presented by the ACR and reviewed by The Lewin Group which determined that weighting the ACR survey data by practice size more appropriately accounted for the small high cost entities in the final PE/HR. MITA believes that CMS has taken the right approach by modifying the weighting

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[6] This report may be found on the AdvaMed web site: http://www.advamed.org/NR/rdonlyres/A91FD8B6-8A45-4B17-8633-FC3935035593/0/medpacsurvey062007.pdf. (accessed on August 6, 2007).

[7] Id.

methodology used to integrate the ACR data into the fee schedule methodology, and we appreciate CMS's willingness to work with these societies to ensure accurate payment for radiology services.

MITA supports the use of the adjusted ACR supplemental survey data for radiology practice expense values.

III. RUC Recommendations for Direct Practice Expense (PE) Inputs and Other PE Input Issues For Specific Procedures

At the February and April 2007 meetings, the American Medical Association's Practice Expense Review Committee (PERC) reviewed numerous CPT® codes to assist in recommending direct practice expense inputs for new and existing CPT® codes. These recommendations were reviewed by CMS.

MITA cautions CMS in adopting some of the recommendations suggested by the PERC. For example, we disagree with the PERC's recommendation for revisions to CPT® codes, 77080-77082, for dual energy x-ray absorptiometry (DXA), the clinical gold standard for detecting osteoporosis. A high level of skill and physician's time is needed to accurately interpret DXA scans; this is critical for accurate diagnosis and determining subsequent therapy for the patient.

Reimbursement for DXA is projected to drop to approximately $36 a scan by January 1, 2010, a decline of 71 percent compared to 2006 levels.[8] Screening for bone density, such as DXA, is already underutilized. Most bone diseases disproportionately affect the elderly, many of whom already experience substantial problems with frailty, reduced functional capacity, and even life-threatening fractures that can lead to hospitalization and long-term care expenses. In fact, there have been a number of Federal initiatives that have attempted to target and increase the number of Medicare beneficiaries who are screened for osteoporosis, such as the United States Preventive Services Task Force, the National Osteoporosis Foundation, and the Surgeon General's Report on Bone Health and Osteoporosis. The universal promotion of screening with DXA is clearly at odds with both the changes to the Physician Fee Schedule and the objectives of the Deficit Reduction Act of 2005 (DRA), which takes aim at reducing the volume of all imaging services, except mammography.

Because most screenings are done in the physician's office, MITA is concerned that an additional reduction to direct practice expense (PE) inputs, by the PERC, may force physicians to no longer provide bone mass measurement screenings to Medicare beneficiaries, leading to higher fracture rates, more expensive hospitalizations and greater economic impact on the Medicare program. It is imperative that CMS properly value the current DXA technology utilized in physicians' offices and properly reflect those costs in the reimbursement rate.

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[8] According to the International Society for Clinical Densitometry: http://www.iscd.org/Visitors/positions/publicpolicy.cfm (accessed August 28, 2007).

We believe it is in the public's and the Medicare program's best interest to ensure that access to and promotion of screening services for bone mass measurement remain available and affordable. We ask that CMS reconsider its decision to implement the PERC's recommendation regarding bone mass density testing using DXA.

IV. Additional Codes for the 5-Year Review of Work RVUs

MITA is extremely concerned with CMS's proposal to package the Medicare payment for color flow Doppler, CPT® code 93325, into all echocardiography procedures. As noted in the proposed rule, CMS justifies this action by stating that color flow Doppler has become "intrinsic to the performance of other echocardiography services."

CMS's justification for eliminating additional payment for color flow Doppler is unsound. Although color flow Doppler may be done concurrently with other echocardiographic tests, it is not intrinsic to the performance of all echocardiography procedures. The performance and interpretation of color flow Doppler increases the sonographer time and equipment time that are required for a study, thereby adding additional resources to the procedure.

Currently, the CPT® coding system includes different descriptors for different types of ultrasound services, based on how and why ultrasound is performed by various clinical specialties. For example, color flow Doppler is treated as an "add-on" code in cardiac ultrasound, but not vascular ultrasound. After our review of the Medicare claims data, provided by a highly competent and reliable researcher through medical societies to CMS, MITA believes that it would be inappropriate to bundle color Doppler into all "base" echocardiography codes. Based on this review of Medicare claims data, it appears that color flow Doppler is not truly "intrinsic" to all echocardiography procedures. That review found that color flow Doppler is actually used less than 50 percent of the time concurrent with other echocardiographic procedures. This is not a sufficient linkage to determine that color flow Doppler is "intrinsic" to echocardiography services. In addition, CMS has not articulated a proposed definition or standard, or a clear threshold in regards to what would constitute appropriate bundling of this procedure.

It is our understanding that a proposal to potentially bundle adult transthoracic echocardiograms, color flow Doppler, and spectral Doppler into one CPT® code has been approved by the American Medical Association's (AMA) Editorial Panel. Thoughtful, selective and clinically appropriate bundling of services, as this may be, is a more supportable pathway over time. MITA supports the medical societies' rationale for not bundling color Doppler across the board on all base echocardiography codes, and we urge CMS to reconsider the proposed packaging of color flow Doppler scans into all echocardiography services.

V. TRHCA -- SECTION 101(b): Physician Quality Reporting Initiative (PQRI)

The Tax Relief and Health Care Act of 2006 - Medicare Improvements and Extension Act of 2006 (Pub. L. 109-432, also known as TRHCA or MIEA-TRHCA) requires that "as part of the publication of proposed and final quality measures for 2008 PQRI the Secretary

shall address a mechanism whereby an eligible professional may provide data on quality measures through an appropriate medical registry."

MITA believes that use of registries for 2008 and beyond is of critical importance to the PQRI, as well as to physicians and other health care professionals. The use of clinical data residing in a registry or an electronic health record (EHR), without the need for special claims-based codes for performance measure numerators, will enhance clinical and billing workflow and increase the accuracy of the reported measures. MITA encourages an approach to data gathering and reporting through registries that does not impose burdens on physicians and other health care professionals who would be utilizing specific registry options to fully satisfy their PQRI obligations.

Furthermore, MITA asks that CMS issue the invitation to self-nominate in the testing of the registry-based quality data submission mechanism as soon as possible so that registries have a full opportunity to evaluate and prepare their responses, and to determine and implement any technical changes needed to meet CMS requirements under the PQRI program.

Looking to the future of the PQRI program, MITA urges CMS to propose measures with ample advance notice to give physicians and vendors sufficient time to plan for use of these measures, and to ensure that the necessary data collection, measure computation, and quality programs are in place.

Lastly, MITA asks that as CMS moves forward with the initial expansion of these quality measures, as well as future measures, that CMS be cognizant of the need for appropriate recognition of imaging technology within these measures. MITA is pleased that CMS has considered and incorporated imaging services within relevant quality measures. However, in doing so, we caution CMS to provide for ongoing innovation of imaging technology, and medical practice when adopting measures for various diseases and conditions. As technology advances and techniques for utilizing equipment improve, it is imperative that physicians be able to deploy the most advanced and medically appropriate imaging technology to diagnose and treat patients. Quality measures should focus on the range of modalities available in the context of the measure, while providing latitude to address emerging imaging advances. Imaging technologies are undergoing rapid specification advances that physicians should be able to incorporate based on their medical decision-making.

MITA looks forward to working with CMS and others as measures that involve imaging procedures are developed, adopted, or modified under the PQRI program.

VI. Physician Self-Referral Provisions

In the proposed rule, CMS outlines several issue areas and a subset of actual proposals to regulatory policy broadly governed by the Omnibus Budget Reconciliation Act of 1993 (commonly referred to as the Stark Law)[9] that relate to physician self-referral rules. CMS

[9] SSA §1877 codified at 42 U.S.C. §1395nn.

has proposed regulatory policies in several areas and invited comment on other related areas, without specific proposals on the latter. In general, MITA believes that it is highly inadvisable for CMS to propose significant new interpretations and policies regarding current physician leasing, and referral arrangements in the context of the Medicare physician fee schedule. Rather, MITA strongly urges CMS to develop any specific proposals governing permissible arrangements within the context of separate proposed rules promulgated to update the Stark Law requirements. That appears to be the more appropriate arena in which to propose changes in the policies that govern permissible arrangements, which in turn set the foundation upon which to propose modified reimbursement rules.

MITA notes that many of the proposals under discussion in this notice penetrate deeply into how physicians, and for that matter, hospitals, structure their working relationships. In fact, in one area under the "in-office ancillary services" discussion, CMS seems to be entering into an especially troubling area, which is to suggest setting policy regarding which types of physicians are qualified to perform which services. This is an area fraught with issues and which is impacted upon by state licensure and scope of practice laws, and individual physician training and acquired practice skills. We think it is not necessary for CMS to wade into those issues to advance its program objectives. Separately, it is not clear that CMS has adequately investigated the common leasing and interactive service contractual relationships in the market, which can be practical and cost-efficient, in compliance with Stark Law requirements, and not necessarily abusive or leading to excessive utilization of services. Therefore, we believe that it would be prudent to proceed cautiously and within the right legal framework for defining what is permissible and what is not, and then to determine how best to structure any Medicare reimbursement changes.

It appears that CMS's underlying real concern is that many of the arrangements may be leading to inappropriate utilization of imaging services. In the CY 2007 Physician Fee Schedule Proposed Rule, CMS states that, "We [CMS] are concerned that allowing physician group practices or other suppliers to purchase...diagnostic testing services...may lead to patient and program abuse in the form of over-utilization of services and result in higher costs to the Medicare program."[10] Although CMS expressed concern regarding the possible existence of arrangements that were not intended under the physician self-referral rules, it is important to note that **self-referral is not a widespread practice in Medicare**, and accounts for only a modest percentage of all referrals for imaging services.[11]

MITA commissioned a study utilizing CY 2005 Medicare claims data to examine self-referral rates. Based entirely on Medicare claims data, we found that the majority of referrals for imaging services are made by physicians who do not stand to realize any financial gain from making the referral.[12] These are physicians (usually family practitioners

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[10] 71 Fed. Reg. 49054 (August 22, 2006).

[11] According to an analysis by Direct Research, LLC of 2005 Medicare claims data. The full analysis is attached for CMS's review.

[12] Id.

or doctors of internal medicine) who order the tests, but are in no way connected to the physicians who then perform the test. For example, referrals for CT, MRI, PET and SPECT services are made on average 94-percent of the time to physicians who do not order the tests. *The data show, in each imaging modality, that the physicians who most often perform the tests are radiologists, who typically are not in a position to refer or self-refer the imaging studies.* This clear separation between the ordering and performing physicians is illustrated, in our analysis, for each major imaging modality.

According to the MITA-commissioned analysis of the 2005 claims data, most imaging for Medicare patients is done in hospitals, primarily in hospital outpatient departments. For instance, 81.3 percent of CT imaging is done in hospitals (including outpatient facilities) whereas 16 percent is in physician offices. Most MRIs are also performed in hospitals; only 34 percent are done in physician offices. We have attached our detailed analysis for CMS's review.

With respect to selected other issues raised by CMS, MITA understands CMS's intentions of preventing inappropriate referrals within the Medicare system, but feels the definition of a "centralized building" needs to be outlined in a more concise manner to ensure that appropriate, cost-effective, mobile radiology services and teleradiology services are not disrupted. It is our view that if CMS has identified one or two clearly questionable situations, the Agency should act on those specific matters rather than propose broader-scope rules that may inadvertently disrupt legitimate service arrangements in imaging.

A. Unit of Service Payments in Space and Equipment Leases

In the proposed rule, CMS proposes to prohibit "time-based or unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity."[13] Specifically, section 1877(e)(1) of the Social Security Act provides an exception to the prohibition of physician referrals for space and equipment leases, but CMS has expressed their concern with these types of lease arrangements, and notes that the Agency believes that "such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee..."[14] MITA recognizes CMS's concern, but it is our opinion that such arrangements may be clearly permissible under current statute and regulations, therefore, we believe CMS should conduct a further analysis prior to moving forward with any specific changes.

Although the proposed restrictions discussed above would not apply where the entity is the lessor, CMS also seeks comments regarding whether the Agency should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee. Based on Congress' intentions, as long as the lease arrangement meets the requirements, and the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner, it should continue

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[13] Id.

[14] 72 Fed. Reg. 38122 (July 12, 2007).

to be allowed.[15] For many solo practitioners, it may be difficult to justify purchasing expensive equipment for their office that may be used only on a part-time basis. Arrangements between physicians and facilities, such as the ones discussed above, also allow physicians to better extend their services to Medicare beneficiaries in rural areas, without adding significant cost to their individual practices. This ensures beneficiaries have access to state-of-the-art imaging equipment, yet the services remain cost-effective for all parties. MITA urges CMS to not prohibit these types of time-based or unit-of-service-based lease arrangements.

VII. Other Issues

Although not formally discussed in the proposed rule, MITA continues to believe that application of the multiple procedure discount policy in the Physician Fee Schedule is redundant and excessive in light of the Deficit Reduction Act of 2005 (DRA) cap. Enacted January 1, 2007, the DRA provision caps the technical component reimbursement for non-hospital outpatient imaging to the lesser of the Hospital Outpatient Prospective Payment System (HOPPS) payment amount or the Medicare physician fee schedule payment amount. Imaging services affected by this provision include CT, MRI and ultrasound procedures.

MITA urges CMS to remove the multiple procedure discount policy from the Physician Fee Schedule for those services held to the "lesser of" rule. The HOPPS rates serve as the basis for the cap, and these rates already factor in the effects and economies of performing multiple imaging procedures during the same session. To apply the multiple procedure discount policy in the Physician Fee Schedule, and then to apply the DRA cap, is essentially "over-adjusting" payment levels to account for economies in multiple procedure imaging.

MITA also asks CMS for clarification regarding the extent to which the DRA cap will be imposed on procedures that are either (a) bundled into other principal procedures under the HOPPS system (e.g. ultrasound guidance procedures); or (b) only one component of a broader package that includes other items and services (e.g. myocardial perfusion (SPECT) procedures whose Ambulatory Payment Classification (APC) rates also include add-on services and radiopharmaceuticals. In the absence of guidance from CMS, we presume that the DRA "cap" will not apply to services, like ultrasound-guidance services and dependent ancillary services (i.e. "add-on" codes) that are not separately payable under HOPPS.

VIII. Conclusion

In closing, we ask CMS to develop policy decisions that accurately recognize that the majority of the growth in imaging services emerges from the genuine medical benefit and clinical support that physicians recognize that they receive from employing imaging technologies in diagnosing and treating injury and disease. Many applications in use today did not exist a mere decade ago. MITA believes that these transformative imaging

[15] 42 U.S.C. §1395nn.

technologies are major contributors to improvements in patient care, and over time are generating off-setting savings through less-invasive care, and quicker recovery and fewer cornplications for patients. These crucial benefits are often overlooked in assessments of growth in imaging spending. A better approach to managing this growing utilization is to rely upon sound evidence of clinical benefit and practice guidelines developed by physicians so that clinically optimal medical protocols are irı place.

Imaging advocacy groups, such as MITA, also feel it is necessary to implement guidelines to promote proper equipment maintenance and utilization. MITA looks forward to sharing its ideas with CMS in the upcoming months. Finally, we urge CMS to look to the future, as developments in molecular, cellular, functional and genetic imaging promise a new era of prediction and prevention of disease, not just diagnosis and treatment.[16]

We strive to continue working with CMS on these matters under the Medicare Physician Fee Schedule. If you have any questions or would like to discuss these matters further, please contact me at 703-841-3279.

Respectfully Submitted,

Andrew Whitman
Vice President

[16] "Advances in Biomedical Imaging," Tempany MC, McNeil BJ, *Journal of the American Medical Association,* 2001, Vol. 285: 562-567.

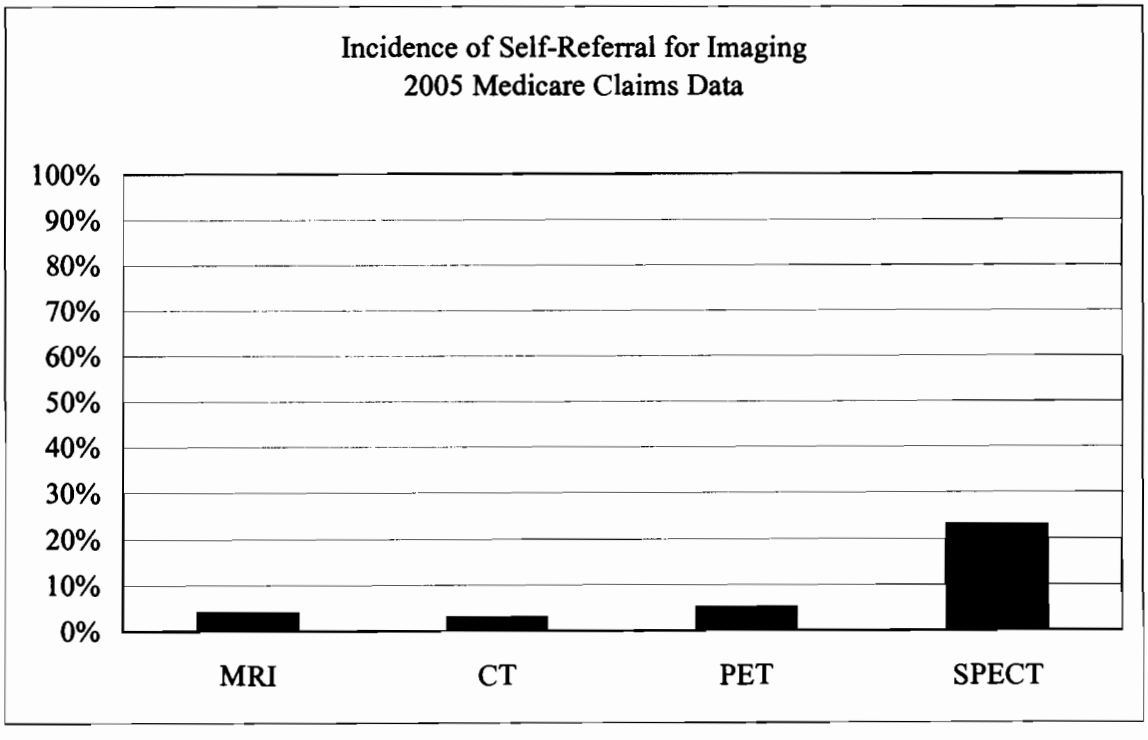
MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA
www.medicalimaging.org

Medicare Data Analysis
Self Referral Rates in Medical Imaging are Low

The term "self referral" is used to describe the practice whereby a physician performs a medical service that he or she has ordered. Although CMS recognized the validity of this practice when done as a part of the rest of the care that a physician provides to a patient in his or her office, discussions of whether the opportunity to self-refer leads to the provision of unnecessary imaging services continue.

According to an analysis by Direct Research, LLC of 2005 Medicare claims data; self-referral is not a widespread practice in Medicare, and accounts for only a modest percentage of all referrals for imaging services.

- The 2005 Medicare data suggest several conclusions about how imaging is used and by which physicians.
  - Referrals for CT, MRI, PET and SPECT are made on average 94% of the time to physicians who do not order the tests.
  - Most physicians who refer patients for imaging scans do not experience economic gain from the referral.
  - Self-referral is not a dominant trend in Medicare for medical imaging; in fact, it occurs in only a small percentage of cases.
- In 2005, the proportion of imaging studies in which the referring physician and the providing physician were one-in-the-same, i.e., in which physicians were self-referring, was 3.9% for MRI services, 2.8% for CT services, 5% for PET services, and 22.8% for SPECT services. On a weighted average basis, fully 94% of imaging studies cannot be described as self-referral.



- The majority of referrals for imaging services are made by physicians who do not stand to realize any financial gain from making the referral, according to the 2005 Medicare data. These are physicians (usually family practitioners or doctors of internal medicine) who order the tests, but are in no way connected to the physicians who then perform the test. The data show in each imaging modality, that the physicians who most often perform the tests are radiologists, who typically are not in a position to refer or self-refer the imaging studies. This clear separation between the ordering and performing physicians is illustrated by the 2005 Medicare data for each major imaging modality.

- Imaging is used for diagnosing, monitoring and guiding treating of common medical conditions, such as stomach pain, back problems, cancer, and heart disease.
  - Top CT procedures by volume are for diagnosing abdominal pain (12%) and lower respiratory diseases (8.2%).
  - Top MRI procedures are for back (27%) and joint disorders (7.3%).
  - Top PET procedures are for cancer (lung 22.2%; non-Hodgkin's lymphoma 13.3%)
  - Top SPECT procedures are for heart disease (38.8%) and chest pain (32%).

- Most imaging for Medicare patients is done in hospitals, primarily in hospital outpatient departments, according to the analysis of 2005 Medicare data.
  - 81.3% of CT imaging is done in hospitals (48.5% of that in the outpatient setting); 16% is in physician offices.
  - 52.6% of MRIs are done in hospitals (34.4% in the outpatient setting); 34.1 percent of MRIs are done in physician offices.
  - 39.2% of PET scans are done in physician offices, while 38.9% are done in hospitals (34.2% of that is in the outpatient setting); 20.7% is done in independent diagnostic testing facilities.
  - 64.5% of SPECT scans are done in physician offices, while 34.3% are done in hospitals (20.3% of that in the outpatient setting).

Memorandum

To: Andrew Whitman, Vice President
Medical Imaging & Technology Alliance (MITA)
From: Christopher Hogan, Direct Research, LLC
Subject: Advanced Imaging Self-Referral Analysis

This report briefly summarizes Medicare carrier-paid claims for MRI, CT, and PET/SPECT services in the US, for 2005 to determine the incidence of self-referral of imaging services as reported in the Medicare carrier-paid claims data.

1. Methodology

- Start from the Medicare 2005 5 percent sample standard analytic file, limited dataset version, carrier claims file.
- Summarize entire file by encrypted Unique Provider Identification Number (UPIN) and specialty to provider a roster of encrypted UPINs.
- Extract MRI and CT services, defined as claims lines with Berenson-Eggers Type of Service (BETOS) codes I1A, I2B (CT) or I2C, I2D (MRI). For PET/SPECT, the codes were extracted by CPT code, as they may be located in any of several BETOS categories.
- Match the UPIN registry to the claim line, by referring UPIN, to identify the specialty of the referring physician.
- Compare the beneficiary state of residence to the provider's state, to flag patients who crossed state borders for care.
- Match to patient counts from the 5 percent LDS denominator file to determine per-capita use rates. (Include only fee-for-service beneficiaries with Part B coverage.)
- Summarize line diagnosis by the Agency for Healthcare Research and Policy (AHRQ) Clinical Classification System (CCS) disease categories to show what the MRIs were used for.
- Define place of service as hospital inpatient, hospital OPD or ER, IDTF (independent diagnostic testing facility), physician office, and other.
- Exclude technical component only claims when counting services per capita.
- Summarize referring and performing specialty, diagnosis, and other aspects of care.

2. Results

This section presents the results of the analysis, with tables of data and conclusions. Results are presented in five tables.

Table 1 shows the most common specialties performing each type of advanced imaging service profiled here. The four advanced imaging services differ markedly in terms of performance by radiologists and freestanding radiology facilities. For MRI and CT, roughly 90 percent of services are performed by radiologists. For PET, if nuclear medicine specialists are included, about 80 percent of services are performed by radiologists. For SPECT, by contrast, cardiologists perform two-thirds of the services.

Table 1: Medicare Advanced Imaging Claims, Most Common Performing Physician Specialties, 2005

	Service Count, 5% Sample	Percent of Claims
CT		
Total	1,062,351	100.0%
Diagnostic radiology	952,463	89.7%
Interventional radiology	28,748	2.7%
IDTF	27,330	2.6%
Radiation oncology	10,910	1.0%
Internal medicine	7,446	0.7%
General/Family practice	5,901	0.6%
Hematology/ oncology	5,245	0.5%
MRI		
Total	391,303	100.0%
Diagnostic radiology	300,767	76.9%
Independent Diagnostic Testing Facility (IDTF)	50,878	13.0%
Orthopedic surgery	9,239	2.4%
Interventional radiology	7,405	1.9%
Neurology	5,836	1.5%
Nuclear medicine	2,589	0.7%
General/Family practice	2,306	0.6%
Internal medicine	2,072	0.5%
Radiation oncology	1,852	0.5%
PET		
Total	4,814	100.0%
Diagnostic Radiology	2,296	47.7%
Independent Diagnostic Testing Facility (IDTF)	998	20.7%
Nuclear medicine	525	10.9%
Cardiology	505	10.5%
Hematology/ oncology	153	3.2%
Radiation oncology	70	1.5%

Table 1: Medicare Advanced Imaging Claims, Most Common Performing Physician Specialties, 2005		
	Service Count, 5% Sample	Percent of Claims
Interventional radiology	64	1.3%
Medical oncology	60	1.2%
Internal medicine	33	0.7%
Neurology	23	0.5%
SPECT		
Total	181,623	100.0%
Cardiology	124,503	68.6%
Diagnostic radiology	31,647	17.4%
Internal medicine	11,009	6.1%
Nuclear medicine	7,829	4.3%
Independent Diagnostic Testing Facility (IDTF)	2,087	1.1%
General/Family practice	1,363	0.8%
Interventional radiology	857	0.5%
Source: Analysis of 5% sample physician/supplier SAF, LDS version.		
Notes: CT defined as BETOS I1A, I2B. MRI defined as BETOS I2C and I2D. PET and SPECT identified by CPT codes for those services. Includes all carrier-paid bills (including TC-only bills)		

Table 2 gives the same breakout by the specialty of the referring (ordering) physician. Diagnostic radiologists ordered slightly more than 1 percent of PET scans. For the other three categories, diagnostic radiologists accounted for less than 1 percent of the services ordered.

Table 2: Medicare Advanced Imaging Claims, Most Common Referring (Ordering) Physician Specialties, 2005		
	Service Count, 5% Sample	Percent of Claims
CT		
Total	1,062,351	100.0%
Internal medicine	227,721	21.4%
Emergency medicine	169,350	15.9%
General/Family practice	141,493	13.3%
No UPIN match/Unk.	102,944	9.7%
Hematology/ oncology	61,405	5.8%
General surgery	42,131	4.0%
Urology	41,321	3.9%
Pulmonary disease	34,972	3.3%
Gastroenterology	28,701	2.7%
Medical oncology	28,192	2.7%
Cardiology	28,068	2.6%
Otolaryngology	13,821	1.3%
Neurology	13,459	1.3%

Neurosurgery	12,929	1.2%
Orthopedic surgery	12,037	1.1%
Diagnostic radiology	**10,775**	**1.0%**
Nephrology	9,663	0.9%
Radiation oncology	8,156	0.8%
Vascular surgery	7,822	0.7%
Obstetrics/ gynecology	7,124	0.7%
Thoracic surgery	5,628	0.5%
MRI		
Total	391,303	100.0%
Internal medicine	83,985	21.5%
General/Family practice	57,117	14.6%
Orthopedic surgery	46,852	12.0%
Neurology	42,817	10.9%
No UPIN match/Unk.	31,506	8.1%
Neurosurgery	13,485	3.4%
Hematology/ oncology	13,452	3.4%
Emergency medicine	8,617	2.2%
Cardiology	8,563	2.2%
General surgery	7,069	1.8%
Physical medicine and rehabilitation	6,146	1.6%
Otolaryngology	6,023	1.5%
Medical oncology	5,943	1.5%
Rheumatology	5,824	1.5%
Pulmonary disease	5,699	1.5%
Nephrology	4,170	1.1%
Gastroenterology	4,169	1.1%
Anesthesiology	3,352	0.9%
Diagnostic radiology	**3,267**	**0.8%**
Radiation oncology	3,009	0.8%
Podiatry	2,807	0.7%
Ophthalmology	2,752	0.7%
Urology	2,511	0.6%
Vascular surgery	2,483	0.6%
PET		
Total	4,814	100.0%
Hematology/ oncology	1,023	21.3%
Internal medicine	586	12.2%
Cardiology	541	11.2%
Medical oncology	482	10.0%
Pulmonary disease	318	6.6%
Neurology	290	6.0%
No UPIN match/Unk.	283	5.9%
General/Family practice	262	5.4%
Radiation oncology	167	3.5%
Otolaryngology	141	2.9%
General surgery	137	2.8%
Thoracic surgery	78	1.6%

Hematology	65	1.4%
Diagnostic radiology	**53**	**1.1%**
Gastroenterology	50	1.0%
Emergency medicine	34	0.7%
Psychiatry	26	0.5%
Cardiac surgery	23	0.5%
Critical care (intensivists)	22	0.5%
SPECT		
Total	181,623	100.0%
Cardiology	66,439	36.6%
Internal medicine	53,745	29.6%
General/Family practice	33,897	18.7%
No UPIN match/Unk.	8,736	4.8%
Emergency medicine	2,752	1.5%
Pulmonary disease	1,737	1.0%
General surgery	1,618	0.9%
Nephrology	1,332	0.7%
Orthopedic surgery	1,008	0.6%
Gastroenterology	962	0.5%
Nurse practitioner	670	0.4%
Endocrinology	664	0.4%
Vascular surgery	616	0.3%
Diagnostic radiology	**535**	**0.3%**
Source: Analysis of 5% sample physician/supplier SAF, LDS version.		
Notes: CT defined as BETOS I1A, I2B. MRI defined as BETOS I2C and I2D. PET and SPECT identified by CPT codes for those services. Includes all carrier-paid bills (including TC-only bills)		

Table 3 shows imaging by place of service, counting each bill (professional component, technical component, or total) as one service. SPECT is primarily an office-based service, with about two-thirds of services taking place in physician offices. Both PET and MRI have a significant volume in independent diagnostic testing facilities (IDTFs).

Table 3: Advanced Imaging Services by Location, 2005							
Col Pct	1:Inpatient	2:OPD/ER	3:Office	4:IDTF	5:Other	Total	Services, 5% Sample
1:CT	32.8%	48.5%	16.0%	2.6%	0.2%	100.0%	1,062,351
2:MRI	18.2%	34.4%	34.1%	12.9%	0.4%	100.0%	391,303
3:PET	4.7%	34.2%	39.2%	20.7%	1.2%	100.0%	4,814
4:SPECT	14.0%	20.3%	64.5%	1.2%	0.1%	100.0%	181,623
Source: Analysis of 5% sample physician/supplier SAF, LDS version.							
Notes: CT defined as BETOS I1A, I2B. MRI defined as BETOS I2C and I2D. PET and SPECT identified by CPT codes for those services. Includes all carrier-paid bills (including TC-only bills)							

Table 4 shows the diagnosis reported on the claim line for the service, grouped by the Agency for Healthcare Research and Quality Clinical Classification System (CCS) categories. The data clearly show the main uses for PET (cancer staging) and SPECT (assessment of cardiovascular problems). CT and MRI, by contrast, are more general purpose tools, used for a broad array of underlying problems.

Table 4: Services by Clinical Classification System Diagnosis Category

CCS	CCS label	Services, 5% sample	Pct of Services
CT			
Total	Total	1,062,351	100.0%
251	Abdominal pain	127,377	12.0%
133	Other lower respiratory disease	87,226	8.2%
244	Other injuries and conditions due to external causes	35,874	3.4%
84	Headache; including migraine	34,027	3.2%
155	Other gastrointestinal disorders	33,445	3.1%
109	Acute cerebrovascular disease	32,245	3.0%
146	Diverticulosis and diverticulitis	27,459	2.6%
205	Spondylosis; intervertebral disc disorders; other back	27,402	2.6%
151	Other liver diseases	27,297	2.6%
259	Residual codes; unclassified	26,032	2.5%
MRI			
Total	Total	391,303	100.0%
205	Spondylosis; intervertebral disc disorders; other back	105,489	27.0%
204	Other non-traumatic joint disorders	28,395	7.3%
109	Acute cerebrovascular disease	20,670	5.3%
95	Other nervous system disorders	15,639	4.0%
84	Headache; including migraine	11,606	3.0%
211	Other connective tissue disease	11,415	2.9%
110	Occlusion or stenosis of precerebral arteries	11,361	2.9%
111	Other and ill-defined cerebrovascular disease	10,675	2.7%
225	Joint disorders and dislocations; trauma-related	9,780	2.5%
112	Transient cerebral ischemia	9,659	2.5%
PET			
Total	Total	4,814	100.0%
19	Cancer of bronchus; lung	1,067	22.2%
38	Non-Hodgkin`s lymphoma	640	13.3%
101	Coronary atherosclerosis and other heart disease	498	10.3%
68	Senility and organic mental disorders	345	7.2%
133	Other lower respiratory disease	318	6.6%
14	Cancer of colon	284	5.9%
11	Cancer of head and neck	254	5.3%
15	Cancer of rectum and anus	201	4.2%
102	Nonspecific chest pain	153	3.2%
22	Melanomas of skin	119	2.5%

SPECT			
Total	Total	181,623	100.0%
101	Coronary atherosclerosis and other heart disease	70,437	38.8%
102	Nonspecific chest pain	58,059	32.0%
117	Other circulatory disease	16,665	9.2%
133	Other lower respiratory disease	10,750	5.9%
106	Cardiac dysrhythmias	5,412	3.0%
108	Congestive heart failure; nonhypertensive	2,843	1.6%
256	Medical examination/evaluation	2,040	1.1%
98	Essential hypertension	1,660	0.9%
104	Other and ill-defined heart disease	1,494	0.8%
237	Complication of device; implant or graft	1,427	0.8%
Source: Analysis of 5% SAF LDS physician/supplier claims, 2005			
Note: Disease entity is line diagnosis code crosswalked to AHRQ CCS category.			

Finally, Table 5 gives summary statistics on performance by radiologists (either diagnostic radiology or IDTF), self-referral, and services and service users per capita. SPECT stands out in terms of self-referral, presumably by cardiologists. For the other services, self-referral rates (as measure by matching UPINs for performing and referring physician) range from about 3 to 5 percent. Almost none of that is self-referral by radiologists -- as noted above, radiologists ordered 1.2 percent of PET scans and 1 percent or less of all other types of imaging.

In terms of users and services, about one in ten PET or SPECT users have multiple bills for those services (other than TC-only bills) during the year. For MRI, about a third of users have more than one (non-TC) MRI bill. For CT, almost two-thirds have multiple (non-TC) bills for CT services over the course of the year.

Table 5: Comparison of Specialty and Use Rates, Advanced Imaging, 2005

	1:CT	2:MRI	3:PET	4:SPECT
Percent of carrier-paid bills with:				
Radiologist or IDTF as performing physician	92.2%	89.9%	68.4%	18.6%
Radiologist or IDTF as referring (ordering) physician	1.0%	0.8%	1.2%	0.3%
With UPIN-based self-referral (referring UPIN matches performing UPIN)	2.8%	3.9%	5.0%	22.8%
Services per capita and users per capita:				
Total including TC	0.61	0.23	0.003	0.11
Total excluding TC	0.59	0.21	0.002	0.10
Fraction of carrier bills TC only	0.03	0.09	0.12	0.08
Users per capita, any service	0.235	0.126	0.0022	0.088
Users per capita with multiple services	0.142	0.046	0.0002	0.007
Source: Analysis of 5% SAF physician/supplier and denominator, 2005, LDS version				

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American Society of
Health-System Pharmacists
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August 31, 2007

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

Re: CMS-1385-P; RIN 0938-AO65; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to compendia for determination of medically accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP is also the publisher of AHFS Drug Information (DI), a comprehensive, independent reference on the clinical use of medications marketed in the United States. Published continuously for 49 years, AHFS DI is recognized through federal legislation and regulation as an official compendium for information on medically accepted uses of medications.

DRUG COMPENDIA

ASHP commends CMS for proposing a process to determine changes to the drug compendia list, and applauds CMS's interpretation of the Deficit Reduction Act (DRA)

regarding successor versus substitute publication for USP DI. ASHP also commends CMS's decision to consider whether a compendium contains the MedCAC-recommended desirable characteristics when reviewing requests for change to the list of compendia. However, ASHP recommends that the extensive breadth of listings characteristic not be a principal determinant in judging the merits of compendial designation; the quality of review and associated processes, not the quantity of listings, are most important in assessing compendial merits. Additionally, ASHP believes that, in addition to the MedCAC-recommended desirable characteristics, the compendia review process should include a strong emphasis on the need for appropriate processes, including editorial independence, which is essential to a designated drug compendium. Finally, CMS should ensure that its process for review is as rigorous as the Health Care Financing Administration's (HCFA) review was when AHFS became a recognized compendium.

ASHP is also concerned about any reliance by CMS on the Technology Assessment of drug compendia used to determine medically accepted uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen commissioned from the Agency for Healthcare Research and Quality (AHRQ). ASHP submitted comments to CMS regarding the draft report (please see Appendix A, Peer Review Checklist); however, these comments were not addressed in the final report. Additionally, the report focused on the quantity of cited references and did not address the quality of those studies as evidence. Evidence quality should have been measured in order for the report to be considered a useful assessment.

ASHP makes the following specific recommendations to CMS:

- ASHP agrees with CMS that recognition of the USP DI compendium after its name change should not continue if the Secretary determines it is now a substitute publication.

- ASHP cautions CMS in its consideration of extending compendial status for Medicare Part B to Thomson's Drugdex database.

- ASHP strongly recommends that the proposed extensive breadth of listing characteristic not be used as a primary determinant in judging the merits of compendial designation.

- ASHP strongly recommends that CMS add the following characteristic to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:
  - Inclusion of safety information for oncology drugs

- ASHP strongly recommends that, in addition to the MedCAC-recommended desirable characteristics, the review process include a strong emphasis on the need for an appropriate process, including editorial independence, which is essential to a designated drug compendium.

- ASHP strongly recommends that CMS add the following characteristics to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:
  - High-quality, controlled content development
  - Well-established expert-review process
  - Demonstrated independence from pharmaceutical manufacturers, health insurances, and pharmacy benefits managers
  - Demonstrated evidence-based objectivity

- However, the Society also recommends that CMS ensure that its process for determining changes to the compendia list remains as rigorous as the process used by HCFA when AHFS DI was included as one of the three original drug compendia.

- ASHP strongly recommends that, because AHFS DI went through a rigorous review process prior to its designation, AHFS DI, as well as any other compendium approved under such a rigorous process, should be evaluated by CMS every five years, rather than every year.

Successor v. Substitute Publication

ASHP applauds CMS's interpretation of section 6001(f)(1) of the DRA that amends both sections 1927(g)(1)(B)(i)(II) and 1861(t)(2)(B)(ii)(I) of the Social Security Act (the Act) by inserting "(or its successor publications)" after "United States Pharmacopeia-Drug Information." CMS interprets this DRA provision as explicitly authorizing the Secretary to continue recognition of the compendium currently known as USP DI after its name change, if the Secretary determines that it is in fact a successor publication, rather than a substitute publication.

- **ASHP agrees with CMS that recognition of the USP DI compendium after its name change should not continue if the Secretary determines it is now a substitute publication.**

In 2007, Thomson Healthcare announced that it was replacing the USP DI with its own previously existing DrugPoints database.[1] While Thomson chose to use the term "succeeded" in its press release announcing the change to subscribers,[2] DrugPoints clearly is not a "successor" database since it bears little resemblance to the previous USP DI database in content or editorial oversight by USP's Expert Committees, and it existed

[1] Thomson Healthcare. Important notice: USP DI drug information for the health care professional. Greenwood, CO; 2007 May. Press release No. HC-4684b rev 05/07.
[2] Id.

simultaneously for many years in Thomson's drug database collection. If CMS is unable to determine whether DrugPoints is a successor or substitute publication, ASHP recommends that CMS contact the originator of USP DI, the United States Pharmacopeial Convention (USP), to advise CMS about the nature of DrugPoints relative to USP DI.

- **ASHP also cautions CMS in its consideration of extending compendial status for Medicare Part B to Thomson's Drugdex database.**

Unlike the original three compendia (AHFS DI, AMA DE, and USP DI), Drugdex was never subject to the same rigorous review by Congress and CMS or opportunity for public comment in the *Federal Register.*[3,4,5] Instead, it achieved compendial recognition for Medicaid by amendment to unrelated legislation and for Medicare Part D by reference to the Medicaid language.[6] While not a scientific analysis by any means, in an October 23, 2003 *Wall Street Journal* article, a prominent investigative reporter questioned Drugdex's editorial approach to evidence as well as connections with the pharmaceutical industry (one cited example in the report was the use by Drugdex of a paid pharmaceutical manufacturer consultant to author the gabapentin [Neurontin] monograph).[7] The policy implications on coverage decisions were substantial, costing state Medicaid programs considerable resources.[8] Drugdex subsequently deleted all author attributions in their database (fall 2005), so it is no longer possible to determine the extent to which such authors have been used and still remain. Unfortunately, neither AHRQ's Technology Assessment nor CMS's MedCAC public meeting on March 30, 2006, probed this editorial record.

MedCAC Desirable Compendial Characteristics

ASHP generally agrees with the MedCAC desirable characteristics identified in the Proposed Rule. In addition, ASHP believes that sound, independent, evidence-based policies are the most critical element in establishing compendial merits.

In 2005, assessment of the loss of USP's evidence-based development process for off-label antineoplastic uses led ASHP to consult with oncology experts to develop a codified model for summarizing AHFS' evidence-based analyses of cancer uses for drugs. The

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[3] Armstrong D. How drug directory helps raise tab for Medicaid and insurers. *Wall Street Journal.* October 23, 2003:A1.
[4] Health Care Financing Administration. Medicare program; catastrophic outpatient drug benefit. 21 CFR Part 410. Proposed rule. [BPD-613-P; RIN 0938-AD91] *Fed. Regist.* 1989;54:37190-37208.
[5] Legislative History for compendial designation for Drugdex: 104th Congress Balanced Budget Act of 1995 (vetoed by President) 105th Congress H.R. 3507 Personal Responsibility and Work Opportunity Act of 1996 (not passed)
[6] Id.
[7] Armstrong D. How drug directory helps raise tab for Medicaid and insurers. *Wall Street Journal.* October 23, 2003:A1.
[8] Id.

goal was to develop a model that provided succinct codified conclusions about specific off-label uses that would be readily actionable. Background information was provided to CMS as part of the AHRQ Technology Assessment in 2006. In the intervening year, ASHP has continued to refine its model.

The characteristics of this codified AHFS model are consistent with those identified as desirable by MedCAC, including expanded coverage (listings); quick throughput; provision of detailed evidence tables in support of each individual assessment, including strength of end point; use of pre-specified criteria for weighing evidence; a well-defined expert-review process with clear strengths of recommendation; a publicly transparent process with editorial independence and firewalls; an explicit "not recommended" category that includes therapy considered inappropriate, obsolete, or unproven; an explicit "not fully established" category that includes equivocal evidence and uses with unclear risk/benefit; explicit recommendations concerning sequential and combination therapies; and a process for identification and notification of potential conflicts of interest. ASHP has received favorable comments from CMS, oncology experts, and others regarding this model. Current plans are to roll it out later this year.

Breadth of Listings

ASHP commends CMS's decision to consider whether a compendium contains the MedCAC-recommended desirable characteristics when reviewing requests for change to the list of compendia.

- **However, the Society strongly recommends that the proposed extensive breadth of listing characteristic not be used as a primary determinant in judging the merits of compendial designation.**

While ASHP recognizes the importance of expanding the coverage of off-label anti-cancer uses in its compendium (and has launched a program to address the gap created by USP's exit from focused attention to this therapeutic area), the quality of review and associated processes, not the quantity of listings, are most important in assessing compendial merits. In fact, a principal flaw with CMS's commissioned AHRQ Technology Assessment was its focus on quantifying study citations rather than on assessing the true quality of the evidence that these studies represented.

ASHP believes that a compendium should engage in evidence-based processes that are guided by objective evaluation of the level of evidence according to a well-defined process, and should not to be driven by goals of achieving extensive listings at the expense of quality assessment. The 2003 *Wall Street Journal* report on the effects of overly broad listings of uses documented the severe negative effects of this approach on government expenditures.[9] To require a compendium to have an extensive breadth of

[9] Id.

listings will encourage the listing of off-label uses for which there may be insufficient evidence to either include or exclude.

In the AHRQ Technology Assessment, the emphasis seemed to be on cataloguing all available evidence regardless of quality and merit while discounting the value of editorial process, evidence analysis, expert review, and clinical judgment. Would this approach, i.e., cataloguing all available evidence, be a worthwhile consumption of considerable compendial resources versus emphasizing an ongoing method of reviewing research, evaluating evidence quality, soliciting expert advice about levels of evidence and strengths of recommendation, and then reporting what is relevant according to explicit criteria and reporting methods? ASHP thinks that it would not, and therefore encourages CMS to emphasize the qualitative not quantitative aspects of the process in determining compendial merit.

ASHP remains committed to expanding its timely coverage of off-label anti-cancer uses in a manner that fully embodies the desirable characteristics identified by MedCAC; However, this process should be driven by established principles of evidence-based quality review rather than arbitrary goals of citation quantity. To this end, ASHP's compendial staff is being expanded by at least five full-time employees, including recruitment of a Board Certified Oncology Pharmacist. The result will be an increased breadth of off-label oncology assessment but not one driven by numbers alone.

A basic value among health professionals and the public is that health care practices (including the use of prescription medicines) must be based on evidence of net benefit to the patient (positive outcomes exceeding negative outcomes). Any standard of care lower than this may result in harm to the patient's clinical condition, emotional state, or quality of life, as well as be wasteful of the patient's or society's financial resources. These issues escalate in importance as the cost of a therapy increases. With respect to drug therapy, a too-lax standard for assessing the evidence supporting off-label use could have real consequences for the patient such as delaying or precluding more effective treatment or fostering unfounded hope for improvement in health status.

Safety and Effectiveness

One important desirable characteristic missing from the Proposed Rule that was discussed by AHRQ and MedCAC was inclusion of safety information. In the current environment of increased attention to safe medication use, it is critical, not just desirable, that drug safety issues be weighed in any therapeutic decision. In fact, the strength of recommendation for a given off-label use can be greatly affected by its toxicity profile relative to other therapies and potentially can obscure clinical evidence findings either positively or negatively.

- **ASHP strongly recommends that CMS add the following characteristic to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:**

  - **Inclusion of safety information for oncology drugs.**

Appropriate Process and Editorial Independence

- **ASHP strongly recommends that, in addition to the MedCAC-recommended desirable characterics, the review process include a strong emphasis on the need for an appropriate process, including editorial independence, which is essential to a designated drug compendium.**

An ideal source for drug information aimed at fostering safe and effective medication use should provide dependable, objective, authoritative information in the context of sound editorial policies; high-quality, controlled content development; a well-established expert-review process; independence from pharmaceutical manufacturers, health insurers, pharmacy benefits managers, and others who may seek to use the source to promote their own interests; an ongoing updating process; a mechanism for correction notification; and broad-based authoritative guideline incorporation. A key aspect of such a resource is the evidence-based objectivity that allows the inclusion of uses and dosages that are not included in the FDA-approved labeling (i.e., off-label/unlabled uses).

- **ASHP strongly recommends that CMS add the following characteristics to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:**

  - **High-quality, controlled content development**
  - **Well-established expert-review process**
  - **Demonstrated independence from pharmaceutical manufacturers, health insurers, and pharmacy benefits managers**
  - **Demonstrated evidence-based objectivity**

Recognition of the authority of a drug information source by professional, government, legislative, regulatory, and private-sector groups should be linked to the strength of its editorial process and the dependability of the information it provides. It also is important that the information be free of undue influence of pharmaceutical manufacturers and other third parties who may seek to use the publication to promote their own interests.

An appropriate process for developing authoritative drug information should involve several key steps: information tracking and gathering, evidence-based information analysis, drug information synthesis and development, a review process, and finalization and management of published information; the process should be well documented, transparent and independent. Maintenance efforts should include periodic updating to

accommodate new information and an assertive accessible alerting and correction-notification process.

AHFS DI applies all of these key steps in its process and is widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers. (See Appendix B, policy relating to editorial independence of AHFS Drug Information approved by the ASHP Committee on Publications and Board of Directors).

Rigorous Review

ASHP commends CMS for its proposal to create a process incorporating public notice and comment to receive and make determinations regarding requests for changes to the list of compendia used to determine medically accepted indications for drugs and biologicals used in anti-cancer treatment.

- **However, the Society also recommends that CMS ensure that its process for determining changes to the compendia list remains as rigorous as the process used by HCFA when AHFS DI was included as one of the three original drug compendia (See Appendix C, Overview of AHFS DI HCFA Review Process).**

This rigorous review by HCFA was an extremely important process, since it ensured that any approved compendium contributed to the information sources available to CMS to determine coverage for appropriate indications. Because of the process AHFS DI went through, CMS should maintain AHFS DI as an approved compendia, and require all other compendia to go through such a rigorous process prior to approval.

- **ASHP strongly recommends that, because it went through this process, AHFS DI, as well as any other compendium approved under such a process, should be evaluated by CMS every five years, rather than every year. In place of an annual review of approved compendia, CMS should consider implementing a certification process that requires approved compendia to certify maintenance of the desirable characteristics during the past year.**

Consensus Opinions vs. Evidence-Based Clinical Trials

ASHP cautions CMS to carefully investigate the independence of a compendia's process, and ensure its process is not biased toward the consensus opinions of its members rather than a rigorous assessment of the evidence from clinical trials and scientific studies. CMS must carefully weigh the outcomes that such a potentially heavily opinion-weighted process may have on its own policies and goals for coverage of off-label uses of drugs and biologics in anti-cancer therapeutic regimens.

CMS versus FDA Standards

CMS should carefully review some of its current standards regarding off-label anti-cancer drug use. For example, as a result of the FDA Modernization Act of 1997, FDA has changed many of its previously stringent requirements for the quality and quantity of evidence required for approval of a new use. [10,11,12] As a result, CMS may be holding coverage of off-label uses for anti-cancer therapies to a higher standard than FDA does for actual approval of labeled uses (e.g., different regimens, different stages, etc).

ASHP appreciates this opportunity to present its written comments on the proposal for a process to determine change to the drug compendia list. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

Justine Coffey

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs

Enclosures/Appendicies

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[10] US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER). Guidance for industry: providing clinical evidence of effectiveness for human drug and biological products. (Clinical 6) 1998 May.

[11] US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER). Guidance for industry: FDA approval of new cancer treatment uses for marketed drugs and biological products. (Clin 7) 1998 Dec.

[12] US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER). Guidance for industry: Clinical trial endpoints for the approval of cancer drugs and biologics. Draft guidance. (Clinical/Medical) 2005 Apr.

APPENDIX A

Peer Review Checklist

"Compendia for Coverage of Off-Labels Uses of Drugs and Biologics in an Anti-Cancer Chemotherapeutic Regimen"

Peer Review Checklist
"Compendia for Coverage of Off-Labels Uses of Drugs and Biologics in an Anti-Cancer Chemotherapeutic Regimen"

Name of Reviewer: American Society of Health-System Pharmacists, Inc. (McEvoy, Welsh, Ford)

Title: See Preferred Mailing Address box

Affiliations: ASHP

Preferred Mailing Address:

Gerald McEvoy, AVP Drug Information, ASHP, 7272 Wisconsin Ave, Bethesda, MD 20814

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Phone: 301-664-8632 Fax: 301-634-5732

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Conflicts of Interest: Please disclose any potential conflicts of interest, such as research in progress, consulting arrangements, or other financial involvements.

All members of ASHP's AHFS Drug Information publishing.

Please use this form to guide your comments. Return your separate written review and this completed form **by August 14, 2006 (N.B.: Extension granted by AHRQ because wrong version initially sent to ASHP)** to the attention of the Technology Assessment Program:

E-mail: ahrqtap@ahrq.gov

If there are any questions, please contact Chuck Shih via e-mail cshih@ahrq.gov or by phone at 301-427-1969.

Name of Reviewer: ASHP

Please indicate your answers to the following questions by placing an "x" in the appropriate column, and add a brief explanation of answers and comments in the space provided.

Questions	YES	SOME TIMES	NO
General Comments			
1. Is the purpose of the assessment clear?		X	
2. Is the technology assessment well structured and organized?		X	
Comments: The authors of the report clearly state what was done, but the underlying methodology is overly simplistic. Evaluation of item 3d on p. 6, presence of bias, depends on definition of "equivocal evidence", which was not explicitly defined by authors according to study limitations section on p. 147.			
Scope and Analytic Framework			
3. Is the scope of the report clearly defined?		X	
4. Were all clinically important issues considered?			X
Comments: The report did not adequately address the quality of the evidence considered. Analysis seems to emphasize the number of study citations included more than the quality of evidence. Reporting which unlabeled uses and what supporting evidence was included by each compendium without analysis of *whether* all such information should have been included is not the most optimal measure of compendial quality. There also seems to be a misconception that a compendium is used to catalog all clinical studies for a drug instead of presenting clinically relevant information based on carefully selected studies. One could also argue the clinical impact of the off-labeled uses that were selected as examples.			
Methods			
5. Are the inclusion and exclusion criteria appropriate?			X
6. Is any published literature or work in progress missing?			X
7. Have we included materials that ought to be excluded or down-weighted?	X		
8. Is the method for grading the quality of individual studies appropriate?			X
9. Is the method for analyzing data appropriate and clearly explained?		X	

Questions	YES	SOME TIMES	NO
Comments: Not all studies conducted for a drug provide clinically relevant information. Searching the literature for all studies and checking that against which studies are cited in various compendia is not a valid measure of quality. Method of selecting agent-cancer combinations for study (new and older agents, common and rare cancers, etc.) is likely not consistent with criteria considered important by compendia for prioritizing inclusion of unlabeled uses; i.e., high degree of therapeutic efficacy, lesser toxicity than current treatments, number of patients potentially affected, lack of alternative therapies. Also, many studies were reported as abstracts, which are not optimal for assessing evidence because of deficiencies in reporting of methods and may not be representative of final study results. (See attached references listed under "Problems with using abstracts to assess evidence from clinical trials".) Editorial decisions regarding inclusion of information on unlabeled uses must balance the desire for expediency in reporting with the need for reliable evidence upon which to make recommendations for therapy.			
	YES	**SOME TIMES**	**NO**
Results			
10. Are adverse effects adequately addressed?			**X**
11. Were the results stated clearly and were the figures, tables and evidence tables clear?		**X**	
Comments: The various compendia offer information on the adverse effects of each drug based on its labeled uses. The cautions and adverse effects information for a drug is relevant when the drug is used for off-labeled uses too. In addition, when certain risks appear to be uniquely related to or affected by the underlying cancer being treated, they can be described. However, it should be recognized that establishing causal relationships, even from large studies, often is difficult. In the context of the often limited clinical data that is available for emerging off-label uses, establishing causal relationships would be even more difficult. NCCN guidelines are not strictly comparable to other compendia since they do not include adverse event information (Table 1F), which is important for clinicians to consider when deciding whether or not to use a particular drug for a given cancer. Data presentation is sometimes inconsistent or incomplete. For example, there is no summary table for the first 8 agent-cancer combinations as there is in Table 16 for the second 6 combinations. Also, text states that an evidence table was not done for docetaxel in ovarian cancer because the large number of citations (143 total, 57 meeting EPC criteria) "exceeded capacity" (?). However, a similar number of citations was found for some other uses yet they were included in evidence tables, e.g., docetaxel for gastric cancer (132 total, 72 meeting EPC criteria). See additional comments at end of this form.			
Conclusions			
12. Are the major findings clearly stated?	**X**		

Questions	YES	SOME TIMES	NO
Comments: The major findings are clearly stated, but not particularly helpful. A compendium should be judged on the rigor of its editorial process and the timeliness and clinical relevance of its content. The selection of off-labeled oncology uses for this report does not recognize that publication of certain off-labeled uses may be prioritized based on the strength of the available evidence and the impact the drug will have for the treatment of a particular cancer; there was no attempt to evaluate the quality/strength of evidence in the technology assessment. Many of the off-labeled uses selected for this report, including those for oxaliplatin, irinotecan, rituximab, and erlotinib, have not progressed to phase III trials. In the constraints of existing resources, editorial priority often is driven to add off-labeled uses that have progressed further in clinical trials because there is greater evidence of efficacy and safety to support these uses. There is also no recognition that keeping clinicians up to date on important cautions information on these drugs is an important mission of a compendium. Safety concerns on proper use and management of adverse effects of the drug generally should be given greater priority over citing unlabeled uses that have little or no supporting evidence. First, do no harm.			

On the following page, please provide:

- **References for relevant studies that we have missed**
- **Any other comments and suggestions for improving the content and format of this review**

Name of Reviewer: ASHP

Name of Reviewer: ASHP

Peer Review Form

Please use this sheet to provide specific comments about the technology assessment below.

ASHP appreciates the opportunity to provide comments on AHRQ's Draft Report on Compendia for Coverage of Off-label Uses of Drugs and Biologics in an Anti-cancer Chemotherapeutic Regimen May 31, 2006.

General Comments about AHRQ's Draft Technology Assessment

Quality of evidence: Reviewing and selecting studies based on the quality of evidence is more meaningful than citing all studies (phase I-IV) as done in this technology assessment. The authors of this report seem to make assumptions that all studies published for a drug are equally important (hence the searching and tallying) and that numbers of studies translate into clinical importance (not necessarily true). Their methodology seems overly simplistic. The table from the statistics web site (Bandolier: http://www.jr2.ox.ac.uk/bandolier/band139/b139-2.html) supports the arguments for selecting studies based on the quality of evidence. The parenthetically noted JAMA study (PubMed ID: 16014596) shows that an initial randomized trial that is widely cited might be contradicted by a second randomized trial, so confirmatory trials are important. In this study, a sizable percentage (16%) of second randomized trials contradicted the findings of the initial trial.

The technology assessment commented on the reference padding employed by Drugdex; it was notable that in 9 of 14 uses, references included in the bibliography were not cited in the text of the monographs. While not a scientific analysis by any means, a prominent Wall Street Journal investigative report (Armstrong D. How drug directory helps raise tab for Medicaid and insurers. WSJ. 2003 (Oct 23):A1) questioned Drugdex' editorial approach to evidence as well as connections with the pharmaceutical industry (one cited example in the report was the use by Drugdex of a paid pharmaceutical manufacturer consultant to author the gabapentin [Neurontin] monograph). Drugdex subsequently deleted all author attributions in their database (fall 2005), so it no longer is possible to determine the extent to which such authors have been used and still remain. Unfortunately, neither the current technology assessment nor CMS' MCAC public meeting on March 30, 2006 probed this. Table 1C of the Technology Assessment also acknowledge that Drugdex' evidence process is designed to be broad and includes case reports.

It is unclear how the authors of this technology assessment are using "tallying" of study citations, abstracts, and numbers of patients as a measure of efficacy and safety. Phase I trials are intended to establish activity of a drug for a particular cancer and dosing ranges and generally would not represent good evidence. Information on some studies is published at intervals in abstract form (e.g., ASCO abstracts) before publication as a full study, so simply "counting" all of these citations would falsely inflate the number of studies. As mentioned above, the use of abstracts as a sole source of evidence may be particularly troubling because of deficiencies in reporting methods in abstracts and

because of possible discordance from final published results or other studies. The section below on "Problems with using Abstracts to Assess Evidence from Clinical Trials" provides additional insights. This certainly is an issue that must be addressed in balancing expediency in reporting versus the need for reliable evidence and associated recommendations. This issue continues to be assessed as ASHP further refines its own evidence rating system.

Many factors, including the numbers of patients with a specific cancer, the stage of the disease, the risk/benefit ratio for treatment, and the presence or absence of standard treatment can affect the level of evidence that would be acceptable in a particular situation. That's why any systematic review of the evidence must recognize these complexities instead of reducing the process to a simple formula.

For some cancers, there are insufficient numbers of patients to conduct large randomized trials, so smaller phase II randomized trials may be acceptable. For some cancers, there is no current standard of therapy, so less rigorous studies, such as uncontrolled phase II studies showing high response rates and acceptable toxicity may be used as justification for further studies to establish efficacy and safety.

The citations and studies for an oncology drug need to be interpreted within the context of the cancer, stage of disease, patient population, existing therapies, and risk-benefit ratio, so a generic tallying of numbers of citations for each unlabeled use in this report as a method of evaluation seems overly simplistic. In addition, there may be other problems with selection of phase II or sometimes, phase III, trials. If many different combination chemotherapy regimens or differing dosage regimens are tested in phase II studies, it is difficult to clearly determine any "recommended" regimen or dosage schedule involving the study drug. Typically, the most promising combinations of agents and the dosage regimens that balance efficacy and toxicity are selected for further study. For this reason, it may be preferable to not cite all phase II studies for a drug in favor of following the progress of the research to identify a reasonable regimen or dosage schedule. Even some published phase III trials select a comparison with a nonstandard regimen or nonstandard dosage schedule for other drugs. In this situation, the comparative efficacy and toxicity of the study drug/regimen versus this non-established regimen does not offer clear benefit and it is difficult to apply the results to clinical practice.

Research versus clinical practice: Overall, this report does not make a distinction between research and clinical practice. The authors seem to discount the value of editorial process, expert review, and judgment. Is it the purpose of a compendium to consume considerable resources in simply cataloguing ALL available evidence or would those resources be better spent in an ongoing effort at reviewing the research, evaluating the evidence, soliciting expert advice about levels of evidence and strengths of recommendation, and then reporting what is relevant for clinical practice at that time? In addition, because there was no determination of the quality or strength of evidence nor on relative clinical importance, a process for establishing assessment priorities could not be developed.

While phase I/II studies are important in the research process, it is not until drugs are further along in phase II and phase III studies that we begin to obtain clinically useful information. Reporting all of those studies is not helpful to a clinician. Reporting the chemotherapy regimen and dosage schedule used in 25 patients in one phase II study and suggesting that clinicians use this information

to start treating their patients would be a misrepresentation of the level of evidence and strength of recommendation. The authors of this report are not recognizing the distinction between research and clinical practice.

By including studies of all design (Phase I-IV) and all studies conducted for a drug for a particular use, the authors of this report fail to acknowledge the diminishing return from less rigorous or irrelevant studies. A reader can simply search Medline or ASCO abstracts or other such sources to obtain unsynthesized information. Is it not an important role of a compendium to sift through the available material, analyze and synthesize it, and attempt to identify and assess what is most useful for the clinician? Unfortunately, the design and tone of the technology report seem to emphasize the tallying of all studies, regardless of quality, rather than this latter evaluative and synthetic process.

Purpose of a compendium: The point of a compendium is to provide a reference for clinicians in which experienced staff have carefully reviewed the medical literature, selected clinically important studies, and then summarized and synthesized this information into discussion that pertains to clinical practice. In this context, evidence tables for key studies can be a useful supplement. But simply pulling all studies and putting the information into evidence tables without any editorial process leaves all the work of evaluation to each clinician. This is an unrealistic expectation.

Despite the considerable time and effort that was put into carefully preparing the detailed evidence tables for all existing studies for each drug/off-label use combination (Appendix detailing the search strategies for the technology assessment), it is not clear how this presentation of the material alone benefits the reader/clinician or dictates what should be reported by a compendium. Unless it is used as a supplement to a discussion that results from an editorial review and synthesis of the literature, this material would leave each reader the unrealistic task of evaluating the entire body of evidence. A compendium is intended to itself serve as a reference containing a summary of the evidence and to provide the reader/clinician with selected bibliographic sources if they wish to pursue the topic in greater detail. While evidence assessments are integral parts of the compendial process in establishing levels of evidence in support of a given use and in soliciting strengths of recommendations from expert reviewers and clinicians, the emphasis on tallying studies (quantitive) in this technology assessment and general lack of assessing the evidence quality could provide the wrong message about the role of compendia.

NCCN is a guideline-based publication for oncology therapy only and distinctly different in approach compared with the other studied compendia. NCCN does not meet the conventional definition of a drug compendium. All of the other compendia provide monographs on the wide variety of prescription drugs in the US addressing a wide array of critical elements needed to safely and effectively use a drug. This is not an equivalent comparison. For example, NCCN does not provide detailed dosage information, information on adverse effects, precautions, warnings, contraindications, etc. In addition, there are other oncology guidelines besides NCCN, such as NIH consensus guidelines, ASCO guidelines, and others. If the intent was to extend the definition of a drug compendium to include to such guidelines, why weren't other such oncology guidelines included in the assessment?

General conclusions: There certainly are useful insights in this report that can be applied by each compendium in improving its process. The discussion section of the document is perhaps most

valuable in this regard. The difficulty in assessing methodological transparency is an important message.

What would have added greatly to the value of this report would have been greater discussion on the importance of assessing evidence quality and on the health policy issues involved, particularly in the context of competing expectations for expeditious evaluation of evidence and more clearly defining thresholds of evidence needed to establish reliable recommendations for therapy. For example, what is the role of a sole meeting abstract in this context? Is evidence truly driving the process or are expectation and opinion?

Perhaps the most valuable health policy conclusion is an implicit one about the overwhelming need for additional resources to address the formidable task of evaluating and synthesizing evidence. For example, what resources were consumed by CMS and AHRQ to simply tally the reported evidence, not even evaluate its quality and make specific recommendations about therapeutic roles, for only 14 uses involving 7 drugs? Now extrapolate this, particularly in the context of clinician and patient expectations.

Specific Comments about AHRQ's Draft Technology Assessment

p 7 (pdf p 9): says source was AHFS 2006 but 2005 edition was used.

Therefore, two *corrections* should be made for unlabeled uses for bevacizumab that appear in January 2006 version of AHFS DI (PDF pages from AHFS can be provided on request.) This discussion is on pdf pp. 28-46 (document pp. 26-44) of the report.

*1. Bevacizumab (Avastin) for treatment of breast cancers - COVERED IN AHFS DI January 2006
*2. Bevacizumab (Avastin) for treatment of lung cancers - COVERED IN AHFS DI January 2006

Tables 2a-c:

bevacizumab - breast cancer

added for AHFS DI January 2006 citing the study of capecitabine vs bevacizumab and capecitabine (Miller J Clin Oncol 2005) and the NCI protocol for a phase III trial of bevacizumab with or without paclitaxel

The discussion in the report is inaccurate because AHFS DI does cover this use and provides current citations for phase III studies.

Tables 3a-c:

bevacizumab - lung cancer (non-small cell lung cancer)

added for AHFS DI January 2006 citing the 2005 ASCO abstract for the Sandler et al Phase II/III trial

The discussion in the report is inaccurate because AHFS DI does cover this use and provides one of the current citations mentioned as supporting evidence.

p 12 (pdf p 14): included all study designs (phase I, phase I/II, phase III or phase IV) - why include phase I studies in a review of evidence?

p 13 (pdf p 15): data extraction done from abstracts: abstracts often contain errors and full text should be requested and reviewed to confirm the information and fully evaluate the study

p 16 (pdf p 18): error - says AHFS DI uses number sign to identify unlabeled use when in fact a dagger is used

p 19 (pdf p 21): Table 1A states that AHFS-DI 2005 was used; why wasn't the 2006 edition, which was available in January, used instead?

Table 1F (p. 24): Clarify that references DO exist for most statements in AHFS monographs, just not published except in electronic version. Material sent for external review is always fully referenced and extensive archival documentation extends back to 1959.

Table 1F (p. 24): Methods for formulating recommendations: Add "External review for comment." This was described in the documentation provided to the Duke Center for Clinical health Policy Research. Unfortunately, this omission was overlooked in the draft reviewed by us in February 2006.

Table 1F (p. 24): Harms: Disagree with comment that harms are not considered in unlabeled uses. Information on adverse effects/precautions is discussed or cross-referenced in uses section when appropriate, e.g., when use in certain patient populations may be associated with increased risk of adverse effects or necessitate additional precautions. In addition, comparative toxicity is typically discussed in Uses section when such information from randomized comparative trials is available. Also, adverse effects info is available in Cautions section from labeled uses of the drug. Toxicity information often is not available if data has only been published in abstract form. Also see earlier discussion under question 10 above.

Table 13b (p. 125). Footnote b under "number of evidence citations" for AHFS DI doesn't correspond to footnote description.

Discussion, p. 144: Contrary to what is stated, AHFS DI often provides information on different therapies for a given condition when alternative therapies are available.

Problems with using abstracts to assess evidence from clinical trials

JAMA. 2006 Mar 15;295(11):1281-7.
Comment in:
JAMA. 2006 Aug 9;296(6):653.

Transition from meeting abstract to full-length journal article for randomized controlled trials.
Toma M, McAlister FA, Bialy L, Adams D, Vandermeer B, Armstrong PW.
The Division of General Internal Medicine, University of Alberta, Edmonton, Alberta, Canada.

CONTEXT: Not all research presented at scientific meetings is subsequently published and, even when it is, there may be inconsistencies between these results and what is ultimately printed. Although late-breaking trials sessions are now integrated into several major scientific meetings and the results are often promptly and prominently communicated, no studies have examined the publication fate and degree of consistency between meeting abstracts or presentations and subsequent full-length article publications for randomized controlled trials (RCTs) presented at these sessions. OBJECTIVE: To compare RCT abstracts presented in the late-breaking trials session vs other sessions at a major scientific meeting and subsequent full-length publications. DESIGN: RCTs were identified by hand searching abstract proceedings booklets and related Web sites for the American College of Cardiology scientific meetings (1999-2002). Subsequent full-length articles were identified via electronic databases. MAIN OUTCOME MEASURES: Publication fate and degree of consistency between meeting abstract results and subsequent full-length publication results. RESULTS: The 86 late-breaking RCTs were significantly larger (median, 2737 patients vs 896; P<.001), were more likely to be preceded by a published design paper (27 [31%] vs 13 [13%]; P = .002), had higher quality scores when eventually published (mean Jadad score 2.69 vs 2.19; P = .01), and were less likely to report favorable results for the intervention than the 100 randomly chosen comparison RCTs presented in other sessions (50 [58%] vs 75 [75%]; P = .01; odds ratio 0.46; 95% confidence interval, 0.24-0.90). RCTs presented at the late-breaking trials sessions were significantly more likely to be published (79 [92%] vs 69 [69%]; P<.001) and appeared earlier after presentation (median 11.5 months vs 22.0 months; P<.001) than RCTs presented in other sessions, an association that persisted even after adjusting for sample size, conclusion of study, and RCT design: adjusted hazard ratio, 1.80 (95% confidence interval, 1.24-2.61). **Sixty (41%) of the 148 RCTs that were subsequently published exhibited discrepancies between the efficacy estimate reported in the meeting abstract vs the one reported in the full-length article for the primary outcome. The mean change in effect was 0.44 SDs and in 20 cases (14%), the point estimate was statistically significant in only 1 member of the pair.** The discrepancy rate was the same for late-breaking RCTs as for RCTs presented in other American College of Cardiology sessions (P = .92). CONCLUSIONS: Late-breaking trials were larger, more likely to be preceded by a design paper, and less likely to report positive results than RCTs presented at other sessions, but **discrepancies between the meeting abstract results and subsequent full-length publication results were common even for late-breaking trials.**

PMID: 16537738 [PubMed - indexed for MEDLINE]

J Clin Epidemiol. 2006 Jul;59(7):681-4.

Reporting of trials presented in conference abstracts needs to be improved.

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shopewell@cochrane.co.uk

OBJECTIVES: To assess how trial information reported in conference abstracts differs to their subsequent full publication. METHODS: Randomized trials reported at the American Society of Clinical Oncology conference (1992) were identified. CENTRAL and PubMed (December 2002) were searched to identify corresponding full publications. A checklist (based on CONSORT) was used to compare abstracts for 37 trials with their full publication. RESULTS: Some aspects were well reported. Ninety-five percent of study objectives, 92% of participant eligibility, 100% of trial interventions, and 84% of primary outcomes were the same in both abstract and full publication. Other areas were more discrepant. **Forty-six percent reported the same number of participants randomized in the abstract and full publication; only 22% reported the same number analyzed (median number analyzed per trial was 96 for abstracts and 117 for full publications). Eighty-two percent of trials were closed to follow-up in the full publication compared to 19% of abstracts. Lack of information was a major problem in assessing trial quality: no abstracts reported on allocation concealment, 16% reported on blinding and 14% reported intention to treat analysis. These figures were 49, 19, and 46%, respectively, for full publications.** CONCLUSION: The information given for trials in conference proceedings can be unstable, especially for trials presenting early or preliminary results, and needs to be improved.

PMID: 16765270 [PubMed - indexed for MEDLINE]

JAMA. 1998 Jul 15;280(3):254-7.

Erratum in:
JAMA 1998 Oct 14;280(14):1232.

Positive-outcome bias and other limitations in the outcome of research abstracts submitted to a scientific meeting.

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CONTEXT: Studies with positive results are more likely to be published in biomedical journals than are studies with negative results. However, many studies submitted for consideration at scientific meetings are never published in full; bias in this setting is poorly studied. OBJECTIVE: To identify features associated with the fate of research abstracts submitted to a scientific meeting. DESIGN AND SETTING: Prospective observational cohort, with 5-year follow-up of all research submitted for consideration to the major annual 1991 US research meeting in the specialty of emergency medicine. PARTICIPANTS: All research abstracts submitted for consideration at the meeting for possible presentation. MAIN OUTCOME MEASURES: Characteristics associated with acceptance for presentation at the meeting and subsequent publication as a full manuscript. RESULTS: A total of 492 research abstracts were submitted from programs in emergency medicine and other specialties affiliated with 103 US medical schools. A total of 179 (36%) were accepted for presentation and 214 (43%) were published in 44 journals. Of the 179 abstracts accepted for presentation, 111 studies were published. Scientific quality of abstracts or prestige of the journal in which the study was eventually published did not predict either of these outcomes. The best predictors (by logistic regression) of meeting acceptance were a subjective "originality" factor (odds ratio [OR], 2.07; 95% confidence interval [CI], 1.13-3.89) and positive results (OR, 1.99; 95% CI, 1.07-3.84), and, for publication, meeting acceptance (OR, 2.49; 95% CI, 1.49-4.35) and large sample size (OR, 2.26; 95% CI, 1.23-4.31). **Forty-nine percent (241) of abstracts did not report on blinding, and 24% (118) did not report on randomization.** Acceptance and publication were both more likely for positive outcomes (P=.03). Funnel plots showed the classic distribution of positive-outcome ("publication") bias at each of the submission, acceptance, and publication phases. Meeting acceptance predicted publication with a sensitivity of only 51%, specificity of 71%, positive predictive value of 57%, and negative predictive value of 66%. CONCLUSIONS: **Positive-outcome bias was evident when studies were submitted for consideration and was amplified in the selection of abstracts for both presentation and publication, neither of which was strongly related to study design or quality.**

PMID: 9676673 [PubMed - indexed for MEDLINE]

J Orthop Trauma. 2006 Feb;20(2):129-33.

The consistency between scientific papers presented at the Orthopaedic Trauma Association and their subsequent full-text publication.

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OBJECTIVES: To determine the consistency of conclusions/statements made in podium presentations at the annual meeting of the Orthopaedic Trauma Association (OTA) with those in subsequent full-text publications. Also, to evaluate the nature and consistency of study design, methods, sample sizes, results and assign a corresponding level of evidence. DATA SOURCES: Abstracts of the scientific programs of the OTA from 1994 to 1997 (N = 254) were queried by using the PubMed database to identify those studies resulting in a peer-reviewed, full-text publication. STUDY SELECTION: Of the 169 articles retrieved, 137 studies were the basis of our study after the exclusion criteria were applied: non-English language, basic science studies, anatomic dissection studies, and articles published in non-peer-reviewed journals. DATA EXTRACTION/SYNTHESIS: Information was abstracted onto a data form: first from the abstract published in the final meeting program, and then from the published journal article. Information was recorded regarding study issues, including the study design, primary objective, sample size, and statistical methods. We provided descriptive statistics about the frequency of consistent results between abstracts and full-text publications. The results were recorded as percentages and a 95% confidence interval was applied to each value. Study results were recorded for the abstract and full-text publication comparing results and the overall conclusion. A level of scientific-based evidence was assigned to each full-text publication. RESULTS: The final conclusion of the study remained the same 93.4% of the time. The method of study was an observational case series 52% of the time and a statement regarding the rate of patient follow-up was reported 42% of the time. Of the studies published, 18.2% consisted of a sample size smaller than the previously presented abstract. When the published papers had their level of evidence graded, 11% were level I, 16% level II, 17% level III, and 56% level IV. CONCLUSIONS: Authors conclusions were consistent with those in full-text publications. Most studies were observational, less than half reported on the rate of patient follow-up. **Many abstracts followed by publication had a smaller sample size in the published paper. Half of all studies were graded level IV evidence.**

PMID: 16462566 [PubMed - indexed for MEDLINE]

General Comments About ASHP's Compendial Publishing

American Hospital Formulary Service Drug Information (AHFS DI): ASHP is the publisher of AHFS DI, which is one of 3 drug compendia originally recognized for making determinations about medically accepted indications for anti-cancer chemotherapeutic regimens under Section 1861(t)(2)(B)(ii)(I) of the Social Security Act (SSA). AHFS DI is the only remaining federally recognized drug compendium published by a noncommercial entity—the American Society of Health-System Pharmacists—a nonprofit professional practice and scientific society.

ASHP supports a vision for pharmacy practice in hospitals and health systems in which pharmacists will lead evidence-based medication use programs to implement best practices. Publication of AHFS DI is an important component in achieving this vision.

The mission of AHFS DI is to provide an evidence-based foundation for safe and effective drug therapy. Widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers, AHFS DI has remained true to this mission for almost 50 years and is the most widely vetted drug compendium. (Background included in documentation provided to Duke.) Recognition of the compendial authority of AHFS has extended over 4 decades.

ASHP holds in high regard the responsibilities attendant to the public and private trust placed in the evidence-based editorial deliberations of AHFS DI. As such, ASHP also considers it essential to protect the integrity and independence of the editorial decisions of AHFS staff by separating the Society's business activities with pharmaceutical manufacturers (e.g., exhibits at educational meetings, journal advertising) from the editorial activities of its drug compendium. Interactions between AHFS staff and pharmaceutical manufacturers are limited to the legitimate exchange of the scientific and medical information needed to fulfill the mission of AHFS DI. Communications are directed to the scientific and medical information areas within the companies; contact with marketing areas is avoided. An editorial independence statement (included in documentation provided to Duke), approved by ASHP's Board of Directors, outlines the principles that AHFS staff apply in ensuring such independence.

ASHP recognizes the challenges of the resource-intensive process involved in conducting evidence-based therapy assessments and remains committed to its vision of fostering evidence-based medication use and publishing its highly regarded drug compendium. The recent loss of USP's evidence-based development process for antineoplastic therapy has prompted the Society to explore opportunities for enhancing its own consideration of such uses via AHFS DI. The codified AHFS evidence rating system that makes use of levels of evidence to reflect strength and quality of existing data as well as recommendation grades is a major initiative aimed at enhancing this effort. As a nonprofit, professional practice and scientific society, resources needed to support such efforts remain a challenge, but our commitment to promoting rational drug therapy through compendial considerations remains steadfast. ASHP remains ready to continue to assist CMS through the Society's authoritative AHFS DI drug compendium in making determinations of medically accepted indications for drugs and biologicals used in anti-cancer chemotherapeutic regimens under Part B of Medicare.

To this end, ASHP continues to work with other nonprofit professional practice and scientific societies such as the Association of Community Cancer Centers (ACCC), American Society of Clinical Oncology (ASCO), American Society of Hematology (ASH), Oncology Nursing Society (ONS), and others in refining its evidence rating system described in the background information provided to the Duke Center for Clinical Health Policy Research.

Appendix B

■ Editorial Independence of AHFS Drug Information

Approved by the American Society of Health-System Pharmacists Committee on Publications and Board of Directors

The mission of *AHFS Drug Information* (*AHFS DI*) is to provide an evidence-based foundation for safe and effective drug therapy. Information included in *AHFS DI* shapes treatment decisions made by clinicians and influences public and private health care policy and decisions. As a result, it is important that the information be authoritative, objective, and free of undue influence from pharmaceutical manufacturers, health insurers, pharmacy benefits managers, and other third parties who may seek to use the compendium to promote their own vested interests. Editorial decisions are evidence-based and made independent of such third parties; final decisions are made solely by the AHFS editorial staff, taking into account the advice of expert reviewers.

Widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers, *AHFS DI* has remained true to its mission for almost 50 years.

AHFS DI is the only remaining official drug compendium published by a non-commercial entity (i.e., by a tax-exempt ["nonprofit"] professional association). The American Society of Health-System Pharmacists (ASHP) is an IRS 501(c)(6) tax exempt entity. ASHP is the national professional association that represents pharmacists who practice in inpatient, outpatient, home-care, and long-term-care settings. ASHP has a long history of fostering evidence-based medication use as well as patient medication safety—efforts designed to help pharmacists improve their delivery of pharmaceutical care.

AHFS DI is published by ASHP under the authority of its elected Board of Directors. As such, the Board exercises oversight through its ongoing Society considerations as well as through its Committee on Publications. This oversight by the Board also involves review and approval of relevant recommendations originating from its appointed Commission on Therapeutics and the advisory and best practices developments of its Councils, House of Delegates, and other policy-recommending bodies.

In addition, hundreds of experts, principally physicians but also other clinicians, leading medical scientists, pharmacists, pharmacologists, and other professionally qualified individuals, participate in an ongoing extramural review process for *AHFS DI*. Participation is solicited but voluntary, and no honorarium nor other benefit (e.g., complimentary subscription) is provided. These experts must provide full disclosure of interest, including any affiliation with or financial involvement in the manufacturer of the drug(s) under consideration and directly competitive products.

ASHP considers it essential that interactions between AHFS and pharmaceutical manufacturers be limited to the legitimate exchange of the scientific and medical information needed to fulfill the mission of *AHFS DI*. To maintain independence from the undue influence of the promotional interests of pharmaceutical manufacturers, communications are directed to the scientific and medical information areas within the companies; contact with marketing areas is avoided.

ASHP holds in high regard the responsibilities attendant to the public and private trust placed in the evidence-based editorial deliberations of AHFS. As such, ASHP also considers it essential to protect the integrity and independence of the editorial decisions of AHFS staff by separating the Society's business activities with pharmaceutical manufacturers (e.g., exhibits at educational meetings, journal advertising) from the editorial activities of its drug compendium. AHFS staff apply the following principles of editorial independence in weighing the propriety of their conduct.

1. AHFS staff should avoid participating in business discussions with pharmaceutical manufacturers and other ASHP staff should avoid engaging AHFS staff in such discussions.

2. AHFS staff must disclose any potential financial conflicts of interest or other external activities that may affect their editorial decisions on specific drugs. AHFS staff should not hold financial interests that conflict or may influence the conscientious performance of their editorial duty.

3. AHFS staff may not solicit or accept any gift or other item of monetary value from any individual or entity seeking official action or influence from the compendium nor from those whose interests may be substantially affected by the performance or nonperformance of the staff's editorial duties.

4. AHFS staff have an obligation to act impartially and not give preferential treatment to any interested individual or organization that might influence their editorial decisions.

5. AHFS staff should avoid actions that might create the appearance that they are violating these principles of ethical conduct and editorial independence. Any such behavior shall be judged from the perspective of a reasonable individual in a similar situation with knowledge of the relevant facts. When necessary, the expert advice of other staff (e.g., professional practice, corporate counsel) should be sought.

6. On occasion, ASHP may determine that the Society's interest in the staff's participation in a particular activity or discussion outweighs any concern that a reasonable individual might question the integrity of the activity.

7. AHFS staff members with questions about their activities that are not addressed by these principles on editorial independence shall refer their questions to the Vice President of Publishing and Editor of AHFS.

APPENDIX C
Overview of AHFS DI HCFA Review Process

The mission of AHFS Drug Information (DI) is to provide an evidence-based foundation for safe and effective drug therapy. AHFS DI is widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers. AHFS DI is one of the three Compendia listed under Section 1861(t)(2)(B)(ii)(I) of the Act that may be used in determining the medically accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen.

In January 1989, HCFA began developing regulations to implement section 202 of the Medicare Catastrophic Coverage Act of 1988 aimed at establishing standards for prescribing outpatient drugs based on accepted medical practice. In establishing these standards, HCFA required ASHP to describe the extent to which AHFS DI met each of the criteria outlined in the Congressional Conference Report relating to the legislation.

HCFA was required by Congress to designate as official only those compendia that based such medical practice standards on review of published scientific and medical information, that provided for a public comment and review process, and that provided adequate assurances that the panelists who establish standards were free of financial (or other) conflicts of interest.

In March 1989, ASHP participated in a public hearing conducted by HCFA's Bureau of Eligibility, Reimbursement, and Coverage on the use of authoritative compendia to determine prescribing standards for the new Medicare outpatient drug coverage.

In September 1989, HCFA published its determination that AHFS DI, along with AMA-DE and USP DI, met the selection criteria as an official compendium in the Federal Register, and requested public comment, thus subjecting its determination to broad-based public scrutiny.[1]

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[1] Federal Register, Vol. 54, No. 172, Thursday, September 7, 1989, 37190, Medicare Program; Catastrophic Outpatient Drug Benefit; Proposed Rule.

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August 31, 2007

Mr. Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Room 455-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington D.C. 20201

Re: Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P)

Dear Mr. Kuhn:

The American College of Radiation Oncology ("ACRO") is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P).[1] With a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology.

ACRO would like to extend its appreciation for the opportunity to comment on the proposed regulations. This letter will comment on the following sections:

- Sustainable Growth Factor, Budget Neutrality and Work RVUs & Resulting Cuts in Reimbursement
- Malpractice RVU Assignment Methodology
- Imaging Provisions in the Deficit Reduction Act
- Equipment Usage Percentage & Equipment Interest Rate
- Independent Diagnostic Treatment Facility Issues
- Physician Self-referral Provisions
- PQRI: Timetable & Commentary on Specific Measures

[1] Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P). *Federal Register*, Volume 72, No. 133, July 12, 2007, p. 38121.

A. **IMPACT: Sustainable Growth Factor, Budget Neutrality and Work RVUs & Resulting Cuts in Reimbursement**

The sustainable growth calculation (SGR) methodology continues to be a flawed system for compensating physicians. In order to preserve beneficiary access to care, physicians must receive annual updates that reflect practice expense increases. Inflation affects us each year as we must pay more for office space rent, professional liability insurance and staff salaries. Managed Medicare plans often require preauthorizations that were not previously required for Medicare patients; adding an additional staffing burden that physicians have incurred over the last few years. ACRO continues to support alternative solutions to the budget neutrality provisions. Medicare must develop a system that fairly compensates physicians and accounts for the actual cost of caring for our patients. **ACRO believes that the SGR should be repealed and replaced with an updated system that reflects increases in costs.**

For 2007, both the Relative Value Update Committee (RUC) and CMS have found compelling evidence to increase many evaluation and management (E & M) codes. Further increases are proposed for 2008 on additional evaluation and management codes. ACRO recognizes the need to fairly value all codes. However, we continue to be concerned that the appropriate changes to selected E & M codes trigger the need to implement an additional budget neutrality provision – in 2008, there will be a further decrease to all work RVUs.

While applying the reduction across all work RVUs maintains the relative relationship between codes, it undermines the provision of fair compensation for services. Furthermore, the now almost 12% reduction to all work RVUs disproportionately disadvantages those physicians that practice in a facility setting, where most income is derived from the work component of compensation. ACRO is concerned that this solution (triggered by the budget neutrality provision) penalizes many physicians instead of otherwise correcting undervalued codes. ACRO would support a more appropriate action to provide CMS with adequate funding for correct valuation of codes without reducing valid and necessary compensation for other codes.

B. **MALPRACTICE: Malpractice RVU Assignment Methodology**

CMS has expressed a willingness to examine the issues that arise when the technical component (TC) malpractice RVU assignment is greater than the professional component (PC) malpractice RVU. The proposed rule requests input on possible actions that can be taken when this situation occurs. ACRO would consider supporting a recommendation to make the TC and PC RVUs equivalent where the PC RVU is less than the TC RVU. This would appropriately compensate for the professional liability insurance that is required. **ACRO opposes any policy that would make the TC malpractice value zero, since there are clearly identifiable malpractice expenditures associated with allied health professionals working in radiation oncology.** Specifically, medical physicists carry liability insurance and are included in the TC RVU valuation. ACRO is willing to evaluate other proposed methodologies that address the current inequities and methodological problems.

C. **Imaging Provisions in the Deficit Reduction Act**

ACRO continues to oppose provisions of the Deficit Reduction Act (DRA) as it is broadly interpreted to include critical components of radiation therapy – the process by which clinicians assure that radiation delivery is targeted to the tumor specifically. The discipline of radiation oncology provides several DRA-subject services only when radiation therapy is delivered and believes that such services should not be considered comparable to traditional diagnostic imaging services. For example, CPT code 76873 - prostate volume ultrasound for brachytherapy planning is only used when planning the treatment for radioactive seed implantation. It is not a diagnostic imaging code, but rather a critical component of cancer treatment. **ACRO continues to object to the broad interpretation of the Deficit Reduction Act as it now includes visualization techniques that are critical components of treatment delivery, not diagnosis.**

As DRA issues are addressed, CMS should reiterate how it intends to handle DRA listed codes when there is now no hospital outpatient payment to be compared against. ACRO understands that, absent any established hospital outpatient payment for a specific code, the comparison of technical component reimbursement with the hospital outpatient reimbursement will not be performed.

D. **RESOURCE-BASED PE RVUS: Equipment Usage Percentage & Equipment Interest Rate**

CMS has postponed the development of equipment use rates at this time, citing the need for additional empirical evidence before proceeding. ACRO appreciates the challenges faced by CMS in developing mutually exclusive categories in order to establish category specific equipment use rates. We support the use of a sound methodology in developing specific equipment use rates. ACRO encourages the consideration of methodologies that would capture differences in patient access based on whether the community served in rural, suburban or urban. Specifically, radiation oncology treatment delivery requires that patients receive care five days a week for many weeks. The treatment itself can be debilitating and excessive drive times should be avoided. ACRO believes that ready patient access, without major inconvenience, is critical to maintaining patient compliance with this life saving treatment. Cancer patients should not be forced to drive an inordinate distance in order for access to appropriate radiation therapy.

Furthermore, radiation therapy differs significantly from diagnostic imaging in the need for ongoing, continuous care. It may be acceptable to Medicare that a one time, diagnostic test requires considerable patient travel. However, ACRO believes that considerable travel for ongoing daily treatment should be avoided, not only due to patient access but quality care and cost efficiency. A patient that does not complete his or her treatment regime due to burdensome travel requirements will likely increase Medicare expenditures and lower quality of care. CMS should consider developing equipment use rates that vary with population density to be sure that all Medicare patients have reasonable access to equipment. **Until such time, ACRO agrees that no action should be taken to change the equipment utilization percentage until data is collected and the full impact is evaluated.**

ACRO also supports the continued use of eleven percent as an appropriate equipment interest rate.

E. RESOURCE-BASED PE RVUS: Continued Decline in CPT 77366

The "bottom up" practice expense methodology is currently in its second year of implementation. The CPT code 77336 continues to decline dramatically. ACRO is concerned that this decline could be a result of incorrect practice expense inputs for this continuing medical physics consult code. As the complexity of radiation therapy has grown over the last five years, the work effort of the medical physicist has also increased. **ACRO encourages CMS to review the practice expense inputs for this code to ensure that adequate reimbursement is established.**

F. IDTF ISSUES

CMS has expanded the independent diagnostic testing facilities performance standards. **The additional IDTF standards support the provision of good patient care and are supported by ACRO.**

G. PHYSICIAN SELF-REFERRAL PROVISIONS:

ACRO shares CMS' concerns that the breadth of the Stark Law "in-office ancillary services exception" ("IOAE") has permitted the exception to be used in a manner that extends well beyond Congress' original intent, and that it has led to abuse. We appreciate the opportunity to echo those concerns as CMS considers possible modifications to the IOAE designed to prevent abuse and restore application of the IOAE to the proper circumstances intended by Congress.

CMS has noted in particular that "services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice" as was contemplated originally by Congress in enacting the IOAE.[2] According to CMS, for example, Stark Law designated health services ("DHS") may be provided by staff that have virtually no relationship to the group practice, particularly when such services are furnished in a "centralized building" remote from the group practice location, but potentially even when provided in the same building. CMS also notes the proliferation of "turn-key" arrangements marketed to "nonspecialist" physicians under which such physicians purchase specialized equipment and acquire the right to bill for the lucrative technical component simply by hiring a specialist as an independent contractor to provide the professional service. ACRO shares CMS' concern that such arrangements extend beyond the original purpose of the IOAE and instead "appear to be nothing more than enterprises established for the self-referral of DHS."

As noted in the August 20, 2007 comment letter submitted to CMS by the American Society for Therapeutic Radiology and Oncology, Inc. ("ASTRO"), a particularly egregious form of IOAE abuse has emerged in the form of for-profit companies that market turn-key Intensity Modulated Radiation Therapy ("IMRT") operations to urologists. These arrangements typically involve the following features:

- A for-profit company will target the premier urology group in a community and offer to provide a "turnkey radiation oncology service" offering only IMRT services for prostate cancer patients. While a typical comprehensive radiation treatment center may offer its prostate patients a full range of radiation therapy treatment options, including low and high dose brachytherapy or seed implantation, radionuclide therapy, and stereotactic radiosurgery, this turn-key model results in the urologist offering only IMRT for his or her patients.

[2] 72 Fed. Reg. at 38181.

- The for-profit "pitch" will emphasize the increase in revenues the urology group will attain by capturing these referrals within the group's business structure. The pitch may also include an opportunity for the physicians to joint venture in an equipment leasing company which will lease the IMRT equipment "to" the group.

- The company will "recruit" a radiation oncologist – usually from an existing radiation oncology center – to provide the radiation therapy services for the urology group. Radiation oncologists from local/regional facilities in danger of volume reductions secondary to the new site development may be coerced into employment arrangements that would otherwise not have been considered.

- The radiation therapy services typically will be set up in a "centralized building" location remote from the urology practice. The radiation oncologist and his/her technical staff will function separate and apart from the group on a day-to-day basis with little or no integration of the physicians, staff, or services.

- The urology group benefits from the revenue flowing from its referrals. The for-profit company may share in those revenues directly and/or through its share of equipment leasing fees, as well as through a management fee.

As noted by ASTRO, such arrangements can lead to over-utilization, higher costs, reduced patient choice, and the potential for lower quality care. There is anecdotal evidence to suggest that mega-urology groups are being formed for the express purpose of aggregating sufficient IMRT referral volume to justify the acquisition of IMRT equipment.

While these concerns already appear well-placed and warrant prompt corrective action, ACRO understands that CMS does not yet propose specific changes to the IOAE. Instead, CMS has asked for input on, among other things, whether certain DHS should qualify for coverage under the IOAE, and whether certain non-specialists should be able to use the exception to refer patients for specialized services provided by specialists and involving the use of equipment owned by the non-specialists, or whether other reforms may be in order. As providers of the specialized service of radiation oncology, ACRO's members are pleased to respond to these inquiries.

ACRO supports CMS' consideration of rule amendments designed to curb abuses of the IOAE that extend beyond its intended purpose and scope. ACRO looks forward to working closely with CMS to develop targeted reforms that eliminate abusive arrangements like that described in this letter without creating unintended consequences that may adversely affect legitimate and beneficial arrangements. **In particular, ACRO believes it is important to address the identified abuses in a manner that preserves the following salutary arrangements (potentially among others):**

- **The ability of radiation oncologists to furnish radiation therapy services to patients who "self-refer" to radiation oncologists;[3].**

[3] CMS previously has recognized that patients from time to time will "refer" themselves to radiation oncologists. To the extent radiation oncologists are unable to take advantage of the "consultation" exception to the Stark Law definition of "referral," they need to rely on the IOAE in order to furnish radiation therapy services to such self-referred patients. See 69 Fed. Reg. 16054, 16066 (March 26, 2004).

- **The ability of medical and radiation oncologists to refer to each other as is medically appropriate within a bona fide group practice offering comprehensive oncology services in an integrated oncology care setting.**

Again, ACRO appreciates the opportunity to comment on the current state of the Stark Law IOAE and to participate in the development of appropriate and targeted IOAE modifications that will eliminate abuses while preserving legitimate IOAE protections.

H. PQRI: Timetable

ACRO has been an active member of the Oncology Work Group. This Group has developed proposed measures through the open, consensus driven, AMA Consortium process. The proposed measures are in the public comment period today and can be viewed at: http://www.ama-ssn.org/ama/noindex/ category/4397.html. ACRO believes that the Oncology Workgroup indicators currently being finalized contain improved measures applicable to radiation oncology and other oncology care practices. ACRO believes that the establishment of these indicators is important to the further support of quality oncology care. ACRO is concerned that the deadlines established in the proposed rule allow little leeway for indicators currently under development. **ACRO strongly supports a dynamic review process that allows measures currently in the public comment period to be adopted for 2008.**

ACRO urges the Administration to access the $1.35 billion Physician Assistance and Quality Initiative Fund to help offset the negative 2008 payment update. Financing for quality reporting should come from a distinct, separate financing mechanism that is outside of the budget neutrality provision and focused solely on the improvement of health care quality.

I. PQRI: Commentary on Specific Measures

ACRO supports modifications should CMS wish to continue using the existing indicator 74 – Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery. We have sent a separate letter to the AMA Consortium outlining these same concerns. At this time, ACRO wishes to take this opportunity to share its observations with CMS regarding the existing indicator 74. The current definition of CPT codes requires that the breast cancer patient be seen by the radiation oncologist as a consult – a referral from one physician to another. ACRO supports expanding the CPT code definition to include those patients that self-refer to a radiation oncologist. As CMS is aware, oncology patients are increasingly active participants in their own medical decision-making and care. This self-advocacy often leads to patients seeking additional input from physicians, outside of the physician immediately managing the clinical care especially in circumstances where a variety of treatment choices exist and patients seek opinions (and management) from a variety of specialists. ACRO supports patient self-advocacy and encourages patients to seek appropriate care and second opinions where needed. Physicians providing this care should be able to participate in the PQRI program as well. Therefore, **both physician directed consultations and patient sought "consultations" should be included in the PQRI data capture.**

ACRO recommends a second change to indicator 74 – Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery. Currently, many patients are receiving their radiation oncologist consultation **in advance** of undergoing breast surgery (other than core or fine needle aspiration biopsy for the establishment of a diagnosis). This allows the patients to make a more educated decision not only about the surgical options but also about the follow up care offered post surgery. As indicator 74 is currently configured, those patients seeing a radiation oncologist in advance of definitive breast surgery fall

in the generic category of G8378 – Clinician documented that the patient was not an eligible candidate for radiation therapy measure. **ACRO encourages the development of a fourth G code to be used when radiation therapy is recommended in advance of definitive surgery.** This change would better reflect the advanced clinical care being provided across the country.

Conclusion

ACRO's comments on the Physician Fee Schedule regulations seek to ensure ongoing access to radiation oncology services. Maintaining patient access is crucial since our patients often require services five days a week for many weeks of life saving therapy. Patient accessibility and continuity are key components of service quality. ACRO appreciates the opportunity to comment on the regulations. We hope that our comments highlight our sincere interest in making radiation oncology services cost effective, properly reimbursed and readily accessible to cancer patients. We look forward to meeting with CMS in the near future.

Sincerely,

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AMERICAN MEDICAL RESPONSE

August 31, 2007

Herb B. Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20021

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and other Part B Payment Policies for CY2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Dear Mr. Kuhn:

American Medical Response ("AMR") appreciates the opportunity to comment on the above-referenced CMS Proposed Rule (the "Proposed Rule"). AMR is the largest ambulance supplier in the country, providing emergency and non-emergency medical transportation to 4,000,000 patients annually in 36 states. As the 911 provider in hundreds of communities throughout the United States, we are a vital part of the nation's healthcare delivery system.

We will comment on the provisions of the Proposed Rule entitled "Beneficiary Signature" and "Geographical Price Cost Indices."

BENEFICIARY SIGNATURE

AMR appreciates that CMS has attempted to address the significant burdens faced by emergency ambulance suppliers and providers (collectively, "providers") in attempting to comply with the current beneficiary signature requirements found in 42 CFR Section 424.35(b) and applicable manual provisions. Unfortunately, however, one of CMS's proposed changes to this regulation would substantially increase, rather than decrease, those burdens. For the reasons below, we request that CMS modify this regulation to entirely eliminate the requirement for a beneficiary signature for all emergency transports. If CMS declines to do so, we recommend as an alternative, that CMS delete the proposed new requirement for a statement by a representative of a receiving facility. We also recommend that CMS permit ambulance providers to rely upon the signature on file at either the sending or receiving hospital in lieu of requiring the provider to obtain a signature in its own records. This proposed change would apply to all transports for which a signature is required.

We will elaborate upon each of these proposals below.

1. **The Requirement for a Beneficiary Signature Should be Eliminated for All Emergency Ambulance Transports.**

CMS proposes to maintain the current requirement for a beneficiary or representative signature for emergency transports, with an exception for situations where the beneficiary is unable to sign and there is no representative available to do so. AMR respectfully submits that the requirement for beneficiary signatures should be entirely eliminated for all emergency transports because (a) requiring such signatures serves no material purpose; and (b) it is unfair and inappropriate to require either patients or their representatives to sign documentation in an emergency situation. CMS has recognized the latter point in creating blanket exemptions from signature requirements in emergency situations under the rules governing the HIPAA Notice of Privacy Practices and Advance Beneficiary Notices.

a. Requiring Beneficiary Signatures for Emergency Transports Serves No Purpose.

Traditionally, there have been three primary purposes for requiring beneficiary signatures prior to the submission of a claim by healthcare provider:

- To authorize the assignment of benefits to the provider;
- To authorize the release of information by the provider (and other providers) to CMS and its contractors; and
- To promote program integrity by providing evidence that the beneficiary received the service.

Recent changes in the law render the first two of these purposes moot and, with respect to the third, the existence of a signature provides no material program integrity benefit.

Assignment of Benefits. As a result of the Medicare Ambulance Fee Schedule rule which became effective April 1, 2002, ambulance claims are now subject to automatic and mandatory assignment. Further, as part of the 2005 Physician Fee Schedule Rule enacted (67 Fed. Reg. 6236), CMS eliminated the requirement that beneficiaries assign claims to a healthcare provider or supplier in those situations where payment may only be made on an assignment-related basis. See 42 CFR Section 424.55(c). Therefore, a beneficiary signature is no longer required to effect an assignment of benefits to the ambulance provider. See also CMS Claims Processing Manual (Pub. 100-04), Chapter 1, Section 30.3.2.

Release of Information. Similarly, a beneficiary signature is no longer required to release medical records to the carrier or other Medicare agency. Regulations adopted under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") eliminated the need for a patient's signature in order for a provider to release such records. Specifically, 42 CFR Section 164.506(c)(3) permits ambulance providers and other "covered entities" to release

protected health information, without patient authorization or a signature, for payment purposes, as well as for treatment or healthcare operations.

Program Integrity. Requiring a patient's signature does not serve, in any material way, program integrity purposes. For every transport of a Medicare beneficiary, the ambulance crew completes a trip report listing the condition of the patient, the treatment rendered, the original destination and other information. Furthermore, the origin and destination facilities complete their own records, documenting that the patient was sent via ambulance or arrived via ambulance, with the date and time. The existence of this documentation obtainable from three separate sources – the ambulance provider, the sending facility, and the destination facility – would provide ample evidence to CMS, the OIG or any investigating agency that a trip has been performed. Requiring the patient or representative to provide a signature and the ambulance provider to self-report the existence of that signature provides no appreciable program integrity benefit whatsoever.

Thus, requiring patient signatures serves none of the traditional purposes underlying the current rule.

b. It is Unreasonable and Inappropriate to Require Beneficiaries or their Representatives to Sign Documentation in Emergency Situations.

The realities of providing emergency ambulance services underscore why beneficiary and representative signatures should not be required in this situation. A typical emergency ambulance patient encounter involves the chaotic scene of an automobile accident, shooting, heart attack or other traumatic incident, where patients are distraught and agitated, even if not fully incapacitated, and any representatives are frequently in a similar state of mind. Under these circumstances, it is unfair and inappropriate to require patients or their representatives to review and sign documentation.

It is for precisely this reason that CMS actually *prohibits* providers from obtaining a signature from beneficiaries or their representatives on ABNs in emergency situations. Specifically, current CMS rules provide as follows:

> "An ABN should not be obtained from a beneficiary in a medical emergency or otherwise under great duress (i.e., when circumstances are compelling and coercive) since that individual cannot be expected to make a reasoned, informed consumer decision. In genuine emergencies, the beneficiary/victim and his or her family/friends (authorized representative) are under great duress, by the emergency circumstances, ***to sign anything*** in order to obtain help."
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> Medicare Claims Processing Manual (Pub. 100-04), Chapter 30, Section 40.3.7 (emphasis added).

HIPAA also contains a blanket exception applicable to emergency situations. Although HIPAA does not require a patient or representative signature to release protected health information, it does require patients or their representatives to sign an

acknowledgment of receipt of the mandated Notice of Privacy Practices. However, the Department of Health and Human Services ("HHS") included an exception to this requirement for "emergency treatment situations," which includes emergency ambulance transports. See 42 CFR Section 164.520(c)(2)(ii). HHS recognized that requiring a signature from either patients or their representatives in such situations would impose unreasonable and unnecessary burdens on both the provider and the beneficiary.

If patients and their representatives are deemed unable to sign an ABN or a HIPAA acknowledgment during episodes of emergency treatment, they should be deemed similarly unable to provide a signature under 42 CFR Section 424.35(b). Identical logic would apply to execution of any of these documents.

We recognize that CMS may not want to eliminate the requirement for signatures in emergencies for all providers and treatment settings. We believe, however, that creating an exception solely for emergency ambulance providers is justified by the special circumstances faced by such providers and their patients. Even under the best of circumstances, where a patient may not be seriously injured and representatives may be relatively calm, the scene of an emergency ambulance response is an inconvenient venue in which to complete paperwork or obtain a signature. There is no waiting room or registration area, nor are there admitting personnel to explain the legal jargon or paperwork the signature rules require them to sign. In short, unlike most other treatment settings, there is no place or opportunity for patients or their representatives to review what they are asked to sign, let alone to sign it.

2. **In the Event CMS Declines to Eliminate the Signature Requirement for Emergency Ambulance Services, the Proposed Rule Should be Amended to Eliminate the Requirement for a Statement from the Receiving Facility.**

The Proposed Rule would create a new exception to the beneficiary signature requirements specifically applicable to emergency ambulance transport services. The new exception essentially duplicates parts of the existing exception found in CMS Benefit Policy Manual (Pub. 100-02), Chapter 10, Section 20.1.2 and the Medicare Claims Processing Manual (100-04), Chapter 1, Section 50.1.6(a)(3)(c). However, it adds requirements for the provider to obtain and maintain certain additional information and documentation. Specifically, the provider must obtain and maintain for four years after the date of service the following:

- A contemporaneous statement from an ambulance employee present during the transport, stating that the beneficiary was physically or mentally incapable of signing, and that no other authorized person was available or willing to sign the claim on the beneficiary's behalf;
- Documentation providing the date and time of the transport, and the name and location of the receiving facility; and
- A contemporaneous statement from a representative of the facility, which documents the name of the beneficiary and the date and time the beneficiary was received by the facility.

The first of these requirements already exists in current rules, which require a representative of the provider to document that the beneficiary was physically or mentally incapable of signing, and that no other authorized person was available or willing to sign on his or her behalf. The second requirement is not currently found in the signature rules, but is not problematic because all ambulance providers obtain and maintain information regarding the date and the time of the transport, as well as the name and location of the receiving facility, for each and every transport.

However, the third requirement is entirely new and highly problematic. This new requirement would compel ambulance providers to obtain a signed statement from a hospital employee. Hospital emergency department personnel already are required to complete extensive documentation and should not be required to take on an additional administrative task which in no way enhances or improves patient care. Imposing this additional (and unnecessary) burden on them will exacerbate the current problems caused by overcrowding in hospital emergency departments. We note that the recent Institute of Medicine Committee Report on the Future of Emergency Care recommended that hospitals find ways to improve efficiency in order to reduce emergency department overcrowding. This new requirement would fly in the face of that recommendation.

3. **Ambulance Providers Should be Permitted to Rely Upon a Signature On File in the Sending or Receiving Health Facility.**

For reasons discussed above, requiring ambulance providers to obtain a patient's signature imposes extreme burdens on the provider and the beneficiary or representative. Unlike a hospital, nursing home, physician's office and most other treatment settings, ambulance providers have no admission office, waiting room or other convenient venue in which a signature can be obtained. Moreover, the circumstances surrounding an ambulance transport make it impractical for providers to obtain patient or representative signatures. This is the case for both emergency and non-emergency transports.

Therefore, for those situations in which CMS ultimately decides to require a signature (we hope this will be only for non-emergency transports), AMR proposes that ambulance providers be permitted to rely upon the signature on file in either the sending or receiving health facility. Almost all ambulance transports are either to or from a health facility. These facilities typically obtain the beneficiary's or representative's signature at the time of admission. The form used by most facilities typically includes language indicating that the signature covers the services rendered by or in the facility, and "any related services." This language is viewed by CMS as covering services rendered by physicians and ancillary service providers in the health facility, even though those services are not rendered by the facility or its employees. We believe it would constitute a small and reasonable extension of CMS's current interpretation of this language if it were deemed as also covering an ambulance transport to or from the facility. Ambulance services provided to or from a facility clearly are a "related service" in this context.

GEOGRAPHICAL PRICE COST INDICES

While AMR recognizes the statutory requirement for CMS to update the geographical price cost index (GPCI), we strongly oppose any reduction in Medicare reimbursement for ambulance service providers which could have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The reductions in reimbursement resulting from the proposed changes in the GPCI is in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled, "Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly" (GAO-07-383). That report determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services. The shortfall is 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services, particularly in super rural areas. We believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affected by the changes in the GPCI. We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers, while ensuring that those providers who would benefit from the changes receive the proposed increases which are desperately needed.

CONCLUSION

In closing, AMR strongly urges CMS to completely eliminate the requirement for a patient or representative signature for all emergency ambulance transports. As CMS has recognized in connection with the HIPAA and ABN rules, this requirement imposes unnecessary and unreasonable burdens on beneficiaries and their representatives at a time when they are under duress. Further, there is no reason to impose this requirement, since signature is not required to effect an assignment of benefits nor is it required for the release of medical information. Moreover, the signature serves no appreciable program integrity purpose, given that ambulance providers and the health facilities to or from which they transport patients maintain voluminous documentation that a transport has occurred.

In the event CMS declines to eliminate the patient signature requirement entirely, we urge the agency to eliminate the proposed new requirement for a statement by the receiving facility. This requirement will impose impossible burdens on ambulance providers, who will not be able to compel hospital personnel to provide the required statement. To the extent hospital personnel are willing to comply, this requirement would distract them from their important patient care duties and exacerbate current emergency department over-crowding problems.

For those transports for which CMS ultimately requires a signature (hopefully, only non-emergency transports), we urge the agency to permit ambulance providers to rely upon a signature on file in a sending or receiving facility.

Finally, we recommend that CMS revise the GPCI provisions in the Proposed Rule to mitigate the adverse impacts it would have on some providers.

Thank you for consideration of our views. If you or your staff should have any questions regarding our comments, we would be happy to provide further information.

Very truly yours,

Executive Vice President

Government & National Services

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August 31, 2007

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Re: Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P)

Dear Mr. Kuhn:

The Florida Medical Association ("FMA") is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P).[1]

The FMA is a professional association representing more than 16,000 physicians on issues of legislation and regulatory affairs, medical economics, public health, education, and ethical and legal issues assistance. The FMA also advocates on behalf of physicians and their patients to promote the public health, to ensure high standards in medical education and ethics, and to enhance the quality and availability of health care. FMA would like to extend its appreciation for the opportunity to comment on the proposed regulations. This letter will comment on the following sections:

- The Sustainable Growth Rate (SGR)
- Geographic Practice Cost Indices (GPCIs)
- Physician Quality Reporting Initiative
- E-Prescribing

[1] Medicare Program, Proposed Rule, (CMS-1385-P). *Federal Register*, Volume 72, No. 133, July 12, 2007, p. 38121.

A. IMPACT: SUSTAINABLE GROWTH FACTOR, BUDGET NEUTRALITY & RESULTING CUTS IN REIMBURSEMENT

The sustainable growth calculation (SGR) methodology continues to be a flawed system for compensating physicians. In order to preserve beneficiary access to care, physicians must receive annual updates that reflect practice expense increases. Inflation affects us each year as we must pay more for office space rent, professional liability insurance, staff salaries, information technology and other medical equipment etc. In this proposed rule, CMS announced its most recent estimate of a 9.9 percent reduction in the conversion factor from $37.8975 in 2007 to $ 34.1456 in 2008. If these cuts begin on January 1, 2008, average physician payment rates will be less in 2008 than they were in 1995, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service. **Physicians simply cannot absorb these severe payment cuts and, unless CMS or Congress acts, physicians will be forced to reevaluate their relationship with Medicare and will be forced to avoid, discontinue or limit the provision of services to Medicare patients.** The FMA believes that patient access to health care is negatively impacted by the budget neutrality restrictions of the current Medicare physician payment structure. FMA strongly recommends that the SGR be repealed and replaced with an updated system that reflects changing costs of providing the services such as the Medicare Economic Index (MEI).

While we understand that a complete overhaul of the SGR formula is not possible without congressional action, we urge CMS to exercise its authority to make administrative improvements to the Medicare physician payment system. In particular, we strongly recommend that CMS take steps to re-evaluate the assumed geographic differences in the cost of providing services to assure that payments approach the costs of services provided efficiently by physicians. Consistent with the position of the American Medical Association (AMA), we ask CMS to remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula.

We agree with CMS that physicians' decisions are central to the health care their patients receive, and believe that the task of identifying ways to provide better support for utilization decisions is critical to development of a unified approach for improving quality, avoiding unnecessary costs and reducing overall Medicare program expenditures. We commend CMS for the leadership it has shown in working with physicians and other organizations to build a consensus around quality and efficiency measures.

However, the FMA believes that the Medicare health care delivery and payment systems are seriously flawed. The current systems are dangerously fragmented and promote perverse incentives that encourage both the under and over provision of care. It is critical that the Medicare program become more patient-centered and that it recognize the sanctity of the patient-physician relationship. We urge CMS to consider these issues and the resources required to provide quality care by thoughtfully formulating and clearly delineating policies with meaningful quality measures, appropriate incentives and timely reimbursement for demonstrable success.

B. GEOGRAPHIC PRACTICE COST INDICES (GPCIs)

CMS proposes to update the GPCIs to reflect more recent data. We strongly support this endeavor. We are concerned that the data sets used to calculate geographic adjustment of the components of the fee schedule are inaccurate and outdated. Medicare's physician fee schedule, which specifies the amount that Medicare will pay for each physician service, includes adjustments to help ensure that the fees paid in a geographic area appropriately reflect the cost of living in that area and the costs associated with the operation of a practice. This geographic adjustment is a critical component of the physician payment system. An adjustment that is too low can impair beneficiary access to physician services, while one that is too high imposes unnecessary expenditures on the federal government. We believe that there is good reason to be concerned about the appropriateness and accuracy of the geographic adjustments. Despite several attempts, the FMA has not been able to examine the data used to construct the 2008 GPCIs for Florida. Therefore we are unable to verify that the calculations are accurate. Based on our initial research, we have very real reason to believe that they may not be. We strongly urge CMS, through its contractor, to make the underlying source data available to state medical societies.

We will address each of the three components that make up the GPCIs: (1) physician work; (2) practice expense; and (3) malpractice:

➢ PHYSICIAN WORK GPCI

The physician work GPCI was updated in 2001, 2003, and 2005 using data from the 2000 Census. CMS defines physician work as the amount of time, skill, and intensity a physician puts into a patient visit. We contend that there should be no difference in the work of physicians in different locations regardless of where the work occurs. We also believe that the premise underlying the selection of proxies to establish the relative physician resource cost differences among areas compared to the national average in a market basket of goods is fundamentally flawed. One of the basic premises behind the resource based relative value scale as it was originally conceived is that the relative value of physician work should not vary across geographic regions.

The proposed physician work GPCI does not reflect the 1.000 floor mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) for 2006 and extended in the Tax Relief and Health Care Act of 2006 (TRHCA) through 2007. We understand that the agency does not have the authority to extend the work GPCI floor for 2009 and beyond, but we want to express our strong support of the provision in the Children's Health Assistance and Medicare Protection Act of 2007 (CHAMP), passed by the U.S House of Representatives on August 31, which extends the work GPCI floor through 2009. CMS states in the rule on page 47502 of the proposed rule, (GPCI) "Indices were developed that measured the relative physician resource cost differences among areas compared to the national average in a 'market basket' of goods." We believe that payment errors are related to and a function of the miscalculation of relative physician resource cost differences among areas compared to the national average and inadequate data sources.

On page 47503, Table 6 lists the specific occupation categories used in development of physician work GPCI. The work GPCI is based on a national sample of median hourly earnings of workers in six professional categories: engineers, mathematicians, teachers, social workers, registered nurses, and writers. Even though the proxies have been utilized for more than 10 years they have never been validated. The proxies result in the redistribution of Medicare payments across the country, using locality-based measurements that bear no proven relationship to the salaries of physicians. Physician earnings were not used in the calculation of the work adjuster, for the stated reason that physicians derive much of their income from Medicare payments, and an index based on physician earnings would be affected by Medicare's geographic adjustments. The problem with this theoretical construct is that the earnings of non-physicians have nothing to do with the earnings of physicians.

We understand CMS is obligated to implement the provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1989 that called for 25 percent of the cost of living variation across regions to be incorporated within the fee schedule. The FMA believes the current method for implementing the congressionally mandated adjustment is flawed, and believes the work GPCI floor should be maintained. We recognize that any alternative proposals will have both strengths and weaknesses. If the work GPCI floor is eliminated, we urge CMS to explore more accurate methods of making the adjustment for cost of living variation and select the method that produces the least amount of variation across payment localities.

- PRACTICE EXPENSE GPCI

The practice expense (PE) GPCI is developed from three data sources: non-physician employee wages, office rents and equipment and supplies. Below we address the non-physician wages and office rent components respectively.

Non-physician Medicare allowable employee compensation

Employee wage data employed by CMS continue to be based on the 2000 Census. To calculate an employee price adjuster, CMS uses the median hourly earnings of four occupational classes found in physician offices: Clerical Workers, Registered Nurses, Licensed Practical Nurses, and Medical Technicians.

While salary data on these four occupational codes CMS utilizes are conveniently available nationwide, much has changed in medicine since the four occupational codes were selected. Non-physician staff salaries have migrated towards more highly compensated professional staff. As a proxy measure the data do not include or account for the variations in costs related to the most highly compensated employed staff: advanced practice providers, physician assistants, administrators, managers, IT programmers, attorneys, accountants, coding and other specialists – many of whom must be recruited from the national, higher priced, market.

FMA asserts that small differences between proxy measurements and the real cost of providing services leads to large differences in payment to Medicare providers throughout the country. We believe that the failure of proxy measurements to reflect the actual cost of providing services has undermined the accuracy of payments for services in different localities

nationwide. We recommend that CMS revise its employee wage proxy categories to establish more accurate measures of the employee wage costs.

Rent Component

Office rents will be calculated in 2008 using HUD rents in the 50th percentile for the physician office rent proxy. We appreciate CMS's acknowledgement that there is a persistent trend toward higher rents across the country. We feel this is especially true in areas at risk for natural disasters, like the vast majority of counties in the state of Florida. These extra costs must be considered in order to assure there is a sufficient supply of Medicare providers, especially in vulnerable areas.

We feel it absolutely essential for CMS to use a dataset that more accurately captures the cost of commercial rents. In general, the HUD residential proxy for commercial rent adequately captures geographic variation in the price of land. It does not, however, reflect the property tax crisis that Florida physicians face and the property insurance crisis that coastal physicians face. In addition, the GPCI formula fails to consider a critical cost in Florida and throughout the Gulf Coast. Specifically, physicians who are not employed by a health care system must prepare for a hurricane-based interruption. Our estimates indicate business interruption insurance functions as an additional 4-5.5 percent increase in office rent.

The HUD fair market rents increased from 9.1 percent (rest of Florida) to 27.4 percent (Fort Lauderdale) from 2004 to 2007. Our projections show increases for triple-net commercial leases and owner-occupied practices that range from 21 percent to 42 percent. Thus, the 2008 GPCI will fail to compensate the vast majority of Florida physicians for rising office rent.

The failure of the practice expense GPCI to fully capture higher building insurance payments, increasing property tax levies and the current business interruption insurance has a sizeable impact. In fact, our projections show the true Rest of Florida practice expense GPCI could be as high as 104.2 rather than the proposed 93.7.

Without a supplemental appropriation for physicians facing the property tax and insurance crisis, we believe access to physician services will suffer. The proposed PE GPCIs will further induce Florida physicians to stop participating in the Medicare program and potentially result in a shortage of quality providers and reduced patient access.

➢ MALPRACTICE (MP) GPCI

Malpractice premium increases are a major driver in the GPCI increases in the Miami-Dade locality. As mentioned above, the FMA has not been able to examine the data used to construct the 2008 GPCIs for Florida to see how the Miami-Dade malpractice data compare to that of other Florida counties.

➢ PAYMENT LOCALITY STRUCTURE

The Medicare statute requires that physician payments be adjusted for certain differences in the relative costs among areas. CMS has expressed concern about the potential impact of increased variations in practice costs within payment locality boundaries, and has studied potential alternatives for several years. CMS is also concerned about the potential redistributive effects of locality changes, given that by statute; changes must be applied in a

budget neutral manner. The FMA shares CMS' concerns about the redistributive effects of locality changes, and does not support taking from one locality to give to another.

However, as demonstrated by the U.S. House of Representative's passage of the Children's Health Assistance and Medicare Protection Act of 2007, member of Congress are willing to dedicate new monies to resolve the GPCI problem in California. The FMA believes that this philosophy, i.e. forgoing budget neutrality, should be extended to any and all necessary country-wide, GPCI improvements.

The agency has identified possible locality reconfigurations to be adopted for California in this proposed rule. CMS would like to study the impact of such a change in California before considering applying the policy more broadly. We feel that although this may be a worthy endeavor, it is premature to consider expanding any of the three options under consideration for California nation-wide given the serious inadequacies of the data used to calculate geographic differences in physician work and office practice expense.

Clearly, proposed options 1 and 2 will not provide any assistance to counties in Florida. These options are based on the premise that "if a county geographic adjustment factor (GAF) is more than five percent greater than the GAF of the locality in which the county resides, it would be removed from the current locality." Florida has no counties that meet this criterion, and only one county (of 67) -- Miami-Dade in locality 04) whose county GAF is greater than five percent above the other county's GAFs. Therefore neither of these options is applicable to Florida. Option 3 involves an interesting concept: grouping counties within a state into localities based on similarity of GAFs even if the counties are not geographically contiguous. We believe many of the current Florida locality groupings were created for administrative convenience, and may in fact, be to the detriment of Florida physicians. Assuming CMS can identify valid data and measurements for physician work, practice and malpractice expenses, we believe localities should be established based on practice costs and not dictated by which option is the least administratively burdensome for CMS.

C. <u>PHYSICIAN QUALITY REPORTING INITIATIVE</u> TRHCA SECTION101(b): PQRI

FMA urges the Administration to access the $1.35 billion Physician Assistance and Quality Initiative Fund to help offset the negative 2008 payment update. Financing for quality reporting should come from a distinct, separate financing mechanism that is outside of the budget neutrality provision and focused solely on the improvement of health care quality.

We believe that its decision to apply the $1.35 billion available in the Physician Assistance and Quality Improvement Fund to buy down the deleterious effects of the 9.9 percent payment cuts scheduled to take effect Jan. 1, 2008 is counter to the intent of Congress and the recommendation of the Medicare Payment Advisory Commission. CMS should overcome the "legal and operational" problems associated with applying the funds to the negative update, as the dire situation posed by the harmful cuts surely prevails over the administrative hurdles. For example, CMS could explore applying the $1.35 billion to past year's SGR debt.

FMA's members are committed to achieving excellence in care for all of their patients. We commend the dedicated and competent CMS staff that has worked diligently to implement a system for reporting data on quality measures area, as required by the statute. FMA is

concerned however, that the process for developing the 2008 Physicians Quality Reporting Initiative (PQRI) is advancing despite the very short time the 2007 PQRI has been operational. Furthermore, we are concerned that the program is going forward without any attempt to evaluate the most basic elements of the 2007 PQRI program, such as impact on patient care, physician participation rates, and implementation costs. While we understand that CMS is required by the Tax Relief and Health Care Act of 2006 (TRHCA) to implement the 2008 program, we urge the agency to use its discretion to closely review the 2007 program before moving ahead.

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

D. PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

The E-Prescribing and the Prescription Drug Program final rule published in the November 7, 2005 Federal Register (70 FR 67568) established standards for the electronic transfer of information in the context of the Medicare Part D Prescription Drug Program. CMS correctly recognized that many physicians using electronic medical records (EMRs) did not yet have direct/interfaced e-prescribing functionality, so they exempted computer-generated facsimiles (faxes) from the specific data transfer standards or "scripts".

This allowed the 15-20 percent of physicians using electronic health record (EHR) to continue generating fax prescriptions. The evolution of the process saw written paper, then fax/ printer, computer to fax, and now interactive computers. Pharmacies finally have the capability for those systems. These improvements in technological capability and new standards and programs rendered older systems incompatible with newer ones, and required significant investments to upgrade. Now a very limited number of prescription programs (e.g. SureScripts) have integrated software connecting newer vendor programs to pharmacies. This has created an interfacing challenge for the large number of diverse electronic medical record programs implemented over the last 15 years. CMS now proposes to eliminate the computer-generated fax/prescriptions exemption for ALL provider/dispenser transactions, effective one year from the issuance of the CY 2008 physician fee schedule final rule. This will have a dramatic effect on the industry, but not as CMS intends. In the approximately 18 months since the standardized prescription system was set up, physicians have not kept up with government

expectations in the acquisition of electronic capability, and we estimate that only a small portion of the 15-20 percent already online have interfaced, computer to computer eRx. The disparate timing of pharmacy standards and implementation with the upgrading required by the 150,000 physicians involved makes the current deadline unrealistic. The main barriers for these EHR-legacy practices are cost and change management, including physician/provider relationships with the vendor. Many vendors are no longer in business or were acquired by others, resulting in changes to their programs and accordingly, to maintenance contracts.

In the proposed rule, CMS implies that practices will "revert to paper" (prescriptions) once the exemption is withdrawn. Many practices may very well do so, especially those that handle a significant number of patients requiring Schedule II drugs, as there is still no legal option for electronically transmitting Schedule II drug prescriptions. These offices may in fact choose to use paper for all Medicare beneficiary (and other patient) prescriptions due to administrative and financial considerations. CMS concedes that this can result in data entry errors and may negatively impact patient safety. Also, patients will be burdened with making extra trips to their physicians' offices to pick up their paper prescriptions, which could be detrimental to patient compliance. In CMS' own words, this result would be "counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing." We predict that Medicare providers may follow the example of so many Florida physicians who have decided not to participate in the Medicaid program due to administrative hassles such as this and low reimbursement. We are concerned that opting out of Medicare will become a viable option for providers if CMS attempts to "accelerate" eRx adoption by penalizing those providers who have already made an investment in expensive IT systems.

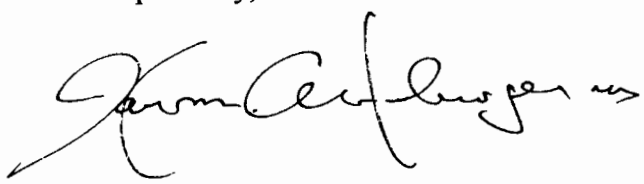
CMS rightfully understands that electronic file scripting will be more efficient, will eliminate mistakes due to illegibility, and will save money with formulary changes. However, the only advantage to the physician is that the file is automatically tied to the chart. Vendors believe that, at best, only 50 percent of practices can be ready by 2009. The Institute of Medicine (IOM) recommended a timeline of 2010. As of yet, no state has addressed the legality of Schedule II drugs in this format either. We suggest that CMS proceed with the late 2008 deadline for computer-generated e-file for newly-installed EMRs. For those Medicare providers with legacy systems, an additional year should be granted to comply with the IOM recommendations. FMA believes this will compel EMR vendors to develop affordable eRx upgrades etc., allow more physicians to make this transition and realize the ultimate financial and safety benefit for their patients.

CONCLUSION

FMA appreciates the opportunity to comment on this proposed rule. As a concerned group of agency constituents, our comments seek to provide CMS with actionable input to help ensure ongoing access to high quality, efficient provision of Medicare services in the state of Florida. We hope that our comments highlight our sincere interest in working with the Agency to ensure care is cost effective, properly reimbursed and readily accessible to Medicare

beneficiaries. Should you have any questions on the items addressed in this comment letter, please contact red Whitson, FMA Director of Medical Economics, 800-762-0233, fwhitson@medone.org.

Respectfully,



Karl M. Altenburger, M.D., President

cc:
Rick Ensor
Edith Hambrick
Stephanie Monroe
Drew Morgan

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PROVIDENCE
Health & Services

August 30, 2007

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

REF: CMS-1385-P

RE: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Dear Mr. Kuhn:

On behalf of Providence Health & Services (Providence), I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to the Medicare Physician Fee Schedule (MPFS). CMS published these changes as part of its Notice of Proposed Rule Making (NPRM) in the *Federal Register* on July 12, 2007.

Providence is a not-for-profit organization extending across five states, including Alaska, Washington, Montana, Oregon and California. The System operates 26 acute care medical centers and hospitals, more than 35 non-acute facilities, physician clinics, a health plan, a liberal arts university, a high school and numerous other health, housing and educational services. In total, more than 45,000 people are employed by Providence. In Alaska, Washington, Montana and Oregon, Providence is sponsored by the Sisters of Providence religious community. In Southern California, the health ministry is co-sponsored by the Sisters of Providence and the Little Company of Mary.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is pleased to submit comments on the **physician self-referral issues** contained in the NPRM for the MPFS which were published in the *Federal Register* (Vol. 72, No. 133, pages 38122-38395) on July 12, 2007. Our comments on other aspects of the proposed changes will be submitted under separate cover.

CMS is proposing significant changes to existing physician self-referral prohibitions. These complex provisions have broad implications for existing and future relationships between physicians and hospitals or other providers. Generally, Providence supports the efforts by CMS through past regulations including Stark I and II as well as the proposed changes to the MPFS to address and prohibit many questionable self-referral practices. However, CMS efforts to date have had a piecemeal approach to fixing problems associated with physician self-referrals and as such do not always account for and may provide barriers to efforts to create integrated, organized systems of care for patients; a more comprehensive regulatory package is needed. Absent such a comprehensive regulation, Providence has several suggestions to offer on the proposed changes included in the MPFS.

We recommend that CMS move forward in a very thoughtful and deliberate fashion in order to minimize any unanticipated consequences that could harm beneficiaries' access to quality health care. Because many of the specific proposals promulgated by CMS could potentially eliminate certain types of arrangements that currently exist, Providence urges CMS to reconsider these blanket prohibitions. In many circumstances, physicians and hospitals or other providers have entered into agreements that, under the proposed rule, would be prohibited, but actually provide necessary and substantial community benefit with safeguards in place to protect the integrity of the arrangement from potential fraud or abuse. Without the ability of physicians to enter into these arrangements, beneficiaries may experience an inability to obtain needed services.

Providence also urges CMS to consider the complexity of existing arrangements when determining expected compliance time frames for finalized provisions of the MPFS. In many situations, physicians and hospitals or other providers may need to revise existing contracts and agreements that have been in place for years. Providence urges CMS to allow adequate time for parties to evaluate any existing agreements and, if necessary, revise or restructure the arrangements to comply with the final provisions so that essential healthcare services remain available to beneficiaries. We recommend that CMS provide at least a one-year time line, that is, allow until January 1, 2009 for existing arrangements to be in compliance with any finalized rules.

While many of the proposals by CMS may impact Providence, we would like to offer specific comments on three provisions.

Unit-of-Service (Per-Click) Payments in Space and Equipment Leases

Current regulations permit payments on a per service basis (per click payments) for personal services, as well as space and equipment leases, so long as the payment per unit is at fair market value and does not change during the term of the arrangement in a manner that takes into account designated health services (DHS) referrals. Accordingly, a physician may lease a piece of equipment to a hospital on a per click basis, even if the physician refers patients to the hospital for services using the equipment.

In this proposed rule, CMS is completely reversing its previously published determination where it specifically permitted time-based or unit-of-service-based payments. During Phase I rulemaking, CMS clearly stated that legislative history showed Congress intended that per-click arrangements were acceptable and many providers, including Providence, reasonably

relied on this interpretation. In this NPRM, CMS indicates that per-click arrangements are inherently susceptible to abuse and proposes a blanket disallowance of this type of agreement.

Providence believes that although some per-click arrangements may be susceptible to abuse, many agreements provide enormous community benefit and have safeguards built in to prevent abuse. One example of a successful per-click agreement involves the Cancer Partnership in Everett, Washington. This collaboration of four leading medical providers offers all aspects of cancer care under one roof and seeks to dramatically improve the quality of cancer care in the Puget Sound region. Not only do patients, including Medicare beneficiaries, enjoy unparalleled access to world-class cancer care, this care is being provided in an efficient way to reduce health care costs and prevent fraud and abuse.

Recommendation:
We urge CMS to reconsider its complete disallowance of all per-click payment agreements and permit such agreements when appropriate safeguards are in place to prevent potential fraud or abuse. These safeguards could take a variety of forms, including:

1. Creating a safe harbor provision using fair market value or average rates to compare physician-owned and non-physician-owned leasing arrangements; those that are physician-owned and have per-click payment agreements that fall within acceptable fair market value or average rate calculations would be allowed.
2. Allowing a de minimis percentage of physician self-referrals under a per-click payment agreement.
3. Recognizing the scale or scope of the agreement and evaluating whether the community benefit far outweighs the disadvantage of possible fraud or abuse. An agreement with a large percentage of community physicians and health care providers is much different than an agreement between a leasing company owned by a medical group and a hospital – while each type of agreement may have be susceptible to fraud or abuse, the larger the scope of providers participating in the arrangement, the less likely fraud or abuse occur.
4. Requiring quarterly medical necessity audits conducted by third party reviewers. This process would provide early identification of any questionable activities on the part of referring physicians attempting to benefit from referrals for DHS.

In the event CMS institutes a blanket prohibition on per-click payment agreements, Providence urges CMS to "grandfather" existing agreements and exclude these agreements from the prohibition. Providence, like many others, reasonably relied on the past statements from CMS that indicated per-click payment agreements were specifically protected by Congress when creating physician self-referral prohibitions and we subsequently structured many contracts with this acceptable form of arrangement. If necessary, we can forego entering into these types of agreements in the future, but undoing existing agreements based on per-click payment schemes could potentially threaten patient access to quality care and services unnecessarily, especially since these existing agreements contain safeguards to prevent fraud and abuse.

Services Furnished "Under Arrangements"

Under current regulations, an entity is not considered the entity that furnishes DHS unless it is the entity that is paid by Medicare for the DHS. Consequently, investment by a physician in an entity that supplies, leases, or otherwise furnishes services or items to a DHS entity that the physician makes referrals to for DHS is not considered ownership or investment by the physician. This is the case even if the physician-owned intermediary entity furnishes or performs the DHS "under arrangements" with a hospital paid by Medicare for the DHS.

In the proposed rule, CMS expresses concerns about "under arrangements" transactions between hospitals and physician-owned intermediary entities that appear to be designed solely to enable the physician-investors to profit from referrals to the hospital and/or enable the hospital to receive the higher provider-based Medicare payment even though the service is furnished in a less medically intensive setting. CMS attempts to ameliorate these concerns by revising the definition of "entity" so that a DHS entity includes both the person or entity that performs the DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. Once again, CMS is proposing a broad policy change that would, in effect, prohibit a significant number of arrangements that have enormous community benefit and provide quality health care services. In circumstances where particular services are required, but not frequently performed, having one provider develop consistent practices and expertise may afford a higher quality of care for patients seeking the service. These arrangements also prevent multiple health care providers from purchasing the same types of equipment in any given community, and as a result, the cost of care is actually reduced because of efficient resource management.

> **Recommendation:**
> Providence urges CMS to institute a degree of materiality into the existing "under arrangements" provisions rather than revising the definition of "entity." For instance, CMS could require a safeguard such that if some material portion of service (perhaps 50%) is outsourced to a provider in a less intensive setting, the hospital will be reimbursed at a reduced rate for the service, rather than the higher provider-based Medicare payment.

"Set in Advance" and Percentage-Based Compensation Arrangements

Current CMS rules state that compensation will be considered "set in advance" if the aggregate compensation, a time-based or per unit-of-service-based amount, or a specific formula for calculating the compensation, is set forth in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. CMS has become concerned about a variety of percentage compensation arrangements that are potentially abusive and has proposed to clarify that a percentage compensation arrangement:

- May be used only for paying for personally performed physician services; and
- Must be based on the revenue directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department.

This clarification by CMS seems to prohibit any gainsharing opportunities between hospitals and physicians, which seems in direct opposition to the current CMS Medicare Hospital

Gainsharing Demonstration project that was authorized by §5007 of the Deficit Reduction Act of 2005. Providence supports the exploration of gainsharing opportunities that improve the quality and efficiency of care by aligning physician and hospital goals; we are concerned that the proposed clarification by CMS will adversely impact the current demonstration project as well as future projects exploring acceptable gainsharing options.

Recommendation:
Providence urges CMS to evaluate the proposed clarifications and their impact to current and future gainsharing programs. CMS should only institute clarifications to the "set in advance" and percentage-based compensation arrangements that will not limit the opportunities to explore gainsharing opportunities that improve the quality and efficiency of care.

In closing, thank you for the opportunity to review and comment on the Medicare Physician Fee Schedule for CY 2008 proposed changes. Please contact Beth Schultz, System Manager, Regulatory Affairs, at (206) 464-4738 or via e-mail at Elizabeth.Schultz@providence.org if you have questions about any of the material in this letter.

Sincerely,

John Koster MD

John Koster, M.D.
President/Chief Executive Officer
Providence Health & Services

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PROVIDENCE
Health & Services

August 30, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
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REF: CMS-1385-P

RE: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

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As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is pleased to submit comments on several areas related to the proposed changes to the MPFS which were published in the *Federal Register* (Vol. 72, No. 133, pages 38122-38395) on July 12, 2007. Our comments on the physician self-referral issues proposed in the rule for the MPFS will be submitted under separate cover.

Before commenting on specific issues, **Providence would like to once again strongly urge CMS to advocate on Capitol Hill for a revamping of the Sustainable Growth Rate (SGR) methodology to ensure greater stability in physician payment under Medicare and to improve payment for primary care physicians, who are increasingly closing their practices to new Medicare beneficiaries**. Many of our physicians are very concerned about the scheduled -9.9% CY 2008 update, particularly as medical practice costs continue to rise and new benefits drive increased demand on the part of beneficiaries. While it is likely that the Congress will pass legislation to at least hold physicians harmless from the negative update for CY 2008, it is important that CMS strongly advocate for more structural reforms to the payment system to improve the accuracy of physician reimbursement and to align physician payment with broad Medicare reform principles. We, like you, are deeply concerned about the potential impact of this cut on beneficiary access to physicians in our communities and the cascading effect that reduced access has on our hospitals and others in those communities.

INDEPENDENT DIAGNOSTIC TESTING FACILITY (IDTF) ISSUES

CMS is proposing to clarify several of the IDTF performance standards and create two new performance standards. Generally, Providence supports the efforts of CMS to clarify existing standards and create additional standards to provide needed guidance for IDTFs, however, we are seeking clarification on several issues related to the specific CMS proposals.

Reportable Events - §410.33(g)(2): CMS is proposing to clarify that an IDTF must report certain changes within 30 calendar days of the change, while other reportable events must be reported within 90 calendar days. Those changes requiring report within 30 days include changes in ownership, changes of location, changes in general supervision, and adverse legal actions. Currently, IDTF changes are reported using CMS-855B, Section 1B. The form lists 9 general types of changes, 4 changes specific to ambulance service suppliers, and 4 changes specific to IDTFs. The categories of changes contained in Section 1B of form CMS-855B are not identical to the language being proposed by CMS and may create unnecessary confusion.

For instance, the proposed language states "changes in general supervision" however there is no corresponding category in Section 1B on form CMS-855B. Providence seeks clarification from CMS that the proposed reporting requirement for changes in general supervision is specifically referring to changes with the "Supervising Physician(s)" requiring the completion of Attachment 2E to form CMS-855B.

Recommendation – Reportable Events: Providence urges CMS to use the specific language contained in Section 1B on form CMS 855B when stating the changes that are required to be reported within 30 calendar days of the change. We suggest that CMS use the following language to clarify the reportable events standard:

> Provides complete and accurate information on its enrollment application. The following categories of changes must be reported within 30 calendar days of the change: Changes of Ownership, Ownership Interest and/or Managing Control Information (Organizations), Ownership Interest and/or Managing Control Information (Individuals), Practice Location Information, Supervising

Physician(s), and Adverse Legal Actions/Convictions. All other reportable changes must be reported within 90 calendar days.

Beneficiaries' Questions and Complaints - §410.33(g)(8): CMS is proposing to clarify the standard regarding beneficiaries' questions and complaints by requiring that the IDTF maintain documentation on all written and oral beneficiary complaints, including telephone complaints it receives. While Providence supports the idea of maintaining documentation of significant or serious complaints, the clarification being proposed by CMS seems to require documentation on "all" complaints regardless of materiality. Additionally, there is no specification for the length of time such documentation must be maintained.

Recommendation – Beneficiaries' Questions and Complaints: Providence urges CMS to adopt a materiality standard to the requirement for documenting complaints as well as a record retention time frame. We suggest that CMS model the documentation requirement for complaints after the Amended Final Regulations for the Mammography Quality Standards Act (MQSA) promulgated by the Food and Drug Administration. These regulations require that a facility must "Maintain a record of each ***serious*** complaint received by the facility ***for at least 3 years*** from the date the complaint was received" (42 U.S.C. §263b) (emphasis added). The regulations state "serious complaint means a report of a serious adverse event" and "serious adverse event means an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner." (21 CFR §900.2) By adopting similar language, CMS will ensure that ***material*** complaints are documented without requiring that insignificant complaints (such as difficulty finding a parking space) be similarly captured.

New Standard – Prohibition on Sharing Space, Equipment, or Staff: CMS is proposing to add a new standard for IDTFs which would prohibit a fixed-base IDTF to commingle office space, staff, and equipment. CMS believes such activities would prohibit it from ensuring that the IDTF establishes and maintains appropriate Medicare billing privileges and that each IDTF meets and maintains all performance standards. While Providence supports CMS' intention to clarify via this revised language that a motel or a hotel are not appropriate sites for an IDTF, we are concerned that the language may be too broad and prohibit other, acceptable behavior. Providence seeks confirmation from CMS that this new standard would not prevent under arrangement services agreements and that an IDTF may continue to lease personnel and equipment from third parties provided the IDTF uses the personnel/equipment exclusively throughout the lease term. Additionally, Providence is concerned that the proposed language may prevent staff that is "shared" for purposes of the Fair Labor Standards Act (FLSA) based on employer affiliation from working at an IDTF that is part of a health system.

Recommendation – Prohibition on Sharing Space, Equipment, or Staff: Providence urges CMS to clearly state that this new standard would not prevent under arrangement services agreements. We also urge CMS to clarify that employees

of affiliated employers under the FLSA are not considered "shared staff" under this new standard.

GEOGRAPHIC PRACTICE COST INDICES (GPCIs)

Under the proposed rule, CMS will create three new GPCIs in northern California to account for changing demographics and local economic conditions that have led to increased variations in practice costs within the payment locality boundaries. Similar circumstances exist in Washington State where there are currently two GPCIs – Seattle/King County and the Rest of Washington. Much of the Puget Sound area (from Everett to Olympia) is urban but, with the exception of Seattle/King County, is considered part of the Rest of Washington GPCI. These communities experience circumstances similar to those in the Seattle/King County area when it comes to non-physician labor and office rents.

Recommendation – GPCIs: Providence urges CMS to reevaluate their current methodology for determining payment localities and consider creating additional GPCIs in western Washington for Snohomish, Pierce, and Thurston counties.

REPORTING OF CARDIAC REHABILITATION SERVICES

CMS has proposed a technical change in billing for cardiac rehabilitation services. Two CPT codes for cardiac rehabilitation would be eliminated (CPT codes 93797 and 93798) and two new Level II HCPCS codes would be established (HCPCS codes Gxxx1 and Gxxx2). While Providence supports the general intention behind this technical change, we are concerned that the wording in the newly established G codes regarding MD service could create confusion and policy changes by Medicare contractors. Current Medicare policy (national coverage policy 20.10) does not require physician presence in the immediate area for CPT 93797 or 93798. By including the term "MD service" in the g code description, CMS may be unwittingly encouraging Medicare contractors to reestablish outdated policies.

Recommendation – Reporting of Cardiac Rehabilitation Services: Providence urges CMS to clarify that the newly established G codes (HCPCS codes Gxxx1 and Gxxx2) do not require physician presence in the immediate area and the national coverage policy 20.10 continues to be current and applicable.

In closing, thank you for the opportunity to review and comment on the Medicare Physician Fee Schedule for CY 2008 proposed changes. Please contact Beth Schultz, System Manager, Regulatory Affairs, at (206) 464-4738 or via e-mail at Elizabeth.Schultz@providence.org if you have questions about any of the material in this letter.

Sincerely,

John Koster MD

John Koster, M.D.
President/Chief Executive Officer
Providence Health & Services

7/2

National Kidney Foundation®

August 30, 2007

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

Dear Sir or Madam:

The National Kidney Foundation (NKF), the oldest and largest voluntary health organization in the United States serving the needs of kidney patients and the kidney health care team, is pleased to respond to the Proposed Revisions to the Medicare Physician Fee Schedule that were published in the ***Federal Register*** on July 12, 2007

Chronic Kidney Disease (CKD) is a public health problem in the United States, affecting 20 million Americans nationwide. Individuals with CKD are ultimately in danger of kidney failure that would require dialysis or a kidney transplant to keep them alive. In addition, the likelihood of cardiovascular events is multiplied by CKD. Early identification of individuals with CKD, combined with appropriate intervention, can delay the progression of kidney disease and its complications, and, thereby, reduce health care expenditures, including those borne by the Medicare ESRD Program. The National Kidney Foundation Clinical Practice Guidelines for the Evaluation, Classification, and Stratification of CKD, developed pursuant to the Kidney Disease Outcomes Quality Initiative (KDOQI), suggest interventions that could be undertaken for Medicare beneficiaries in each stage of CKD. (See, ***American Journal of Kidney Diseases***, Vol 39, No 2, Suppl 1, February 2002.)

Based on these considerations, NKF congratulates CMS for including the following potential measures for the Physician Quality Reporting Initiative in the Proposed Rule. They parallel recommendations from NKF Clinical Practice Guidelines, including the one referenced above:

*GFR Calculation in patients with Chronic Kidney Disease (CKD).
*Blood Pressure Measurement in patients with CKD.
*Plan of Care for patients with CKD and Elevated Blood Pressure.

*ACE Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy in patients with CKD.
*Calcium, Phosphorus and Intact Parathyroid Hormone Measurement in patients with CKD.
*Lipid Profile in patients with CKD.
*Hemoglobin Monitoring in patients with CKD.
*Erythropoietin Overuse in patients with CKD and normal Hemoglobin.

The National Kidney Foundation is ready, willing, and able to assist CMS in its efforts to enhance the outcomes of Medicare beneficiaries with early stage CKD.

Sincerely,

Allan J. Collins, MD
President
National Kidney Foundation, Inc.

MEDICIS®

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JASON D. HANSON
Executive Vice President and General Counsel

August 30, 2007

Mr. Herb Kuhn
Deputy Administrator (Acting)
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850.

ATTN: FILE CODE CMS-1385-P

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; ASP ISSUES

Dear Mr. Kuhn:

Medicis submits this comment on the proposed revisions to the physician fee schedule (PFS) for calendar year (CY) 2008. This comment addresses the average sales price (ASP) reporting requirements with respect to bundled price concessions by a drug manufacturer.

Medicis is the leading independent specialty pharmaceutical company focusing primarily on the treatment of dermatological conditions. We appreciate CMS's decision to provide additional guidance with regard to the treatment of bundled sales. We hope that additional clarity with respect to the reporting obligations will ensure accurate payment for Part B drugs.

ASP Reporting for Bundled Arrangements

In the CY 2007 PFS final rule with comment period, CMS did not establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for purposes of the ASP calculation. This has led to uncertainty among manufacturers regarding reporting discounts on bundled products, and has lead to inconsistent industry practices. In the 2008 Proposed Rule, CMS defines bundled arrangements to include all arrangements under which

> the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biologcial or other drugs or biologicals or some other performance requirement.

8125 North Hayden Road, Scottsdale, AZ 85258
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Web Site: http://www.medicis.com

CMS proposes that "the total value of all price concessions on all drugs sold under a bundled arrangement must be allocated proportionately according to the dollar value of the units of each drug sold under the bundled arrangement."

Medicis supports the approach CMS has taken to treating bundled price concessions. We believe that this methodology for allocating discounts associated with bundled arrangements will provide consistency between a manufacturer's reported ASP and the fair market value of its products.

We are submitting this comment to request that CMS provide further clarification with respect to the definition of bundled arrangements and the policy for reporting price concessions. Specifically, we suggest that CMS include the following clarifications in the Final Rule:

- bundled arrangements include arrangements where a price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals *(including both Part B and non-Part B drugs or biologicals)*;

- in reporting manufacturer average sales price, the total value of all price concessions on all drugs *or other products included in a bundled arrangement* must be allocated as proposed in § 414.804;

- a manufacturer is only required to allocate price concessions for bundled arrangements offered by that manufacturer, and is not responsible for any price concessions or bundled arrangements offered by other manufacturers with respect to the same drug or biological.

CMS Should Clarify That Bundled Arrangements Include both Part B and Non-Part B Drugs and Products

Based on industry practice some bundling arrangements will condition price concessions for a non-Part B drug, biological, or other product on the purchase of that manufacturer's Part B drug. It is our interpretation that the proposed rule would require a drug manufacturer to report sales data for the Part B-drug component of a bundled sale, along with any price concessions granted for that manufacturer's non-Part B products as part of the ASP calculation. If "bundled arrangements" are limited to only Part B products, it would enable drug manufacturers to insulate certain price concessions that are integral to the sale of their Part B drugs from the ASP reporting requirement. The effect would be to artificially inflate the reported ASP of the Part B drug, and, with it, the Medicare payment rate.

In order to address this concern, **drug manufacturers should be required to apportion price concessions granted for their non-Part B drugs, biologicals, and other products when those price concessions are conditioned on the purchase of that**

manufacturer's Part B drug. Such a clarification is necessary to ensure that drug manufacturers do not misrepresent the actual market price of Part B drugs.

In this context, CMS should further clarify what constitutes a price concession for non-Part B drugs that may not have an established price under Part B. For non-part B products, "price concessions" should be defined as the difference between the price offered as part of the bundled arrangement and the price that would be available to the purchaser if the drug was purchased separately (outside any bundled arrangement). CMS should also specifically address the treatment of free goods offered as part of a bundled arrangement. If free goods are offered contingent on the purchase of Part B drugs, the cost of the free goods should be treated as a 100% price concession for those goods, which should be appropriately allocated using the methodology established in § 414.804.

This conclusion is consistent with CMS's proposed definition of a "bundled arrangement," which does not distinguish on its face between products based on their coverage status under Part B. However, we believe that additional clarification in this area would be useful to provide guidance to manufacturers in identifying bundled arrangements, and correctly allocating discounts made therein.

Bundled Arrangements Should Include Sales of Non-Drug Products

It is our understanding that some manufacturers provide discounts or other price concessions as part of bundled arrangements that include sales of Part B drugs and other non-drug products. In order to appropriately capture the market price of Part B drugs, these arrangements should also be considered bundled arrangements.

This approach is consistent with the Medicaid final rule (CMS-2238-FC), which defines a Bundled Sale to include arrangements involving "the same drug, drugs of different types . . . or another product or some other performance requirement" (emphasis added). In the Physician Fee Schedule Proposed Rule, CMS stated its intent to establish a consistent approach to bundled arrangements between the Medicare and Medicaid programs, where appropriate. Including "other products" in the definition of bundled arrangements will both reinforce this consistency, thereby reducing manufacturer reporting burdens, as well as encouraging the most accurate price reporting for both programs.

In adopting this definition, CMS should clarify that "another product" includes all non-drug products and devices associated with a bundled arrangement as defined.

Manufacturers Are Only Responsible for Reporting Bundled Sales

Medicis further requests that CMS clarify that reporting requirements for bundled price concessions apply only to sales made and concessions granted by the reporting manufacturer. For the purpose of the ASP reporting requirements, the term "manufacturer" covers a broad range of entities, including not only parties engaged in

the literal production and processing of prescription drug products, but also their "packaging, repackaging, labeling, relabeling, distribution." However, a manufacturer submitting an ASP report to CMS would only have access to information about its own bundled arrangements, and would not be able to evaluate the sales arrangements of other "manufacturers" who sell the same product.

In order to avoid confusion among manufacturers with respect to the reporting of bundled price concessions, CMS should clarify that a manufacturer is not required to report price concessions granted by some other, independent entity for sales of the same product. We believe that this interpretation is consistent with the language and intent of the ASP statute and regulations, as well as the present standard practice of manufacturers.

Conclusion

Medicis appreciates CMS's efforts to ensure the accuracy of the ASP calculation. In order to support this goal and ensure uniformity in manufacturer reporting, we encourage CMS to clarify that the methodology for reporting discounts associated with bundled sales arrangements should apply to both Part B drugs and biologicals as well as drugs, biologicals, and other products that are not covered under Part B. In addition, CMS should make clear in the final rule that manufacturers are not required to report price concessions granted by third parties.

Thank you for your attention to this important matter.

Sincerely,

Jason D. Hanson
Executive Vice President, General Counsel
& Corporate Secretary

LabCorp
Laboratory Corporation of America

COMMENTS OF LABORATORY CORPORATION OF AMERICA HOLDINGS ("LABCORP") ON THE 2008 PHYSICIAN FEE SCHEDULE PROPOSED RULE

CMS-1385-P

Laboratory Corporation of America Holdings ("LabCorp") is pleased to have this opportunity to comment on the Physician Fee Schedule Proposed Rule for 2008 ("Proposed Rule"). 72 *Fed. Reg.* 38122 (July 12, 2007). LabCorp is one of the world's largest clinical laboratories, testing more than 370,000 specimens daily for over 220,000 clients nationwide. Because the Proposed Rule includes several provisions of significance to clinical laboratories, it will have a direct impact on LabCorp. As a member of the American Clinical Laboratory Association ("ACLA"), LabCorp endorses and fully supports the comments that ACLA has submitted on the Proposed Rule. We write separately to emphasize two points related to the physician self-referral provisions of the Proposed Rule: (1) The proposed changes will have no adverse effect on the quality or cost of, or access to, pathology services; and (2) The proposed changes are simply clarifications of requirements that already exist, and are designed to close loopholes that have been exploited in ways that were never intended. LabCorp commends CMS for addressing these issues, and urges CMS to finalize the physician self-referral provisions of the Proposed Rule without any further delay or grace period.

Physician Self-Referral Provisions

A. *The Proposed Rule will have no adverse effect on the quality of, or access to, pathology services.*

Proponents of the joint venture arrangements that are the subject of the physician self-referral provisions of the Proposed Rule often argue that such arrangements are necessary to ensure that patients have access to services that they would not otherwise obtain, or in order to ensure the quality of the services provided. For example, because many of the arrangements are targeted at particular specialties, such as urologists, gastroenterologists, or dermatologists, it is sometimes argued that these joint venture arrangements are able to specialize in analysis of these types of specimens and thereby provide a higher level of service. Nothing could be further from the truth, and to the extent that comment is made, we strongly urge CMS to reject it.

First, many national and regional laboratories and pathology groups have pathologists who are subspecialty certified and perform pathology services within those subspecialties. These specialists have training and experience that is at least comparable (if not superior) to the training of pathologists working at the joint venture laboratories. Indeed, many of the individuals who

now work at these joint venture entities received their training and experience working for other independent laboratories.

Second, pathology groups and independent laboratories, *because* they have no financial ties to the referring group, must compete on the basis of diagnostic capability, quality, turnaround time, and service - the very factors that a referring physician should consider in furtherance of patient care. In contrast, where a practice maintains a financial interest in each referral that is sent to his own group practice laboratory, there is an additional financial element to the decision of where to send the biopsy that is not solely driven by patient interest.

Further, if referring physicians are concerned that these specialized services are not available elsewhere, and that the Proposed Rule would discourage and create barriers to the delivery of innovative, quality health care, there is nothing in CMS' current proposals that prevents delivering pathology services to patients in the same way. A physician can still refer specimens to one of these laboratories. The only thing that the physician cannot do is mark up the cost, when billing Medicare. Thus, the only thing that is affected is the referring physician's ability to earn a profit—not the referral itself. Alternatively, the pathologist performing the service can simply bill Medicare directly for the service, and be paid the full reimbursement level.

This argument, which attempts to confuse access to the services with the ability to earn a profit on them, has often been made when Medicare threatens to take action against such arrangements. When Medicare proposed changes to the Stark law, the exact same argument was made. One commenter argued that certain restrictions would force patients to travel long distances to obtain services and discourage them from obtaining needed services. CMS correctly rejected this argument. It noted:

> The law only imposes restrictions on a physician who makes a referral for a designated health service if he or she has a financial relationship with the ancillary services provider... However, nothing in the law prevents physicians from making available convenient ancillary services when the physician has no financial interest in the provision of the services. For example, a physician may arrange for a diagnostic services provider to perform diagnostic tests in the physician's office for which the diagnostic services provider bills... *Section 1877 of the Act reflects the Congress' unmistakable intent to recognize and accommodate the traditional role played by physicians in the delivery of ancillary services to their patients, while constraining the abuse of the public fisc that results when physician referrals are driven by financial incentives.*

66 *Fed. Reg.* 856, 861-862 (Jan. 4, 2001) (emphasis added).

The CEO of "the nation's biggest" company that organizes these joint venture arrangements has publicly weighed-in in favor of the proposed rule, endorsing both the objective ("we agree with CMS's desire to prevent program abuse") and the specific provisions ("I do not see any problems [with the proposed rule] that we can't address"). *See* Jondavid Klipp, *Laboratory Economics*, Vol. 2; (7) at 2 (July 2007). Thus, there is no basis to believe that access to quality services will be impaired.

The argument that the Proposed Rule will drive up the cost of health care and discourage efficiency is simply without foundation, and is plainly inconsistent with the wealth of empirical data that supports the correlation between physician affiliation with an entity to which it refers diagnostic testing and increased utilization of the services offered by that entity, which ultimately increases Medicare expenditures.

Just recently, the HHS Office of Inspector General ("OIG") released audits of three physician practices that were engaged in the type of joint venture arrangements that are the subject of CMS' concern.[1] In all three audits, the OIG found exceptional increases in utilization once the practices entered into these joint venture arrangements. A consistent pattern of significant increases in utilization by each of the practices was demonstrated.

Utilization by one joint venture laboratory in Leesburg, Florida was 65% more than at other Medicare providers in the same carrier jurisdiction. This practice showed the lowest increase in the number of specimens per case billed by the group, an increase of 26% after the financial relationship was formed. A second joint venture laboratory in Sarasota, Florida claimed payment for 58% more services than the average Florida Medicare provider, and its utilization of prostate biopsies was ***seven times (699%) greater*** after it entered into the arrangement. Substantial increases also occurred with a group practice affiliated with a San Antonio, Texas joint venture laboratory. This practice increased utilization from four to nearly twelve specimens per patient, an increase of ***230%*** after it entered into a financial relationship with a joint venture laboratory. The services performed by this group were, according to the OIG report, ***124% higher*** than the average claimed by other Medicare providers in the same carrier jurisdiction. Even assuming there were new standards in practice evolving, as the groups alleged, it is noteworthy that the groups did not implement these new standards until after they became participants in one of these arrangements, and thereby obtained the ability to profit from these referrals.[2] Given these studies, it is clear that the arrangements about which CMS has

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[1] *See* Review of Pathology Services Claimed by Urology Tyler, P.A. Tyler, Texas From May Through December 2004, OIG, A-05-05-00037 (June 2007); *see also* Audit of Pathology Laboratory Services Claimed by Atlantic Urological Associates, P.A. for Calendar Year 2004, OIG, A-04-05-03002 (June 2007); *see also* Audit of Pathology Laboratory Services Claimed by Florida Urology Physicians, P.A. for the Period September Through December 2004, OIG, A-04-05-03005 (June 2007).

[2] The conclusion in each of the reports that medical necessity and documentation requirements were generally complied with is qualified by the absence of national or local standards for the number of tissue samples that should be examined for urology patients with prostate-related diagnoses. In these cases, OIG concluded that medical necessity for biopsies could not be determined in the absence of national or local coverage determinations by Medicare.

expressed concern incentivize physicians to request additional services for patients, which ultimately increases Medicare expenditures.

The existence of such financial relationships creates a substantial risk that the treating physician's selection of a pathologist or pathology lab for patient care will be determined solely or primarily by profit potential, rather than an objective assessment of the quality, service and qualifications of the pathologist to perform the type of pathology service needed. Rather than improving quality and access to efficient services, these arrangements expose patients to more frequent, more numerous, and potentially unnecessary biopsies, significantly increasing expenditures for pathology services while compromising the quality of care. By removing the financial incentives to increase utilization of pathology services through the provisions of the Proposed Rule, CMS will eliminate this dangerous conflict of interest. Thus, CMS should reject any concerns that suggest that access or quality of care, or its cost, will be adversely affected by these new provisions.

B. *The proposed changes are simply clarifications of requirements that already exist, and are designed to close loopholes that have been exploited in ways that were never intended.*

As CMS has noted, these provisions are simply a clarification of certain requirements that already exist. Since 1994, Medicare has limited the ability of physicians to mark up the cost of the Technical Component of a pathology service. 58 *Fed. Reg.* 63626 (Dec. 2, 1993). Thus, the new proposals simply make clear that the "contractual arrangement" exception to the reassignment rules added by the Medicare Modernization Act ("MMA") does not abrogate this existing limitation. It is true that CMS is adding a similar limitation to the purchase or reassignment of the Professional Component, but there were already other limitations that existed on those arrangements.

Some providers of services have apparently argued that they are not subject to the purchased diagnostic testing rules because they are not *purchasing* the services, but are simply reassigning them. As CMS has noted, if the services are being furnished by an outside supplier who is not a full-time employee, there is no practical distinction between the "purchase" of a service and the "reassignment" of a service. In either case, the service is being furnished by an outside supplier, who is not an employee. The group is paying the supplier for that service, at a deeply discounted rate, and then billing for it at the full charge. It makes little difference whether that payment is characterized as a "purchase" or a "reassignment"—the net result is the same.

CMS should reject arguments that the Proposed Rule simply represents yet another attempt to micromanage physician practices, and that in doing so it only adds more layers of confusion and regulation, forcing physicians to incur legal fees to interpret the law and restructure longstanding relationships previously thought to be acceptable. The Proposed Rule is a relatively straightforward, common sense approach to resolving the confusion that arose when CMS first moved to implement Section 952 of the MMA, which created the contractual arrangement exception to the reassignment rule. The regulatory complexities and confusion

created by the contractual arrangement exception and its implementation led to a proliferation of abusive joint venture arrangements that sought to exploit regulatory loopholes in ways that were never intended. The Proposed Rule simplifies and clarifies the physician self-referral and Medicare billing rules by more clearly prohibiting that about which both CMS and the OIG have long expressed concerns; to the extent that the Proposed Rule will require either discontinuance or restructuring of certain longstanding relationships, no one can claim that their acceptability has not been highly suspect for years.

The Stark law is a legislative recognition that financial interest by referring physicians in the entities to which they refer leads to higher utilization and higher program costs. This has been demonstrated by numerous studies that were the foundation for the Stark law. The starting premise of the Stark law was that all referrals to an entity in which the physician had a financial interest would be banned. The law, under Section 1877(b)(4), allows only such exceptions that "pose no risk of program or patient abuse." The in-office pathology arrangements at issue in the pod situation are precisely the type of arrangement that the Stark law was designed to regulate. This is not an attempt to micromanage physician practices, but to address the very fundamental concerns leading to the Stark legislation. It can hardly be said that these arrangement pose "no risk of program or patient abuse" where an exception ought to apply. The recent OIG audits point to a substantial potential for program abuse and higher Medicare and patient copayment costs. In all three practices that were audited, utilization increased substantially after the financial relationship was established. In once case, the increase was nearly seven hundred percent.

Even before CMS expressed concerns about the growth of these ventures in 2004, the OIG had long expressed concerns about joint ventures involving a referrer and an entity that supplies the requested services. In the very first set of anti-kickback "safe harbor" regulations, the OIG expressed concern about joint ventures between referring physicians and a supplier of the goods and services requested by the physicians. It noted that such arrangements "are not arms length transactions where the joint venture shops around for the best price on a good or service. Rather, it has entered into a collusive arrangement with a particular provider or supplier or items or services that seeks to share its profits with referring physician partners." 56 *Fed. Reg.* 35952, 35978 (July 29, 1991).

In 2003, the OIG issued a Special Advisory Bulletin about similar entities that it called "contractual joint ventures," which bear a remarkable similarity to the arrangements that CMS described in last year's Proposed Rule. It noted that in many of these arrangements, the venture's "Owner" was the health care provider that purported to go into a new line of business with another "Manager" or "Supplier" that managed the business. However, according to the OIG:

> [T]he Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts out substantially all of the operations of the new business. The Manager/Supplier typically agrees to provide not only management services, but also a range of other services, such as the inventory necessary

> to run the business, office and health care personnel, billing support, and space. While the Manager/Supplier essentially operates the business, the billing of insurers and patients is done in the name of the Owner. ...While the contract terms of these arrangements may appear to place the Owner at financial risk, the Owner's actual business risk is minimal because of the Owner's ability to influence substantial referrals to the new business.

Special Advisory Bulletin, *Contractual Joint Ventures*, OIG (April 2003).

In this year's Proposed Rule, CMS recognizes that these new arrangements create the exact same type of concerns as the OIG noted. According to CMS:

> [A]llowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare program.

72 *Fed Reg.* 38122, 38179.

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In sum, there is little question that these proposals are necessary and will help prevent unnecessary utilization and protect the Medicare Trust Fund. Opponents of the proposed rule Thank you for the opportunity to comment. If you have any questions or need any further information, please do not hesitate to contact us.

F. Samuel Eberts III
Senior Vice President & General Counsel
Laboratory Corporation of America
430 South Spring Street
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Bayer HealthCare

August 31, 2007
By Hand Delivery

Herb B. Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Re: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

Bayer HealthCare LLC

400 Morgan Lane
West Haven, CT 06516

Phone: 203-812-2000

Bayer Healthcare LLC ("Bayer") thanks the Centers for Medicare and Medicaid Services ("CMS") for its continued efforts to ensure that beneficiaries have access to high-quality drugs and biologicals under the Medicare program. For over 100 years, Bayer has dedicated itself to the development and production of such high-quality drugs and biologicals.

We appreciate this opportunity to comment on the Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (the "Proposed Rule").[1] We present the following comments, in summary, for your consideration:

- *Sustainable Growth Rate Cut.* In order to preserve beneficiary access to life-saving therapies, Bayer requests that CMS act to the fullest extent permissible to mitigate the effects of the sustainable growth rate cut on physician reimbursement.

- *Bundled Price Concessions.* Bayer supports CMS' efforts to harmonize the treatment of bundled arrangements in the

[1] 72 Fed. Reg. 38,122 (Jul. 12, 2007).

Medicaid and Medicare Part B contexts. At the same time, we remain deeply concerned that the proposed definition represents a significant expansion of, and substantive change in policy from, the bundled sale definition from the Medicaid Rebate Agreement. Bayer requests that CMS clarify that, consistent with the Administrative Procedures Act, the new bundling rule will be applied prospectively only. Bayer also requests that CMS clarify that drugs and unique delivery devices packaged and sold together under the same National Drug Code ("NDC") do not constitute a "bundled arrangement."

- *Clotting Factor Furnishing Fee.* Bayer supports CMS' proposal to issue the clotting factor furnishing fee update in program instructions, rather than annual rulemakings.

- *Widely Available Market Prices ("WAMP") and Average Manufacturer Price ("AMP") Threshold.* Bayer supports CMS' proposal to maintain the applicable threshold percentage at 5 percent and thanks CMS for its cautious approach to potential price substitutions. Bayer strongly supports CMS' proposal to give manufacturers adequate notice regarding any potential price substitutions. We request that such adequate notice be given more than 1 full quarter prior to the planned implementation of any substitution. Furthermore, Bayer requests that CMS develop, through separate, formal rulemaking, the process and criteria that CMS will use in exercising its authority to substitute WAMP or AMP for ASP.

- *Equipment Usage Percentage.* Bayer supports CMS' efforts to determine an equipment usage percentage that appropriately reflects actual equipment utilization rates and does not create incentives for over- or under-utilization of equipment.

- *Competitive Acquisition Program ("CAP") Issues.* Bayer thanks CMS for its efforts to improve the competitive acquisition program and facilitate physicians' access to Part B drugs and biologicals. We strongly believe that any improvements to

CAP, particularly those that would permit the transportation of CAP products or transfer of CAP products from their original containers, must only be implemented with adequate safeguards to ensure the proper storage, handling, and transport of the CAP products.

- *New Clinical Diagnostic Laboratory Test.* Bayer strongly supports CMS' efforts to increase public participation in the determination of the proper basis and amount of payment for new clinical laboratory tests. Bayer also supports increased transparency with respect to CMS' decision-making and requests that CMS make public its rationale for its determinations regarding the basis or amount of payment for new tests.

- *Drug Compendia.* Bayer strongly supports CMS' adoption of a transparent process for the evaluation of compendia and its proposal to use the MedCAC recommended desirable characteristics of compendia and additional criteria in reviewing requests for revision of the drug compendia list. Below, we discuss specific criteria that CMS should consider with respect to its evaluation of drug compendia, including transparency, conflicts of interest, compendia recommendations, open communication channels, and breadth of listings. We also request that CMS clarify that carriers must consider all indications supported by the listed compendia to be "medically accepted indications."

- *Physician Quality Reporting Initiative ("PQRI").* Bayer supports CMS' proposal to retain and include in the final 2008 PQRI measures the 2007 PQRI measures presented in Table 16 of the Proposed Rule, as these measures provide reliable and useful information about physician quality, and will incentivize physicians to improve the quality of care afforded Medicare beneficiaries.

These comments are discussed in further detail below.

SUSTAINABLE GROWTH RATE

Without adequate physician reimbursement under Medicare, we fear that physicians reluctantly will cut back on the services and treatment provided to beneficiaries, jeopardizing access to potentially life-saving drugs and services. Accordingly, Bayer remains very concerned that under the Proposed Rule there would be an estimated negative 9.9 percent update to the physician fee schedule, threatening physicians' continued ability to treat Medicare beneficiaries.

As in previous years, legislative action will be needed to avoid the cut in physician reimbursement and the deleterious effects on beneficiaries that would undoubtedly follow such a significant cut. Bayer understands that, by statute, CMS has limited ability to reduce the proposed cut in physician reimbursement and must properly act within the confines of the Social Security Act (the "Act") in determining the sustainable growth rate for the subsequent calendar year. Nonetheless, Bayer urges CMS to use all permissible discretion within the bounds of the statutory sustainable growth rate requirements to mitigate the effects of this cut.

ASP ISSUES

Bayer offers comments on the following ASP-related issues: bundled price concessions, clotting factor furnishing fee, and the WAMP and AMP threshold.

Bundled Price Concessions

1. *CMS Should Clarify that the New Definition of "Bundled Arrangement" Does Not Apply Retrospectively.*

Bayer appreciates the need for harmonization of bundling rules across the Medicare and Medicaid programs, as a consistent body of rules will help reduce errors and ease manufacturers' burdens with respect to the calculation and reporting of Average Sales Price ("ASP"), AMP, and Best Price. However, the definition of "bundled arrangement" that CMS has proposed for ASP,[2] and the nearly identical definition of "bundled sale" that CMS has adopted for AMP

[2] 72 Fed. Reg. at 38,214 .

and Best Price, extend far beyond the Medicaid Rebate Agreement ("MRA") definition of "bundled sale" to which CMS remains legally bound. Bayer strongly believes that CMS should adopt the MRA definition of bundling in both the Medicaid and Medicare contexts. In the event that CMS finalizes its "bundled arrangement" definition as proposed, however, Bayer strongly maintains that the substantive policy change embodied within this new definition should not, and lawfully cannot, be applied retrospectively to manufacturers.

Although CMS has always maintained that price concessions offered for bundled products be apportioned properly across the bundle, CMS' proposed definition of "bundling arrangement" significantly broadens the agency's policy with respect to what will be considered a bundle. For example, the MRA definition of "bundled sale" refers to *purchases* of *different drugs* where the offered price concession is conditioned on purchase of the package, or exceeds the price concessions that are offered individually on the different drugs. The proposed definition of "bundled arrangement" drastically expands the definition beyond *purchases* to include *performance requirements* (*e.g.*, achievement of market share or formulary conditions), and beyond *packages* of *different drugs* to include *arrangements* involving the *same drug*.

That the new definition of "bundled arrangement" represents a significant change in CMS policy is evidenced by the fact that CMS' bundling rules have been the subject of three different sets of rulemaking within one year—the CY 2007 physician fee schedule (Dec. 2006),[3] the AMP Final Rule (July 2007),[4] and the CY 2008 proposed physician fee schedule (July 2007).[5] A mere clarification would not call for such considerable discussion.

The Administrative Procedures Act ("APA") requires prospective-only application of substantive changes in regulatory policies after notice-and-comment rulemaking. In fact, the APA defines a substantive rule as "the whole or a part of an agency statement of general or particular applicability and future effect

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[3] 71 Fed. Reg. 69,624, 69,673-75 (Dec. 1, 2006).
[4] 72 Fed. Reg. 39,142, 39,158-60 (Jul. 17, 2007).
[5] 72 Fed. Reg. at 38,150-52.

designed to implement, interpret, or prescribe law or policy."[6] As Justice Scalia explained, "The only plausible reading of the italicized phrase is that rules have legal consequences only for the future."[7] Moreover, the Supreme Court has made clear the U.S. Department of Health and Human Services cannot promulgate retrospective rules under the Act without express authority from Congress.[8] Therefore, retroactive application of the "bundled arrangement" definition would plainly violate and "make a mockery" of the APA.[9]

Even if retrospective application of CMS' new bundling rule were permitted by the APA, to do so here would penalize manufacturers for their compliance to date with the MRA and ASP guidance on bundling. Indeed, retrospective application would be manifestly unfair given CMS' December 2006 directive to manufacturers to "make reasonable assumptions in its calculations of ASP" given that CMS "[did] not yet fully understand the variety of bundling arrangements that exist in the marketplace."[10]

To be clear, Bayer firmly supports CMS' efforts to require manufacturers to fairly and accurately apportion bundled price concessions and believes CMS' proposed methodology to be a reasonable and manageable solution to the often challenging issue of bundled arrangements. However, CMS' proposed expansion of the arrangements it considers to be "bundled" along with its proposed adoption of a sales- and dollar-based apportioning methodology that many manufacturers may not have previously used, strongly counsels against the retrospective application of the new rule. More importantly, the APA requires that CMS' new ASP bundling rule be applied prospectively only. Therefore, Bayer respectfully requests

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[6] 5 U.S.C. § 551(4) (emphasis added).
[7] *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 216 (1988) (Scalia, J., concurring) (emphasis added).
[8] *Id.* at 208 (1988) (holding that "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms").
[9] *Id.* at 225 (Scalia, J., concurring).
[10] 71 Fed. Reg. 69,623, 69,675 (Dec. 1, 2006).

that CMS clarify this point in the CY 2008 physician fee schedule final rule.

2. *CMS Should Clarify that Drugs and Unique Delivery Devices Packaged and Sold Together Under the Same NDC Do Not Constitute a "Bundled Arrangement."*

CMS' proposed definition of "bundled arrangements" does not appear to clearly address those drug or biological products that consist of a drug or biological coupled with a unique delivery device, such as an intravenous fluid coupled with a needle-pen delivery device. The fact that a drug and delivery device are packaged and sold under one NDC as one unique product should not lead to the erroneous conclusion that the drug and delivery device have been "bundled." Bayer respectfully requests that CMS clarify that, where the drug or biological and device are packaged and sold together under the same NDC, that such drug/device combination product will be treated like any other drug or biologic product and will not be considered a "bundled arrangement." In other words, CMS should clarify in the final rule that a bundling arrangement would potentially exist only where a drug, sold under its own NDC, and a delivery device, sold separately, are priced and sold in a non-independent manner that otherwise falls within the "bundled arrangement" definition. Such a clarification would be consistent with statutory requirements that manufacturers report ASP by NDC.

Clotting Factor Furnishing Fee

Bayer continues to believe that the clotting factor furnishing fee is critical to ensure beneficiary access to this treatment. We appreciate CMS' discussion of the clotting factor furnishing fee update in the Proposed Rule.[11] Bayer understands that this annual update is not affected by agency discretion nor by public comment. Accordingly, we agree that communication of the clotting factor furnishing fee update through program instructions outside of the annual rulemaking process would be appropriate. Further, to ensure adequate notice to potential stakeholders, we suggest that CMS announce the update on applicable list serves as opposed to simply posting the update on its website.

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[11] 72 Fed. Reg. at 38,152.

Widely Available Market Prices ("WAMP") and AMP Threshold

Bayer fully supports the prudent course of action proposed by CMS with respect to the determination of the WAMP and AMP applicable threshold percentage.[12] Maintaining the applicable threshold percentage at the 5 percent level originally set by Congress for CY 2005 represents the proper course of action, given that very little additional data has been collected since then that would support a change in the threshold percentage.

Furthermore, any data that has already been collected by the Office of Inspector General ("OIG") or others will likely need to be re-evaluated given the recent changes and clarifications to ASP and AMP. The new ASP and AMP regulations and guidance should create consistency between manufacturers' reported price values, providing OIG with a better data set from which to compare ASP with WAMP and AMP. Moving forward, Bayer expects OIG to develop, and CMS to have available, a more robust data set from which to set a different threshold percentage. Until that time arrives, however, Bayer respectfully suggests that CMS maintain the threshold percentage at the 5 percent status quo.

In addition, Bayer thanks CMS for its thoughtful proposal to proceed cautiously in this area and provide drug manufacturers and other stakeholders with "adequate notice" of CMS' intentions regarding potential price substitutions. We believe that such notice to manufacturers will only be "adequate" if given more than 1 full calendar quarter prior to any potential price substitution. Manufacturers will need at least 1 full quarter in order to review their ASP, WAMP and AMP and determine the causes underlying any difference in ASP and WAMP/AMP of more than 5 percent.

More importantly, CMS and interested stakeholders will need at least one full calendar quarter, if not longer, to determine whether a potential price substitution would negatively impact physician and beneficiary access to vital Part B drugs and biologicals. Physicians, patients, and patient advocates must be given a voice during this period to inform CMS as to whether, for example, a substituted price will reimburse certain segments of the physician market less than

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[12] *Id.*

their drug acquisition costs and threaten beneficiary access to the drugs.

In light of the serious impact that any price substitution would have on physicians and beneficiaries, Bayer strongly urges CMS to develop a set of criteria that it will use in determining whether to exercise its authority to substitute WAMP or AMP for ASP, and a formal process for notifying manufacturers and interested stakeholders of the potential price substitution. This formal process should provide at least one full quarter for manufacturers to determine and validate the causes for exceeding the 5 percent threshold percentage, and for other stakeholders to comment on the consequences of such a price substitution on physicians and beneficiaries.

Moreover, because price substitution will impact such a wide variety of stakeholders, we would suggest that CMS develop its formal price substitution process and decision-making criteria through notice-and-comment rulemaking. As CMS so successfully demonstrated in the recently promulgated AMP and Best Price regulations, and demonstrates annually with the physician fee schedule, CMS can address complex issues and formulate thoughtful, administrable rules in a short time period with the assistance and input of interested stakeholders. We invite CMS to consider doing so in the price substitution context as well.

RESOURCE-BASED PE RVUs — Equipment Usage Percentage

Bayer appreciates CMS' thoughtful discussion of the equipment usage percentage in the Proposed Rule.[13] We agree that the percentage set by CMS should appropriately reflect the actual equipment utilization rates, and we share CMS' concern that inappropriately determined percentages could create incentives for the over- or under-utilization of equipment. We remain confident that CMS will address this issue in a manner that ensures that beneficiaries will have appropriate access to medical equipment and associated services and providers receive adequate reimbursement for the same.

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[13] *Id.* at 38,132.

CAP ISSUES

We thank CMS for its efforts to improve the CAP by facilitating access to vital Part B drugs and biologicals for those physicians who voluntarily opt-out of the traditional "buy and bill" model. However, we strongly maintain that any such improvements must safeguard beneficiaries' health and safety, and properly ensure that Part B drugs and biologicals are properly stored, handled, and transported by CAP vendors and physicians.

Many Part B drugs and biologicals are complex medications that must be stored and handled in accordance with the Food and Drug Administration ("FDA") approved product labeling. CMS' requirements that CAP drugs and biologicals be shipped directly to the location where they will be administered, and that vendors supply the drugs in the original containers supplied by the manufacturer or distributor, serve as reliable, conservative means to ensure that CAP drugs and biologicals are safely administered to physicians. The elimination or loosening of these safeguards raises the possibility that, for example, product sterility, potency, or safety may be compromised by improper transfer of product from the original to a new container.

Therefore, any changes to CMS' policy on the transportation of CAP products, or the transfer of CAP products from their original containers to new containers, must only be implemented with adequate beneficiary safeguards. For particularly risky procedures, such as transferring sterile drug product into prefilled syringes or other containers, CMS should require each CAP vendor to provide and seek approval of written policies and procedures demonstrating that such drug product will be handled in a manner that protects its efficacy and safety. In conclusion, we encourage CMS to continue to find ways to improve physician and beneficiary access to Part B drugs and biologicals through both the CAP and the ASP reimbursement models, provided such improvements ensure the proper storage, handling, and transport of Part B drugs and biologicals by CAP vendors and physicians.

CLINICAL LABORATORY ISSUES

Bayer appreciates CMS' proposals to increase public participation in the determination of the proper basis and amount of payment for new clinical laboratory tests. We strongly believe that clinical laboratory tests should be properly reimbursed by CMS in order to ensure that physicians and laboratories can afford to purchase and provide these new tests to Medicare beneficiaries. Formalizing a method whereby manufacturers, physicians, laboratories, and other interested stakeholders can submit charge, cost, and clinically detailed information will allow these stakeholders to meaningfully participate in the payment determination and provide CMS with additional data from which to reconsider its initial determinations.

Bayer simply requests that CMS clarify that it will fully disclose and explain the rationale for its initial determinations and any redeterminations regarding the basis of new test payments or the amount of new test payments. Without explaining the reasoning underlying its determinations, interested stakeholders will not be able to meaningfully support, challenge, or comment upon CMS' proposals or provide specific information likely to affect CMS' payment determinations. All stakeholders would benefit from such transparency, and we believe that better payment policy will result.

DRUG COMPENDIA

Bayer remains committed to the development of life-saving drugs and biologicals to help patients in their fight against cancer. We thank CMS for its proposal to implement its authority to revise the list of drug compendia for determining medically-accepted indications for oncologic drugs. We fully agree with CMS that the evaluation of compendia should be conducted annually through a transparent, notice-and-comment process that involves the participation of interested stakeholders. We believe that the information provided by stakeholders may prove to be instrumental in CMS' evaluation of the compendia, given the stakeholders' long history of involvement with the compendia.

A listed drug compendium must have pre-specified and scientifically- and procedurally-sound criteria for drug evaluation in

order for it to serve as a reliable source of medically-accepted indications for oncologic drugs. The compendium should serve as the final word as to medically-accepted oncologic indications, and the compendial determinations should not be subject to further interpretation by CMS or carriers. Therefore, it is of great importance that CMS' evaluation of drug compendia be thoughtful and rigorous, and benefit from the expertise of interested stakeholders.

Bayer strongly supports CMS' proposal to use the MedCAC-recommended desirable characteristics of compendia and additional criteria in reviewing requests for revision of the drug compendia list, as the use of such criteria will help ensure broad patient access to oncologic drugs consistent with the best available clinical and scientific evidence. Below, we focus our comments on the following criteria: transparency, conflicts of interest, use of "not recommended" listings, open communication channels, compendia recommendations, and breadth of listings. We believe that CMS' adoption of these criteria will ensure that drug compendia establish and follow pre-specified criteria and procedures for reliably and accurately evaluating the clinical and scientific evidence.

- *Transparency*

Of the MedCAC-recommended desirable characteristics, Bayer believes that the characteristics dealing with transparency of the compendial process are perhaps the most important, as they help ensure that the compendial decision are based upon reliable evidence and free from conflicts of interest. These characteristics include: (1) use of pre-specified published criteria for weighing evidence; (2) use of pre-specified published criteria for making recommendations; and (3) publicly transparent process for evaluating therapies.

In addition to these three MedCAC characteristics, Bayer recommends that CMS also consider the following factors related to transparency: (4) public identification of the members of the compendia's advisory and scientific review committees; and (5) use of, and adherence to, pre-specified timelines for evaluating and making recommendations regarding therapies. Full disclosure of the decision-makers and the decision-making timeline will provide added reliability by alerting the public to potential conflicts of interest or

improprieties in the review process. In the past, there have been significant delays in the decision-making process, and we are hopeful that inclusion of this aspect as a desirable characteristic will incentivize compendia to move at a measured pace, consistent with the ever-evolving practice of oncology.

- *Conflicts of Interest*

Bayer also recommends that CMS define the term "conflict of interest" and clarify the standards that compendia must meet to avoid and manage such conflicts. We believe that, at a minimum, a conflict of interest includes any direct or indirect financial interest in any entity, such as a manufacturer or prescription drug plan, that would benefit from a decision regarding a compendial listing. We think that all editorial board members should be required: (1) to sign conflict of interest statements revealing economic or other relationships with entities that may benefit from a compendial decision; and (2) to recuse themselves from discussions or votes in situations involving any drug or manufacturer that presents a conflict of interest or the appearance of a conflict of interest.

- *Use of "Not Recommended" Listings*

Bayer believes that all recommendations should accurately reflect the underlying validated evidence. When that evidence is equivocal, then the compendia should use an "equivocal" listing; when that evidence does not support a particular indication, then the compendia should use a "not recommended" listing. Compendia should not use a "not recommended" listing when the validated evidence is equivocal.

- *Open Communication Channels*

CMS is well-acquainted with the benefits that flow from soliciting stakeholders' comments on important issues. As such, Bayer strongly believes that, just as with CMS decision-making, interested stakeholders should be able to communicate with the compendium's editorial and advisory medical boards in an appropriate and transparent manner. Open communication channels allow stakeholders to facilitate a meaningful exchange of the latest

scientific evidence and analysis and ensures well-informed decision-making resistant to bias. Therefore, CMS should evaluate whether the compendia have established a formal process through which interested stakeholders can submit their views, as well as appropriate safeguards, for example, to prohibit *ex parte* communications.

- *Carrier Interpretation of Compendia Recommendations*

Bayer respectfully requests that CMS take this opportunity to clarify that carriers must consider all indications supported by the listed compendia to be "medically accepted indications." The Act defines the term "medically accepted indication" as a use of an FDA-approved drug supported by such compendia.[14] The Act further permits carriers to identify *additional* medically accepted indications based on certain approved publications.[15] Importantly, the Act does not permit local contractors to interpret the determinations of "medically accepted indications" made by the listed compendia. We believe that a restatement of the circumstances under which carriers may and may not exercise discretion would be helpful as CMS continues its work in this area. Furthermore, as a related matter, we request that CMS finalize its updated list of journals and publications that carriers may rely upon in their administration of the Medicare Part B program.

- *Breadth of Listings*

We strongly believe that a compendium's listings must be robust and comprehensive, reflecting a broad survey of oncologic drugs, rather than a narrow, biased one. We also believe that the listings for each drug should, when appropriate and properly supported by validated evidence, include recommendations regarding drug dosing and route of administration. We ask CMS to clarify that the criterion "extensive breadth of listings" refers not only to the number of drugs listed, but also to the recommendations listed per drug, and that broad, comprehensive compendia generally will include recommendations on drug dosing and route of administration, when appropriate.

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[14] Social Security Act § 1861(t)(2)(B).
[15] *Id.*

TRHCA—SECTION 101(b): PQRI

Bayer thanks CMS for its proposal to retain and include in the final 2008 PQRI measures the 2007 PQRI measures presented in Table 16 of the Proposed Rule, contingent upon National Quality Forum ("NQF") endorsement of each such measure. Because NQF represents a voluntary consensus standards body that includes significant stakeholder involvement and voting participation in the standards development process, these PQRI measures necessarily reflect widely-held and accepted procedures and treatments integral to the proper care of Medicare beneficiaries.

As a manufacturer of products designed to control diabetes, we are particularly sensitive to ensuring that beneficiaries suffering from this condition receive the highest quality treatment. Hemoglobin A1c testing, for example, is essential for managing patients' diabetes and reducing their risk of developing microvascular complications.[16] We strongly support the inclusion of A1c testing in the 2008 PQRI measures, and the continued collection of data coded with respect to whether patients' A1c levels are either below 7.0%, from 7.0% to 9.0%, or above 9.0%. The collection of such detailed data will not only permit CMS to detect "poor" control of A1c (A1c > 9.0%), but also A1c control that falls short of the American Diabetes Association's standard of care (A1c $\leq$ 7.0%).

Furthermore, we believe that incentivizing physicians and other practitioners to collect and report data on quality measures can lead to significant improvements in beneficiary care for diabetes and the other serious conditions listed in Table 16. Bayer is hopeful that PQRI will yield important data regarding the treatment of these conditions, and will ultimately increase the quality of care provided to patients. We commend CMS for its fine efforts on behalf of all Medicare beneficiaries.

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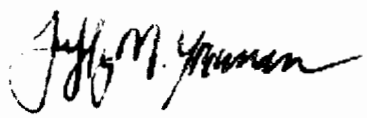
[16] 2007 Physician Quality Reporting Initiative Specifications Document.

CONCLUSION

We appreciate this opportunity to comment on the Proposed Rule, and we thank you for your consideration of the above comments. We would be happy to further discuss any or all of the aforementioned issues with CMS, and we look forward to continuing to work with CMS to improve the health of Medicare beneficiaries.

Sincerely,



Jeffrey M. Greenman
General Counsel and Secretary
Bayer HealthCare LLC and Bayer Pharmaceuticals Corporation

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[redacted]

Talecris BIOTHERAPEUTICS

August 31, 2007

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

Dear Mr.Kuhn:

Talecris Biotherapeutics ("Talecris") submits the following comments in response to the Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (the "Proposed Rule").[1] We are committed to working openly with the Centers for Medicare and Medicaid Services ("CMS" or the "Agency"). Your efforts will have a critical effect on health care access for Medicare beneficiaries, and we commend you for your work on their behalf.

Talecris is a company proud to have inherited a legacy of more than 60 years of providing lifesaving and life-enhancing plasma-derived therapeutic proteins. We are perhaps best known for our intravenous immune globulin ("IVIG") product, Gamunex® (Immune Globulin Intravenous (Human), 10% Caprylate/Chromatography Purified). We aim to be the recognized global leader in developing and delivering IVIG and other premium protein therapies.

In summary, Talecris presents the following comments for consideration:

- **Coding-Payment for IVIG Add-on Code:** Talecris appreciates the Agency's continued attention to IVIG access-related issues; however, we strongly disagree with CMS' statements regarding the increase in off-label use for IVIG, which evidence demonstrates has actually decreased as a proportion of total IVIG use.

- **Sustainable Growth Rate:** We encourage CMS to make all permissible regulatory changes within the boundaries of the statutory requirements to alleviate the 9.9 percent conversion factor cut and ensure that Medicare adequately reimburses physicians for the costs of services provided.

- **Clotting Factor:** Because the furnishing fee update process is statutorily determined and based on an index that is not affected by administrative

[1] 72 Fed. Reg. 38,122 (Jul. 12, 2007).

discretion or public comment, Talecris supports CMS' proposal to communicate updates regarding blood clotting furnishing fees in program instructions.

- **Widely Available Market Prices ("WAMP") and AMP Threshold:** Talecris thanks CMS for its thoughtful approach to the determination of the applicable WAMP and AMP threshold percentage. Because we believe it is imperative that manufacturers and other stakeholders receive adequate notice from CMS for all potential price substitutions, we are encouraged by this proposal. As such, we invite CMS to consider providing at least three calendar quarters notice to afford appropriate opportunity for stakeholder comment.

- **Bundled Price Concessions:** We support the general policy that any bundled relationship should have price reporting treatment that accurately reflects the value of the bundle to the products that are the subject of that bundle. Despite CMS' assertions to the contrary, however, we firmly believe that the proposed definition of "bundled arrangement" represents a significant policy shift and thus should be applied prospectively only.

- **Drug Compendia:** We generally agree with CMS' proposal regarding the addition of approved compendia. As part of CMS' review of approved compendia, Talecris believes that evidence-based compendia, transparency, appropriate communication channels and robust protections against conflicts of interest are imperative to the determination of approved compendia and should be prioritized accordingly. We encourage CMS to refine its consideration of transparency, open communications and conflicts of interest, among other issues, in this context.

We thank you in advance for consideration of our comments on these issues, which are discussed in detail below.

I. CODING—PAYMENT FOR IVIG ADD-ON CODE

As an IVIG manufacturer, Talecris read with interest the Agency's proposal to extend the add-on payment for IVIG pre-administration-related services.[2] This proposal demonstrates CMS' prudent exercise of its discretion to facilitate beneficiary access to this critical therapy.

We thank the Agency for its continued attention to access-related IVIG issues. Moreover, we commend CMS for its recent decision to create product-specific codes for non-lyophilized IVIG products, effective July 1, 2007. We believe the decision to issue separate codes will substantially alleviate beneficiary access to IVIG. Accordingly, we encourage CMS to act swiftly to create permanent J-codes for IVIG products as part of CMS' commitment towards ensuring reliable access to this often life-saving therapy.

[2] *Id.* at 38,146.

[redacted]

Although we believe that CMS' treatment of IVIG is generally headed in the right direction, we were disappointed by the inclusion of a statement regarding off-label usage of IVIG. Talecris was particularly concerned with CMS' comment that "the demand for this product has grown because of off-label uses."[3] We are deeply troubled by the conclusory nature of the comment when, in fact, there is strong evidence to the contrary.

We direct your attention to a recent report by the University of Chicago, *The Impact of Medicare Modernization Act Reimbursement Changes on the Utilization of Intravenous Immune Globulin*.[4] (Attachment A). This research examined trends in off-label IVIG use, measuring whether there had been an expansion in off-label use and comparing trends in IVIG use in both Medicare and non-Medicare populations. While the report found that a majority of IVIG use is off-label, it concluded that off-label use has generally remained constant over time.[5] The report found that, overall, the proportion of off-label use of IVIG remained relatively constant, stating that "while the majority of IVIG users in [its] data have claims for off-label indications, the *proportion* of off-label users has remained relatively unchanged from 1997 to 2005. Clearly, therefore, changes in off-label use do not explain shortfalls in IVIG access."[6] Interestingly, in 2005, when IVIG access issues were initially reported by Medicare beneficiaries, the report found that off-label use actually *decreased* as a proportion of all use during that year.[7] We believe that inadequate reimbursement, which has been partially addressed by the separation of codes, has been the major driver of beneficiary access to IVIG.

Implicit in CMS' statement regarding off-label IVIG usage is the concern that coverage for some indications may be questionable. If CMS wishes to consider the appropriateness of off-label uses of IVIG, we believe it would be most appropriate for CMS to do so on a local level. The local coverage determination ("LCD") process is more than adequate to ensure prompt review of any concerns that CMS may have about the appropriate use of this therapy. If CMS were inclined to review the appropriateness of some indications, we fear that opening a national coverage determination ("NCD") restricting IVIG coverage would create great uncertainty in the IVIG marketplace. Accordingly, in the event CMS determines such a review to be necessary, we believe that the LCD process would be the most adequate forum for such coverage determinations.

In sum, we are encouraged by CMS' continued attention to IVIG access issues. We urge the Agency to issue separate, permanent codes for all liquid IVIG products expeditiously. And, as CMS continues to assess IVIG, we ask the Agency to examine carefully the available research demonstrating that off-label use of this therapy is not disproportionately driving demand among Medicare beneficiaries.

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[3] *Id.*

[4] Tomas Philipson, Ph.D and Anupam B. Jena, Ph.D., *The Impact of Medicare Modernization Act Reimbursement Changes on the Utilization of Intravenous Immune Globulin* (2007). This White Paper was commissioned and the costs of conducting research were paid for by Talecris. However, the findings contained in were those of the authors' alone.

[5] In 1997, almost 60 percent of IVIG users had at least some off-label claims for IVIG with this number remaining nearly unchanged in 2005. *See id.* at 9.

[6] *Id.* at 3.

[7] *Id.* at 9.

[redacted]

II. SUSTAINABLE GROWTH RATE CUT

Providers are the cornerstone to the Medicare program. Without adequate Medicare reimbursement, beneficiary access to their care will suffer. A steep cut in reimbursement rates may force many physicians to no longer participate in the Medicare program. Our experience with IVIG access issues demonstrates the devastating impact that inadequate Medicare reimbursement can have on beneficiary access.[8]

Accordingly, Talecris urges the Agency to ameliorate the estimated -9.9 percent CY 2008 Physician Fee Schedule conversion factor update by taking all permissible regulatory steps within the boundaries of the statutory requirements to alleviate this cut in provider reimbursement.[9] While we believe the recent CMS decision to issue separate product-specific codes will significantly alleviate IVIG access issues, we fear that this significant cut in Medicare reimbursement may exacerbate existing access issues and reverse our progress to date. As such, we respectfully request CMS make all permissible regulatory changes to alleviate potential cuts in provider reimbursement.

III. AVERAGE SALES PRICE ISSUES

Based on our review of the Proposed Rule, we offer comments on the following proposals related to ASP: publication of clotting factor furnishing fee changes, the WAMP and AMP threshold, and definition of bundled arrangement,

A. Clotting Factor

Talecris supports the payment of adequate blood clotting factor furnishing fees to physicians. As a result, we read with interest CMS' proposal to cease discussion of the furnishing fee update for blood clotting factors in the annual rulemaking process, and instead, communicate the blood clotting furnishing fee in CMS program instructions.[10] Because the furnishing fee update process is statutorily determined and based on an index that is not affected by administrative discretion or public comment,[11] we agree with CMS' proposal to issue communications regarding the furnishing fee updates in program instructions. We encourage CMS to adopt this provision as proposed.

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[8] In its report, *Intravenous Immune Globulin: Medicare Payment and Availability*, the Department of Health and Human Services Office of Inspector General concluded that "certain ASP-related issues" related to inconsistent acquisition prices and reimbursement rates for IVIG in 3Q 2006 caused significant beneficiary access issues. *See* Department of Health and Human Services, Office of Inspector General, *Intravenous Immune Globulin: Medicare Payment and Availability* (2007). Providers often cited inadequate Medicare payment amounts as a reason they began to shift patients to other sites of service. *Id.* Because nearly half of the distributors and physicians were unable to purchase IVIG at or below Medicare payment rates, it is clear that inadequate Medicare reimbursement was a significant cause of patient access issues.

[9] 72 Fed. Reg. at 38,214.

[10] 72 Fed. Reg. at 38,152.

[11] Social Security Act § 1842(o)(5). The statute specifies that the furnishing fee for subsequent years will be equal to the year for the previous year increased by the percentage increase in the consumer price index ("CPI") for medical care for the 12-month period ending with June of the previous year.

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

Talecris commends CMS for its thoughtful approach to the determination of the threshold for the substitution of WAMP or AMP for ASP.[12] We agree with CMS' proposal to maintain the 5 percent threshold for CY 2008.

We are pleased to see CMS' proposal to proceed cautiously in their decisions regarding the applicable threshold for substitution.[13] Manufacturer calculations of ASP and AMP have been significantly impacted by CMS' promulgation of the ASP final rule. Together with the recent changes to AMP contained in the final rule with comment period, the potential implications for substitutions remain unknown. These price reporting changes may significantly affect the comparisons between WAMP, AMP and ASP. As such, we agree that CMS should proceed cautiously in their determination of the substitutability of these various price calculations. This is particularly true where WAMP or AMP is less than ASP, as such changes in reimbursement may lead to significant beneficiary access issues.

In addition, we thank CMS for recognizing the importance of giving manufacturers and other stakeholders "adequate notice" of potential price substitutions.[14] More than one quarter's notice is necessary for manufacturers to be able to provide CMS sufficiently detailed information regarding the potential impact of a proposed substitution. We suggest that CMS consider providing no less than three quarter's notice, which would allow all stakeholders to be appropriately engaged in such a determination and its impact can be fully assessed. Alternatively, we suggest that CMS consider a formal rulemaking process for the determination of WAMP or AMP substitutions.

Again, we thank CMS for its well-reasoned decision to maintain the 5 percent threshold and provide for "adequate notice" of a substitution, which we believe should be no less than 3 quarters in length.

C. Bundled Arrangement

Talecris supports CMS' efforts to find a method of individually apportioning price concessions to bundled products in a manner that accurately reflects the value of the bundle.[15] We support the general policy that any bundled relationship should have price reporting treatment that accurately reflects the value of the bundle to the products that are the subject of that bundle. We applaud CMS for providing further guidance on the proper method to apportion price concessions among drugs sold under bundling arrangements.

In reading the Proposed Rule, however, we note that the proposed definition of bundled arrangement in the ASP context—similar to the proposed definition of bundled sale in the Average Manufacturer Price ("AMP") final rule with comment period—inexplicably differs from the Medicaid Rebate Agreement ("MRA") definition of bundled sale.[16] Despite CMS'

[12] 72 Fed. Reg. at 38,152.
[13] *Id.* at 38,153.
[14] *Id.*
[15] *Id.* at 38,151.
[16] Similar to the definition of "bundled sale" in the AMP context, without question, the proposed definition for "bundled arrangement" for ASP purposes is a new definition. To illustrate the extent of substantive

suggestion to the contrary, a plain reading of both its ASP and AMP bundling proposals demonstrates that the definitions constitute much more than a mere clarification, as CMS suggests in AMP context.[17] We are particularly troubled by this suggestion because such a reading implies a retrospective application, which we believe is prohibited by the Administrative Procedures Act ("APA"), as a retrospective, substantive policy change.[18]

IV. DRUG COMPENDIA

Pursuant to section 1861(t)(2)(B)(ii)(I) of the Social Security Act (the "Act"), three drug compendia may be used in the determination of medically accepted indications of drugs and biologicals used in anti-cancer chemotherapeutic regimens—American Hospital Formulary Service-Drug Information ("AHFS–DI"), American Medical Association Drug Evaluations ("AMA–DE") and United States Pharmacopoeia-Drug Information ("USP–DI") or its successor publications.[19] Due to changes in the pharmaceutical reference industry, fewer of the statutorily named compendia are available for CMS' reference.[20] AMA-DE, for example, has not been published for some time. Fortunately, the Act provides the Secretary the authority to revise the list of compendia for determining medically accepted indications for drugs.

We generally agree with the proposed process to be used by CMS in the review of requests for adding certain compendia.[21] Talecris is hopeful that it will pave the way to robust stakeholder participation and sound decision-making. While we thank the Agency for its proposal of a thorough, formal process, we have significant concerns regarding the Proposed Rule's allusion to the elimination of recognized compendia. Because the elimination of a compendium would have a significant impact on beneficiary access to life-saving therapies, we urge great caution in doing so.

In addition to CMS' proposal regarding an approval process, Talecris was equally pleased with the Proposed Rule's discussion of the criteria CMS will consider in approving additional compendia. Talecris believes that evidence-based compendia, transparency, appropriate communication channels and robust protections against conflicts of interest should be imperative in CMS' determination of adding compendia. We were pleased that MedCAC identified many of these as desirable characteristics, and we hope that these issues will be at the forefront of CMS' analysis regarding compendia recognition.

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changes, we have underlined the portions of the proposed "bundled sale" in the AMP context which vary from the MRA definition: "Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."

[17] 72 Fed. Reg. at 39,158.

[18] *See* Coalition for Common Sense in Gov't Procurement v. Sec'y of Department of Veterans Affairs, 464 F.3d 1306, 1308-09 (Fed. Cir. 2006) *citing* Paralyzed Veterans of America v. West, 138 F.3d 1434, 1436 (Fed. Cir. 1998).

[19] Effective July 1, 2007, the DrugPoints System replaced USP-DI.

[20] 72 Fed. Reg. at 38,177.

[21] *Id.* at 38,178.

[redacted]

Talecris believes that the use of the MedCAC-recommended desirable characteristics of compendia will help ensure broad patient access to oncologic drugs consistent with the best available clinical and scientific evidence. Because of the evolving nature of cancer care, it is of great importance that CMS' evaluation of drug compendia be thorough and principled. In approving a drug compendium, we encourage CMS to look for pre-specified and scientifically- and procedurally-sound criteria for drug evaluation. We believe that this will be an important aspect for CMS to review in making the determination as to whether a compendium will serve as a reliable source of medically-accepted indications for oncologic drugs.

We are hopeful that the criteria listed in the Proposed Rule will assist CMS in its recognition decisions. Transparency, for instance, is a key attribute we consider to be essential to CMS' consideration. To ensure a greater level of transparency in the compendia process, we propose that CMS look for compendia that use pre-specified published criteria for weighting evidence and making recommendations, and use of a publicly transparent process for evaluating therapies. Moreover, we encourage CMS to seek out compendia that publicly identify the members of the advisory and scientific review committees. Finally, we urge CMS to consider whether a compendia uses transparent timelines in making decisions regarding use of different therapies. In the context of oncology treatments, anything less than a prompt response to constantly evolving medical evidence should not be tolerated.

Similarly, we are concerned that the MedCAC criteria do not explicitly include open communication channels between the compendia and the stakeholders as a desirable characteristic. Open communication ensures that interested stakeholders are permitted to participate in the evaluation prices of the latest scientific evidence on anti-cancer therapies. It also protects against potential bias and conflicts of interest. That being said, there should be reasonable limits upon open communication so that inappropriate communications, such as *ex parte* communications, are prohibited. Because such open communication is particularly important, we believe CMS should include the levels of open communication between a compendia and a stakeholder in CMS' evaluation of compendia.

Talecris is also particularly concerned about potential compendia additions or eliminations and their conflict of interest procedures. We believe CMS should clarify how such conflicts of interest could be avoided and managed by a particular compendia by issuing clear guidance on standards for a compendia's conflict of interest provision. Such guidance could include standards for handling conflicts of interest, disclosure statements of conflicts, and standards for a compendia's recusal from decisions regarding particular therapies. We urge CMS to look for these safeguards when evaluating compendia.

We further propose that CMS examine a compendium's use of substantial and reliable clinical and scientific evidence in its decision-making process for recommendations regarding the use of therapies. Regarding "not recommended" listings in a particular approved compendia, Talecris suggests CMS rely on such decisions only when validated clinical and scientific evidence is available. We oppose the use of "not recommended" listings when the validated evidence is equivocal.

Again, we thank you for your thorough consideration of the process and criteria appropriate for CMS to use in approving compendia. We look forward to continued developments in this area and urge the Agency to consider our suggestions regarding

transparency, open communications, conflicts of interest and treatment of "not recommended" listings.

V. CONCLUSION

On behalf of IVIG patients, we thank CMS for its ongoing work to ensure beneficiary access to critical, life-saving therapies. Please let us know how we can be of further assistance to you in developing the final rule.

Sincerely,

Bruce Bunyan
Vice President
Corporate Communications and Public Policy

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17TH DISTRICT, CALIFORNIA

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August 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
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File code: CMS-1385-P
Re: GPCI

Dear CMS:

I write today to comment on the proposed rule as noticed in the July 12, 2007 *Federal Register* regarding geographic practice cost index (GPCI) matters. I urge the CMS to redefine Physician Payment localities in California as precisely as possible based on the most accurate data available using a consistent and appropriate methodology to do so.

It is no secret that CMS has erroneously designated a number of counties in California as "Rest of California" otherwise known as Locality 99 when their GAFs clearly make them eligible for separation out of Locality 99 and into a new locality per CMS' own rules. That CMS has failed to do so demands correction. Thankfully, CMS in its proposed rules for Physician Reimbursement for CY2008 has offered three options to correct the GPCI oversight.

For years CMS has acknowledged that a number of California counties – Santa Cruz, Monterey, and Santa Barbara, and San Diego, to name just a few – have GAFs far above CMS' 5% threshold that define when a county deserves its own locality calculation. The consequences of not implementing locality reform for these counties have been enormous. For example Santa Cruz County doctors are paid the lowest rate ("Rest of California) while neighboring doctors in Santa Clara County are paid at one of the highest rates. The disparity between the two counties is the greatest in the entire United States. Even common sense tells us that such situations are not defensible. Besides driving doctors away from the Medicare system, this erroneous CMS payment policy has created access issues for local seniors, compounding the problem.

I support Option Three because it uses the 5% iterative methodology that CMS used to reconfigure localities in 1996. However, in order to promulgate a rule that is honest and fair I offer suggestions to modify Option Three in order to make it more accurate and precise.

As you know, shortly after the July 12 *Register* notice, the GAO published a report on CMS' locality designations and GPCI calculations and found that CMS over time has revised localities

under a variety of different approaches and never uniformly. Unfortunately, Option Three as published in the July 12 *Register* suffers from this inconsistency.

The *Register* text accompanying the GPCI update provisions states that "The geographic adjustment factors (GAFs) for more than 90 percent of counties are developed using proxies based on larger geographic areas" (page 38139). Using the same census data as CMS, the GAO was able to calculate individual work and practice expense GPCIs for 1091 counties that were part of a metropolitan statistical area (MAS) (GAO-07-446, page 46). However, there seems to be a discrepancy – a significant one – in the GAF for San Benito County, California between what the CMS says the GAF is and therefore into which locality San Benito falls, and what the GAO says the GAF is for San Benito and into which locality it falls. GAO gives San Benito a GAF of 1.081 (page 54 of GAO report 07-446) while CMS gives San Benito a GAF of .971 (page 38142 of the *Register*). This discrepancy cannot be explained by differences in rent indices and/or malpractice GPCIs.

It would seem that CMS used the wrong MSA-derived census data. San Benito County resides in the San Jose (CA) MSA, not California Non-Metropolitan Areas as suggested by the CMS GAF.

Consequently, though Option Three provides the fairest methodology for redesignating physician payment localities, it uses the wrong data to do so. I wonder, too, if this is the reason that CMS lists the GAF for Monterey and Santa Cruz counties in Option Three as being different from those counties' GAFs as listed in Options One and Two? If CMS intends to promulgate Option Three, or any option for that matter, it should do so using data that is appropriate, accurate and without doubt. It is simply wrong to write rules that use faulty data.

I am too painfully aware of the budget sensitivity of promulgating one of these options. However, it is my belief that the Secretary has sufficient discretionary powers that could ameliorate any offsetting cuts to Locality 99 that would otherwise occur. It is also my belief that had CMS acted more promptly in addressing this issue it would not be at crisis level today. Nonetheless, failing to act only exacerbates the problem. Action today is imperative – but action that is based on real data and the correct methodology.

Thank you for the chance to comment on this proposed rule. I hope you will give these comments serious consideration and do what is fairest for the California doctors and Medicare beneficiaries.

Sincerely,

SAM FARR
Member of Congress

SF/rsd

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MEDICAL GROUP

August 1, 2007

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

Re: CMS–1385–P: CODING - ADDITIONAL CODES FROM 5-YEAR REVIEW

On behalf of Pediatrix Medical Group and its affiliated pediatric cardiology practices, we appreciate the opportunity to comment on CMS' proposed rule "Proposed Revisions to Payment Policies under the Physician Fee Schedule, and other Part B Payment Policies for CY 2008" [CMS-1385-P]. Our comments address the proposed coding change to bundle CPT 93325 (Color Flow Doppler Echocardiography) into codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350, and focus on those aspects of direct concern to pediatric cardiologists and their patients: namely, the lack of administrative due process followed in this instance, the extremely negative impact this regulatory action would have on pediatric cardiology practices, and the potential impact on patient access to care.

Pediatrix is a large national medical group of physicians and advanced nurse practitioners, including over 60 pediatric cardiologists. We provide pediatric subspecialty services, including neonatology, maternal-fetal medicine, as well as cardiology and other services in 32 states and Puerto Rico. Our physicians and other practitioners care for premature and critically ill newborns, sick and injured children, and women with high-risk pregnancies.

First, with regard to the administrative process, we believe it is important to note that the CPT Editorial Panel already recommended earlier this year that a new code be established that would combine 93325 with 93307 and 93320, for implementation in 2009. The RUC is scheduled to evaluate the recommended relevant work and practice expense for this new code at its next upcoming meeting. Importantly, the CPT editorial panel did not recommend bundling 93325 with other echocardiography base codes, other than 93307.

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

However, as a result of this proposed rule to bundle 93325 into CPT codes other than those recommended by the RUC/CPT Editorial Panel, the 93325 bundling issue now directly impacts a distinctly non-Medicare population – namely, pediatric cardiology practices. Further, because the proposed regulation runs contrary to the normal administrative process followed for such changes, specialty societies have not been able to evaluate the proposed change and its impact on pediatric cardiology and develop appropriate new Work and Practice Expense proposals for consideration by the RUC.

Our second concern focuses on this issue: namely, the extremely adverse impact this proposal will have on pediatric cardiology. The surveys performed to set the work RVUs for almost all of the echo codes utilized specifically by pediatric cardiologists and affected by this proposed change were performed more than 10 years ago. As a result, particularly with respect to 93325, the RVUs are reflective of a focus on the cost of the

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technology and not the advances in care that have been developed as a result of the technology. Particularly among pediatric cardiologists, new surveys are needed which we believe would show that the work and risk components of the procedures that involve Doppler Color Flow Mapping have evolved to the point where the relative value of the procedures have shifted to a significantly greater work component and a lesser technology component.

This shift is reflected in the development of national standards such as those present in the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) initiative to develop and implement an echo lab accreditation process. The focus of this initiative is on 'process', meaning work performed, and not on the 'technology' associated with the provision of echocardiography services. This echocardiography accreditation initiative will be mandated by many payors within the next year.

In 1997 there were specific echocardiography codes implemented in CPT for congenital cardiac anomalies to complement the existing CPT codes for echocardiography for non congenital heart disease. "The codes were developed by the CPT Editorial Panel in response to the American Academy of Pediatrics and the American College of Cardiology's request to delineate more distinctively the different services involved in *assessing* and *performing* echocardiography on infants and young children with congenital cardiac anomalies." *(CPT Assistant 1997).*

Consistent with this, we are concerned with proposals that place adult and pediatric patients in the same grouping, as it pertains to evaluation of the work associated with providing care to these significantly different patient populations. Because the adult cardiology population is much larger than the pediatric population, the RVUs for procedures that are common to both are established exclusively using adult patients as the basis. The Work and Practice Expense associated with providing care to pediatric patients is not considered. The inaccuracies that result from this approach can be linked to anatomical differences between pediatric and adult patients (size, development, etc. - see references from the CPT Assistant below) as well as the basic issue of getting a child to be still while performing complex imaging procedures. Examples follow:

CPT Code 93325 describes Doppler color flow velocity mapping. This service is typically performed in *conjunction* with another echocardiography imaging study to define structural and dynamic abnormalities as a clue to flow aberrations and to provide internal anatomic landmarks necessary for positioning the Doppler cursor to record cardiovascular blood flow velocities.

Pediatric echocardiography is unique in that it is frequently necessary to use Doppler flow velocity mapping (93325) for diagnostic purposes and it forms the basis for subsequent clinical management decisions. CPT Assistant in 1997 references the uniqueness of the 93325 for the pediatric population stating that Doppler color flow velocity is "... even more critical in the neonatal period when rapid changes in pressure in the pulmonary circuit can cause significant blood flow changes, reversals of fetal shunts and delayed adaptation to neonatal life." It should also be recognized that Doppler flow velocity mapping is an essential medical service being provided to patients with congenital and non-congenital heart disease in the pediatric population.

The following vignettes will illustrate the importance of the Doppler color flow velocity mapping (93325) remaining as a separate and distinct medical service and as an add-on code (+) for pediatric echocardiography services. These are just a few examples of the many complex anatomic and physiologic issues that we as pediatric cardiologists face on a daily basis when performing echocardiograms on infants, children, and adults with complex congenital or non-congenital heart disease. These are not unusual cases for us.

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Vignette 1 (*quoted from CPT Assistant 1997*) (example of Congenital Heart Disease)

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

Vignette II (example of non-congenital heart disease)

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

Vignette III (example of congenital heart disease)

An eight year-old child (or a 23-year-old young adult), with complex cyanotic congenital heart disease (functional single ventricle) is post-op completion of a fenestrated Fontan procedure several years ago. He has had a progressive decrease in saturations over the last year. There are several possible explanations and the pediatric cardiologist performs an echocardiogram to help determine the etiology. Color flow Doppler (93325) is essential to help elucidate the postoperative anatomy and blood flow patterns, but the process is complex and time-consuming involving assessment of the surgically constructed lateral tunnel or extracardiac conduit searching for a residual fenestration shunt or obstruction to flow, assessment of flow patterns through the previously surgically constructed Glenn anastomsis between the superior vena cava and pulmonary artery, assessment for obstruction to flow through the bulboventricular foramen, assessment for significant AV valve or semilunar valve insufficiency, and assessment for collateral vessels directing venous (desaturated blood) into the heart that may have developed over time. Any or all of these findings will then help dictate the next step in the care of this patient.

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

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On behalf of Pediatrix Medical Group and its 60+ cardiologists, we respectfully urge CMS to withdraw the proposed change with respect to bundling 93325 with other pediatric cardiology echocardiography codes until such time as an appropriate review of all related issues can be completely analyzed. Once this review is completed an appropriate solution can be developed.

Thank you for your consideration of this serious matter.

Sincerely,

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August 31, 2007

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

Subject: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Weems:

On behalf of our 70,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the Center for Medicare and Medicaid Services (CMS) Proposed Notice regarding "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Part B Payment Policies," published in the July 12, 2007, *Federal Register*.

The physician fee schedule is currently the basis of payment for outpatient therapy services furnished by therapists in private practice, hospitals, rehabilitation agencies, public health agencies, clinics, skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities (CORFs). Therefore, the physician fee schedule rules have a significant and direct effect on payments to physical therapists.

These comments address: 1) the fee schedule update formula; 2) the therapy standards and requirements; 3) the recertification requirement; 4) the therapy cap; 5) the extension of the physician quality reporting initiative (PQRI); 6) the use of registries; 7) the physician self-referral provisions; and 8) CORF provisions. Our comments on each of these provisions are discussed in further detail in the following paragraphs.

Therapy Standards and Requirements (page 38191)

CMS proposes to update the personnel qualifications for physical therapists (PTs), physical therapist assistants (PTAs), occupational therapists (OTs), and occupational therapist assistants (OTAs). Specifically, the Agency is proposing to broaden the current grandfathering requirements to recognize practicing physical therapists, occupational therapists, physical therapist assistants, and occupational therapist assistants who meet their respective state qualifications (e.g., have been

licensed, certified, registered, or otherwise regulated by their state as PTs, OTs, PTAs, or COTAs) before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than two years. Individuals who begin practicing as physical therapists, physical therapist assistants, occupational therapists, and occupational therapy assistants after January 1, 2008, would be required to meet the new qualifications proposed in the regulation at section 484.4. CMS does not propose to broaden the grandfathering provisions for physical therapists working in home health agencies.

In the rule, CMS seeks comments regarding the following:

1) Appropriate grandfathering provisions relating to qualifications of therapists and assistants to assure that skilled therapists and assistants with comparable and appropriate education and training treat Medicare beneficiaries in all settings.
2) Whether the personnel qualifications in section 484.4 should be applicable to other settings.
3) Qualifications for PTs that include a curriculum and a national examination each approved by the APTA
4) Appropriate qualifications for PTAs.

APTA's response to the information requested by CMS is included below.

"New Grandfathering Provisions for Physical Therapists and Physical Therapist Assistants"

In the rule, CMS adds grandfathering provisions for physical therapists and physical therapist assistants in sections 409.17, 409.23, 410.60, 485.70, 485.705, 491.9. The regulatory text below is proposed in the rule.

> *A physical therapist and a physical therapist assistant must meet one of the following qualifications:*
>
> *(1) As set forth in §484.4 of this chapter.*
>
> *(2) **Qualified physical therapists (emphasis added)** or physical therapist assistants must have been licensed, certified, registered, or otherwise recognized as physical therapists or physical therapist assistants by the State in which practicing before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.*

APTA strongly recommends that CMS amend the new grandfathering language (referenced above) to remove "qualified physical therapists" from this provision. All physical therapists currently practicing meet the education and licensure requirements included in section 484.4. Therefore, it is unnecessary to include qualified physical therapists in this "new" broadened grandfathering provision.

However, we agree with CMS that this new grandfathering provision is necessary for physical therapist assistants. The definition of physical therapist assistants included in the existing section 484.4 requires that after 1977 a PTA be a graduate of a two-year college level program approved by the American Physical Therapy Association. The existing provision does not address PTAs who are trained outside the United States or trained in the military. Some states, such as California, allow individuals who are not graduates of a two-year college level physical therapist

assistant program to be licensed and practice as physical therapist assistants if the individual successfully passes the licensure exam in the state in which he or she practices and meets certain training or education requirements. We believe that these individuals who have been licensed, registered, certified, or otherwise recognized by their state as a physical therapist assistant prior to January 2008 should be able to continue to provide covered services to Medicare beneficiaries. This grandfathering clause would enable them to do so.

The proposed regulations would require that, in order for the new grandfathering clause to apply, the PTA must "continue to furnish Medicare services as least part time without an interruption in furnishing services of more than 2 years." **We recommend that CMS clarify in the final rule that the two year requirement applies to services furnished after January 2008. The requirement should not apply prior to January 2008.**

In the rule, CMS states that this broadened grandfathering provision would apply to all settings except for home health agencies and hospices. **We recommend that CMS make the definitions uniform and apply the new grandfathering provision to home health agencies and hospices in addition to the other settings**. There is no reason to have different standards for personnel in home health and hospice compared to other settings.

Qualifications for Physical Therapists in 484.4

CMS proposes to amend the language in section 484.4 to establish new requirements for individuals beginning their practice on or after January 1, 2008. APTA has several recommendations for amendments to the proposed definition of physical therapist.

First, we recommend that CMS remove the requirement that a physical therapist pass a National Examination approved by the American Physical Therapy Association. The proposed language would require that all physical therapists be licensed in their state. Currently, all states require individuals to pass a national licensing exam in order to be licensed. Therefore, we do not believe this language is necessary.

Second, we recommend that CMS remove the equivalency requirement for individuals trained in the United States military. All physical therapists trained in the United States military are graduates of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE). Therefore, it is unnecessary to establish a credentials evaluation process for physical therapists trained in the military.

It is necessary, however, to revise the regulations to require a credentials evaluation process for individuals educated outside of the United States who want to be recognized as physical therapists to ensure that the education of a foreign educated physical therapist is substantially equivalent to that of a physical therapist educated in the United States. The language pertaining to physical therapists educated outside the United States included in the existing section 484.4 is outdated and does not require that foreign trained physical therapists have education that is comparable to U.S. trained physical therapists. This language has two prongs, one relating to education and the other to the individual's personal characteristics. As to the education prong, the clause applies to any foreign-educated individual who graduated from a program "approved in" any country in which there is a membership organization of the World Confederation for Physical Therapy (WCPT). The education prong does not say what or who must have

"approved" the curriculum. It merely states that the individual must "meet the requirements for membership" in one of the national associations. This prong does not even require that the individual be a member, only that he or she "meet the requirements" Therefore, under this definition, many foreign educated individuals would be able to qualify as a Medicare "physical therapist" under this clause, even if their education is not comparable to U.S. trained physical therapists.

APTA recommends that CMS modify the proposed language to clarify that a foreign educated physical therapist must be a "graduate of an education program that by credentials evaluation conducted by an organization approved by the APTA is deemed to be substantially equivalent with respect to physical therapist entry level education in the United States. We recommend that the approval be of the "credentialing organization" rather than the "credentialing process."

As the national professional organization representing physical therapists, APTA strongly recommends that we be recognized to approve the organizations evaluating the credentials. APTA's goal is to ensure that physical therapy services are furnished by physical therapists who meet professional standards with respect to education and training. If APTA were to approve credentialing evaluations organizations, we would be able to ensure that appropriate decisions are made regarding whether foreign educated physical therapists have met the educational standards of U.S educated physical therapists. As a national professional organization, APTA would have a broad perspective regarding all the available credentialing organizations.

The Commission on Accreditation in Physical Therapy Education (CAPTE), a standing committee of the APTA, sets standards for qualifications of physical therapists domestically and for curricula for physical therapist and physical therapist assistant education programs. The Association's goal is to advance academic quality through the CAPTE accreditation process. APTA also has access to the expertise of CAPTE in curricular assessment and therefore can make determinations regarding whether credentialing organizations have processes in place that result in appropriate decisions regarding whether a foreign educated physical therapist's coursework is substantially equivalent to that of a CAPTE accredited program. Although APTA through CAPTE develops standards for physical therapist and physical therapist assistant education programs, neither APTA nor CAPTE performs credentials evaluation itself. Therefore, APTA has no financial interest in performance of credentials evaluation.

APTA has a proven record of developing formalized, equitable, transparent, open, consensus-based processes for development of professional standards and CAPTE, a standing committee of APTA, has a similar record of developing accreditation standards for physical therapist and physical therapist assistant education programs. CAPTE has the highest level of approval from the United States Department of Education and the Council for Higher Education Accreditation (CHEA).

With respect to the education program, CMS proposes that it be determined to be comparable with respect to physical therapist entry level education in the United States. Rather than using the term "comparable" we recommend that CMS replace it with the term "substantially equivalent." Most states use the term "substantially equivalent" in their practice acts when referencing foreign trained programs. This term is also used by APTA in its policies regarding licensure and regulation (refer to PHYSICAL THERAPIST AND PHYSICAL THERAPIST

ASSISTANT LICENSURE/ REGULATION HOD P05-07-09-10 (Program 32) [Amended HOD 06-99-13-16; Initial HOD 06-91-25-33] [Position on Physical Therapist and Physical Therapist Assistant Licensure].

In the rule, CMS includes draft text of the regulation defining physical therapists at section 484.4. In this text the following language is included:

> *(iv)(e) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977;*

We strongly recommend that CMS delete the text above from the rule. As worded, it would allow an individual with two years of experience as a physical therapist who has **not** graduated from a physical therapist education program to provide services to Medicare beneficiaries. We recognize that this language is included in the current version of 484.4, but it is outdated and should not be included.

To ensure that qualified physical therapists furnish physical therapy services to Medicare beneficiaries, we recommend that CMS revise the definition of physical therapist to state the following:

> **Physical therapist.** *A person who is licensed by the State in which practicing, and meets one of the following requirements:*
>
> *~~(1) Requirements for individuals beginning their practice on or after January 1, 2008. Meets all practice requirements set forth by the State in which the physical therapy services are furnished and meets one of the following educational/training requirements on or after January 1, 2008:~~*
>
> *(a) Has Graduated after successful completion of a ~~college or university~~ physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); ~~and~~ or*
>
> *~~(B) Passed the National Examination approved by the American Physical Therapy Association.~~*
>
> *(b) If educated outside the United States ~~or trained by the United States military~~ graduated after successful completion of an education program that~~, by~~ a credentials evaluation **organization** ~~process~~ approved by the American Physical Therapy Association, is determined to be **substantially equivalent** ~~comparable~~ ~~with respect~~ to physical therapist entry level education in the United States; ~~and~~ or*
>
> *~~(B) Passed the National Examination approved by the American Physical Therapy Association.~~*
>
> *~~(2) Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008. Has graduated from a physical therapy curriculum approved by one of the following after December 31, 1977 and before January 1, 2008:~~*
>
> ***(c) Has graduated prior to January 1, 2008 from a physical therapy curriculum approved by:***
>
> *~~(i)~~ (1)The American Physical Therapy Association, **or***

~~(ii)~~ *(2) The Committee on Allied Health Education and Accreditation of the American Medical Association,* ***or***

~~(iii)~~ *(3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association;* ***or***

~~*(3) Requirements for individuals beginning their practice on or after January 1, 1966 and on or before December 31, 1977. Had 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977.*~~

(d) Prior to January 1, 1966,

~~*(4) Requirements for individuals beginning their practice before January 1, 1966. Meets one of the following requirements before January 1, 1966:*~~

~~(i)~~ ***(1)*** *Was admitted to membership by the American Physical Therapy Association,* ***or***

~~(ii)~~ ***(2)*** *Was admitted to registration by the American Registry of Physical Therapists,* ***or***

~~(iii)~~ ***(3)*** *Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education;* ***or***

~~*(iv)(e) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or*~~

(e) *Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy;* ***or***

(5) ~~*Requirements for individuals trained outside of the United States before January 1, 2008.*~~ *If trained outside the United States before January 1, 2008 meets the following requirements:*

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Qualifications for Physical Therapist Assistants in section 484.4

CMS proposes to amend the language in section 484.4 related to physical therapist assistants who begin practicing after January 2008. **APTA supports this proposed language.**

The existing section 484.4 would not allow individuals educated outside the United States or individuals trained by the military to be recognized as physical therapist assistants under the Medicare program. **We believe CMS should adopt a policy that allows for the evaluation of educational programs and military training to determine whether that education is substantially equivalent to physical therapist assistant entry level education in the United States.** If individuals meet these educational requirements along with licensure or other applicable state laws, then they should be recognized.

It is critical that CMS require that the credentials evaluations organization be approved by the American Physical Therapy Association to ensure that foreign trained physical therapist assistants receive an education equivalent to PTAs educated in the U.S. CAPTE, a standing committee of the APTA, sets standards for curricula for physical therapist assistant education programs. APTA has a proven record of developing formalized, equitable, transparent, open, consensus-based processes for development of professional standards and CAPTE has a similar record for development of accreditation standards for physical therapist and physical therapist assistant education programs. As noted above, CAPTE has the highest level of approval from the United States Department of Education and CHEA. The Association has no financial interest in credentials evaluation and therefore is impartial. Thus, it is logical that APTA would be in a position to make determinations regarding bodies that evaluate credentials for other education programs.

APTA recommends that section 484.4 be revised to read:

Physical therapist assistant. ***A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, and*** *meets one of the following requirements:*

~~*(1) Requirements for individuals beginning their practice on or after January 1, 2008. A person who provides certain physical therapy services under the supervision of a qualified physical therapist and is licensed, registered, certified or otherwise recognized as a physical therapist assistant, if applicable, by the State in which practicing, continues to meet all practice requirements set forth by the State in which physical therapy services are furnished, and meets one of the following educational/training requirements:*~~

(a) ***Has graduated from*** ~~*Graduated after successful completion of*~~ *a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association;* ***or***

(b) If educated outside the United States or trained in the United States military, graduated ~~*after successful completion of*~~ ***from*** *an education program that by a credentials evaluation* ~~*process*~~ ***organization*** *approved by the American Physical Therapy Association, is determined to be* ***substantially equivalent*** *to physical therapist assistant entry level education in the United States;* ***or***

~~*(c) Prior to January 1, 2008 Requirements for individuals beginning their practice before January 1, 2008. s licensed as a physical therapist assistant, if applicable, by the State in which practicing, meets either of the following requirements:*~~

~~*Has graduated prior to 2008 from a 2-year college-level program approved by the American Physical Therapy Association, or*~~

(c) Prior to 2008, *has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapist assistant after December 31, 1977.*

Application of Consistent Therapy Standards

In the rule, CMS states that it believes therapy services should be provided according to the same standards and policies in all settings to the extent possible. Therefore, the Agency revises the

regulations (sections 409.17 and 409.23, etc) that pertain to services furnished at inpatient hospitals and skilled nursing facilities (SNFs), and several other settings to state that "physical therapy, occupational therapy or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants or speech-language pathologists who meet the requirements specified in 484.4. **APTA strongly supports CMS's decision to establish the same definitions for physical therapists and physical therapist assistants in all settings. In addition, it is our position that physical therapy services should be furnished by a physical therapist or appropriately supervised physical therapist assistant.**

As CMS moves forward with this revised language, it is imperative that the Agency not inadvertently develop a policy that prevents students from receiving their clinical training. CMS must recognize that providers that accept students from clinical education programs incur significant additional expenses associated with staff/supervisor teaching time related to patient care. It is extremely important for therapy students to have the opportunity to receive clinical experience in SNFs, hospitals, and outpatient therapy settings. Working with Medicare beneficiaries provides students with the clinical training needed to appropriately render physical therapy services to the geriatric population. Because the elderly population often needs rehabilitation and is rapidly growing in the United States, it is crucial to have professional therapists clinically trained in providing care to this population. CMS should ensure that policies do not prevent or discourage therapy students from receiving the clinical experience that they need in order to safely and effectively treat geriatric patients.

CMS may want to consider delaying implementation of the policy requiring that physical therapy, occupational therapy or speech-language pathology services be furnished by individuals meeting requirements specified in section 484.4. In certain settings, such as skilled nursing facilities, the proposed policy would result in confusion because it is inconsistent with language previously issued by CMS in rules pertaining to the SNF setting that allowed services provided by aides and students in the "line of the sight" of the therapist to be counted as therapy minutes on the Minimum Data Set (MDS). For that reason, it would be appropriate for CMS to consider a reasonable delay in implementation of the policy to avoid disruption and confusion.

Plan of Care

CMS proposes additional regulations for inpatient hospital services and skilled nursing facility services to require a plan of treatment for therapy services consistent with the plan currently required for outpatient therapy services. CMS invites comment on PT, OT, and SLP plan of treatment policies that are appropriately applied to all therapy services in both Part A and Part B.

Section 409.23 references section 409.16(b) through (e) regarding the plan of care. We presume that CMS intended section 409.23 to reference section 409.17 (b) through (e). If so, this reference in the rule should be amended.

CMS explains that since inpatient hospital services are always provided under the care of a physician, the agency believes that the physician's review and certification of the therapy plan of treatment is implied by the physician's review and approval of a facility plan that includes therapy services. Therefore, there would be no additional certification requirements for the inpatient hospital setting.

We agree with CMS that in the hospital setting the physician's review and approval of a therapy plan should be implied by the physician's review and approval of a facility plan that includes therapy services. We believe the same rationale applies to services provided in skilled nursing facilities and urge CMS to state that in the SNF Part A setting, review of the therapy plan is implied by the physician's review of the facility plan.

Although CMS states that there should be no additional certification requirements for the inpatient hospital setting, the language proposed in section 409.17(e) appears to be inconsistent with this policy. Specifically, section 409.17(e) states

> *(e) Review of the plan. The physician, nurse practitioner, clinical nurse special or physician assistant reviews the plan as often as the individual's condition requires, but at least prior to certification.*

We request that CMS amend this language to clarify further. We are concerned that as written the policy would be interpreted to require specific review of the therapy plan rather than the facility plan. Requiring a review of the therapy plan in the inpatient hospital setting and skilled nursing facility (Part A) setting could result in significant delays in treatment.

As CMS revises policies related to the plan of care, CMS should recognize that it is necessary in the IRF and SNF setting to have the flexibility to modify the utilization of rehabilitation services so that they are appropriate to fit the patient's medical condition on a particular day. In the IRF and SNF setting there is frequently the need to adjust the type (PT, OT, or SLP) and extent of therapy services delivered by a particular discipline from day to day. Due to unstable medical conditions, delivery of services is based on the patient's needs as well as tolerance and endurance.

Outpatient Therapy Certification Requirements

In the rule, CMS proposes to amend the regulations to change the plan of treatment recertification schedule. Currently, the physician must initially certify a plan of treatment at the time the plan is established or as soon thereafter as possible. If the need for treatment continues beyond 30 days, the plan of treatment must be recertified every 30 days. CMS proposes that the physician (or non-physician provider, as appropriate) recertify the plan of care every 90 days.

APTA commends CMS on its recognition that it is unnecessary for a physician to recertify a plan of care every 30 days. In fact, it is APTA's position that Medicare beneficiaries should be able to directly access the services of a physical therapist without unnecessary referral or certification requirements. Physical therapists are well-qualified, both through formal education and clinical training, to evaluate a patient's condition, assess his or her physical therapy needs and, if appropriate, safely and effectively treat the patient. Physical therapists are also well-qualified to recognize when patients demonstrate conditions, signs, and symptoms that should be evaluated by other health care professionals before therapy is instituted. Physical therapists recognize when it is appropriate to refer patients to these other health care professionals for consultation. The professional training and expertise which characterize physical therapists has been recognized by 44 states which have removed the out-dated provisions requiring a referral by a physician, from their statutes.

We recognize that Congress would need to pass legislation to enable Medicare beneficiaries to have direct access to physical therapist services. We commend CMS on the steps it has taken in this proposed rule to eliminate unnecessary barriers to access. **APTA strongly supports the proposal to extend the 30 day recertification requirement to 90 days. To ensure that standards are consistent, APTA also recommends that the CORF regulations be amended to change the 60 day certification period to 90 days.** The 30 day recertification is overly burdensome for physicians and physical therapists and is not an effective means of controlling utilization of therapy services. In recent years CMS has implemented many other policies that have ensured that utilization of therapy services is appropriate. As CMS states in the rule, therapy services are subject to a therapy cap, there are many local medical review policies pertaining to therapy services, and there are a number of system edits such as the "Correct Coding Initiative" (CCI) edits that have been implemented. In addition, the Agency has set forth extensive documentation requirements in its Medicare Benefit Policy Manual that physical therapists must follow to justify the medical necessity of services.

Requiring recertification can result in delays in care if the referring physician is not available to review the plan and recertify at the 30-day interval. Physical therapists are well-trained professionals who are able to use their professional judgment to identify whether services are medically necessary. APTA commends CMS on its proposal to make a change that will protect patient's access to physical therapy services and reduce unnecessary administrative burdens on physicians, physical therapists, and Medicare contractors.

TRHCA – Section 201: Therapy Caps

In the rule, CMS discusses implementation of the therapy cap in 2008. The Agency states that in accordance with the statute, it will continue to implement the therapy caps, but the therapy cap exceptions process will no longer be applicable beginning January 1, 2008. Congressional action is necessary to repeal the therapy cap, place a moratorium on its implementation, or extend the exceptions process in 2008. The dollar amount of the therapy caps in 2008 will be the 2007 rate ($1780) increased by the percentage increase in the Medicare Economic Index (MEI) (rounded to the nearest multiple of $10).

APTA is deeply concerned about the negative impact that implementation of the financial limitations on therapy services without the extension of the exceptions process will have on Medicare beneficiaries needing therapy services. As CMS is aware, the *AdvanceMed* study published in November 2004 indicated that in 2002 14.5% of patients would exceed the physical therapy cap. Once exceeded, if there is no exceptions process in place beneficiaries will not receive services that are medically necessary unless they seek treatment from hospital outpatient departments or pay out-of-pocket for their care. As a result, the cap can be expected to have a significant detrimental effect on beneficiaries needing rehabilitation services and could lead to complications, ultimately resulting in greater costs to the Medicare program. We recognize that it will take Congressional action to provide additional statutory authority and prevent the implementation of the therapy caps, and we continue to strongly urge Congress to take timely action to pass legislation that would repeal the therapy cap or, at a minimum, extend the exceptions process if repeal is not feasible.

APTA commends CMS on the significant amount of work that the Agency has conducted over the past few years in an effort to identify an alternative to the therapy cap. We strongly believe

that therapy care should be based on the needs of the patient, not governed by an arbitrary financial limit. **We urge CMS to place a high priority in resources and funding on continuing to conduct research that could be used to identify alternatives to the cap that would ensure that patients receive medically necessary therapy services.** While we recognize that the Agency faces many important priorities in allocating limited funds for research and pilot projects, we believe that few would have as direct and immediate impact on beneficiaries as finding an appropriate alternative to the therapy cap. This research is a key factor in identifying more clinically appropriate ways to control the growth in Medicare spending.

Before making any major reforms to the payment system for outpatient therapy services, we urge CMS to obtain more information about therapy users and their outcomes. This could involve the use of patient assessment tools that gather relevant information regarding patients that would impact the need for therapy services. CMS also would need to consider differences in patients and risk adjust to account for those differences.

Based on discussions we have had with CMS, we are aware that there is a plan to release a statement of work that would involve gathering more information regarding therapy users. We urge CMS to move forward with this initiative and to ensure that the national professional organizations, such as the American Physical Therapy Association, have a meaningful opportunity to participate and provide input as your proceed with research. We look forward to assisting the Agency as you proceed with these studies and the development of alternatives to the therapy cap.

APTA has discussed with the Agency its concept for a possible alternative based on patient assessment according to the severity of the patient's condition and the intensity of the physical therapist's mental effort and judgment, technical skill and physical effort, and stress. The Association intends to conduct independent research to develop and validate this "severity/intensity" structure, but we encourage CMS to include evaluation of this system in any research projects it conducts to gather meaningful information regarding patient use of therapy services. We look forward to working with the Agency and its contractors to develop this concept.

Lastly, **we recommend that CMS analyze the claims data from 2006 and 2007 to determine the impact of the therapy cap exceptions process on utilization.** Such analysis is critical to determine whether the therapy cap exception process has been effective and in making decisions regarding any refinement of the therapy cap exceptions process in the future if Congress passes legislation extending the exceptions process.

Medicare Payment Rate for 2008: SGR methodology

APTA is also alarmed at the potential impact of the 9.9% reduction in payment that CMS is predicting for 2008. As the Agency is aware, the "sustainable growth rate" (SGR) is a seriously flawed formula that will continue to result in significant, unsustainable payment cuts in the future. These cuts are forecasted to total 37 % or more by 2015, while the practice costs faced by physical therapists and other providers continue to rise.

The potential impact of SGR cuts are further magnified this year when combined with the proposed budget neutrality adjustment to the work relative value units (RVUs). The combination of these adjustments would result in a cut in payments of around 9% for physical therapists and even more significant cuts for many other health care professionals in 2008. APTA is deeply troubled that these cuts will significantly hinder the ability of physicians to care for their patients and of physical therapists to care for Medicare beneficiaries needing rehabilitation services.

These proposed cuts undermine the goal of Congress and CMS to create a Medicare payment system that preserves patient access and achieves greater quality of care. If health care professionals experience significant and compounding cuts in payment at a time of rising practice costs, access to care for millions of elderly and disabled will be jeopardized.

Clearly, a new formula that bases updates on the increases in the cost of delivering health care services is needed. We recognize that it will be necessary for Congress to act to change the formula. However, until a new formula is adopted CMS should assist Congress in resolving the SGR problem by taking administrative actions that would reduce the size of the projected cuts.

To reduce the cost of an SGR solution, CMS should remove spending on physician-administered drugs from calculations of the SGR, retroactive to 1996. Drugs should not be considered physician services and therefore should not be included in the physician SGR pool. In addition, when establishing the SGR spending target, we urge CMS to take into account regulatory changes such as national coverage decisions that result in increases in spending. When the impact of the regulatory changes are not taken into account, the cost of the new benefits and program changes are financed by cuts in payments to physicians, physical therapists, and other health care professionals.

TRHCA – Section 101(B): PQRI

The proposed rule discusses in detail plans for implementing the second year (2008) of the Physician Quality Reporting Initiative (PQRI) for physicians, physical and occupational therapists, speech-language pathologists, and other practitioners billing under the physician fee schedule. CMS is proposing a significantly expanded list of clinical and structural measures and identifies sources for these measures in the rule

With the exception of those measures previously endorsed or adopted by the National Quality Foundation (NQF) or Ambulatory Quality Alliance (AQA), the proposed rule states that no measure will be used for the 2008 measure set that has not been endorsed by NQF or adopted by AQA by November 15, 2007. The preamble to the proposed rule includes a lengthy discussion of the criteria that must be met by organizations proposing quality measures. Organizations must develop measures through the use of a consensus-based process. The statute references two organizations – NQF and AQA – as examples of such organizations but leaves the Secretary discretion to recognize other organizations.

As CMS proceeds with the Physician Quality Reporting Initiative, APTA urges the Agency to ensure that non-physician groups such as physical therapists have a meaningful opportunity to participate in the development of measures.

In the rule, CMS is proposing that there be approximately 161 measures for 2008. **APTA strongly urges the Agency to provide sufficient advance notice to providers regarding the new measures and their specifications.** Providers need to be able to understand the new measures if they choose to report to CMS on them in 2008. In addition, providers need adequate notice to make any necessary changes to their procedures and systems to report on any new measures.

APTA is concerned that physical therapists who work in certain outpatient therapy settings such as hospitals, rehabilitation agencies, and skilled nursing facilities (Part B), are unable to participate in the PQRI initiative. Section 101 of the Tax Relief and Health Care Act of 2006 identified covered professional services and eligible professionals who could participate in the PQRI program. Specifically, section 101 states:

> *(3) COVERED PROFESSIONAL SERVICES AND ELIGIBLE PROFESSIONALS DEFINED- For purposes of this subsection:*
> *`(A) COVERED PROFESSIONAL SERVICES- The term `covered professional services' means services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.*
> *`(B) ELIGIBLE PROFESSIONAL- The term `eligible professional' means any of the following:*
> *`(i) A physician.*
> *`(ii) A practitioner described in section 1842(b)(18)(C).*
> *`(iii) A physical or occupational therapist or a qualified speech-language pathologist.*

Clearly, physical therapists are included as eligible professionals. Physical therapy services provided by physical therapists in hospitals, SNFs (Part B), rehabilitation agencies, and comprehensive outpatient rehabilitation facilities (CORFs) are reimbursed under the physician fee schedule. Therefore, CMS should allow these settings to participate in the PQRI initiative. The Agency has stated that these practice settings cannot participate in the PQRI program because they do not use the 1500 or 837-P claim form. Instead, they submit claims using the UB-04 or 837-I and there is no place on this claim form to report the individual NPI of the physical therapist furnishing the service. **APTA strongly urges CMS to identify a method to enable physical therapists providing services in these settings to report on these quality measures.** It is in the best interest of the Medicare program to take steps to improve quality in all settings.

Registries

The proposed rule includes a discussion of CMS plans to evaluate and test mechanisms for collecting quality measures from medical registries or electronic health records (EHR). This approach to reporting data would be an alternative to submitting data through the claims processing system. CMS describes five options for data submission from medical registries to CMS:

- Registries could provide measurement codes and beneficiary/service identifiers that could be linked with Medicare claims data;
- Registries could provide quality measure codes and diagnosis codes that could be linked to beneficiary claims data;
- Registries could calculate and submit directly to CMS measures and performance rates for Medicare beneficiaries by NPI and tax identifiers;

- Registries could provide all of the claims data elements using the Part B claims process; or
- Registries could provide their Medicare data ("data dump") to CMS.

APTA strongly supports the use of registries and EHR as a means to measure and report quality and outcomes of care. By using systems that are easily incorporated into clinical practice, CMS will circumvent the need for redundant data collection methods and may address the immediate needs of the PQRI while establishing a framework for quality control and program effectiveness for the future. Linking PQRI data with comprehensive clinical and demographic data that can be found within EHR and comprehensive data registries will significantly increase the potential to assess this quality measures program and may lead to the development of new or enhanced quality indicators. Furthermore, APTA supports the view that national professional associations should become intimately involved in registry and EHR selection or development for the PQRI. Professional expertise is essential in determining appropriate data points to assess in determining provider and patient care quality.

In addition, APTA views the use of registries as a way to address limitations that prevent certain practitioners from reporting on quality measures to Medicare. Presently, some physical therapists in hospital outpatient departments, skilled nursing facilities (SNFs), rehabilitation agencies, and CORFs cannot participate in the PQRI program because there is no place on the claim form for their individual National Provider Identifier (NPI). By accepting data directly from registries and EHRs, CMS will enable a greater proportion of physical therapists to participate in this quality initiative resulting in greater impact on patient care.

APTA firmly believes that developing a health information technology infrastructure to support quality improvement, providing physical therapists with evidence-based clinician decision support, and tools to ensure compliance and incorporate quality performance measurement in their practices, are all key to improving the quality of care. To this end, we have dedicated significant resources to improve the access of evidence based information, including quality measures, to practicing physical therapists. As an example, we have developed an EHR that houses our national outcome database system and has incorporated the quality indicators approved by the PQRI. This system, called APTA CONNECT, has the ability to analyze a comprehensive set of demographic and clinical data that can be tied to the PQRI quality indicators. Hence, the provider can determine in real time if the quality indicator affects the quality of patient care on an individual and patient population basis. This system can easily incorporate new quality measures, analyze their effects on other measures, and report the findings immediately. APTA CONNECT has the potential to perform the data collection and analysis detailed in all five options suggested in the proposed rule if increased communication between the CMS claims and CONNECT databases are enabled.

In the rule, CMS discusses its plans to evaluate and test the mechanisms to use registries for the reporting of PQRI data. APTA is interested in participating in the testing of the registry-based quality data submission mechanism and looks forward to seeing more details from CMS in the near future.

Physician Self-Referral Issues

Abusive Physical Therapy Practice Arrangements under the In-Office Ancillary Services Exception

In the proposed rule, CMS addresses revisions to the federal physician self-referral laws (also known as the Stark laws) to minimize fraudulent and abusive practices permitted under the law. In particular, the rule addresses growing concerns for loopholes created by the "in-office ancillary services exception". APTA applauds the Agency's efforts to enforce the Stark laws to eliminate abusive financing arrangements that undermine the intent of the Congress when creating these laws. We strongly support any efforts to eliminate abusive financing arrangements under the Stark law that are created solely for profit without regard to the best interest of the Medicare beneficiary.

CMS, in this proposed rule, specifically states that, "In response to [Stark] Phase II, [the Agency] received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices." This comment stills stands true and is becoming an even larger problem. **We strongly urge the Agency to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.**

As illustrated in the white paper, *Why Physician-Owned Physical Therapy Services Should Be Unlawful Under the Stark Law*, provided to the Agency in our August 22 meeting, physician ownership or interest in physical therapy, other specialty services and medical equipment has become a growing problem and often leads to overutilization and a decline in quality health care. This has been evidenced in OIG studies[1] and reports published by the Medicare Payment Advisory Committee (MedPAC)[2]. Of particular concern to the profession of physical therapy are the increasing instances of physician-owned physical therapy service (POPTS) models appearing across the country. POPTS is a financial relationship in which a physician refers patients for physical therapy treatment and gains financially from the referral and are generally created under the cloak of the in-office ancillary exception to the Stark law.

By eliminating physical therapy as a DHS furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, overutlization of physical therapy services under the Medicare program, and enhance the quality of patient care.

In the proposed rule, CMS has posed the following question regarding the in-office ancillary exception to the Stark rule:

> *Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident-to basis, and services that are not needed at the*

[1] Office of the Inspector General, Department of Health and Human Services. 1994. *Physical Therapy in Physician's Offices*, no. OEI-02-90-00590. Washington, DC: OIG and OIG, Physical Therapy Billed By Physicians (May 1, 2006).
[2] Medicare Payment Advisory Committee. 2004. *Report to Congress: Growth in the Volume of Physician Services.* Washington, DC: MedPAC.

time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment)?

The in-office ancillary services exception allows patients of a sole practitioner or physician in a group practice to receive ancillary services in the same building in which the referring physician or his or her group practice furnishes medical services. This practice was designed to allow flexibility and convenience for the patient while receiving care. We contend that physical therapy services do not meet the criteria or stated purpose of the exception.

Physical therapy services are recurring services and are administered over a prolonged period of time that requires the patient to return up two to three times a week for therapy. In the course of this treatment, it is very rare that the patient is seen by the physician. Generally, the physical therapist develops the plan of care and consults with the physician for their input. After consultation, the physical therapist proceeds with the plan of care and the physician may, at their discretion, check on the status and progress of the patient on a periodic basis. Therefore, we contend, based on the general model of physical therapy treatment, that it is no more convenient for the patient to receive physical therapy services in the physician's office than it is for the physician to refer the patient to an independent physical therapy clinic in which the physician has no financial ties.

One general commonality behind the in-office ancillary services exception is that the services furnished under the exception are incident-to services; meaning that services are integral and necessary to the physicians primary treatment and therefore require direct physician supervision. To the contrary, it is becoming commonplace that physician-owned physical therapy services are not furnished under the Medicare incident-to provisions. Physicians are employing physical therapists who are obtaining their own individual provider numbers from Medicare and then furnishing and billing for these services under their individual provider numbers and benefits are then reassigned to the physician group practice for payment. Under this structure, there is little physician involvement during physical therapy treatment and the physical therapist treats the patient independent of physician supervision.

Thus, it can only be concluded that physical therapy services can be effectively delivered independent of the physician and that these services are not needed at the time of the physician visit to determine the diagnoses of the patient or the plan of care. As illustrated above, there is no prevailing quality of care need or added patient convenience realized by including physical therapy as a permissible service under the in-office ancillary services exception. Therefore, it is evident that that physical therapy should be removed as a DHS under the in-office ancillary exception.

Secretary Authority to Remove Physical Therapy from the In-Office Ancillary Services Exception

There is no doubt that CMS has ample authority to revise the Stark regulations in the manner suggested, both under the Secretary's general rulemaking authority, and under specific authority conferred in the Stark law itself.

The Social Security Act grants the Secretary authority to promulgate such rules "as may be necessary to carry out the administration of the [Medicare program]." [3] In the face of an agency's exercise of such expressly-delegated rulemaking authority, the agency's decisions about what regulations are necessary are subject to judicial deference, and will be overturned only if they are arbitrary, capricious, or "manifestly contrary to the statute."[4] In the case of the Medicare program, which involves the public as well as the health and welfare of a vulnerable population, it has also been observed that the Secretary "retains a large reservoir of express and implied power to adopt rational requirements that guard against waste and fraud. Such regulations may include reasonably based presumptions and policy determinations reflecting the Secretary's judgment as to what is required to make the program work." [5]

As discussed in the *White Paper*, the evidence is overwhelming that POPTS is an overutilized service, leading to significant Medicare overpayments, and that it offers no offsetting patient care or convenience benefits. The *White Paper* also makes clear that this situation derives from the financial conflict of interest that is inherent in the POPTS business model. As such, there is no case to be made that excluding physical therapy from the permissible in-office ancillary services would be arbitrary or capricious. Quite the contrary, it would be a reasonable and prudent response to a documented abuse of the Medicare program.

Nor can it reasonably be argued that removing physical therapy from the permissible in-office ancillary services would be contrary to law. The best articulation of this argument would be that because Congress acted to exclude certain items of durable medical equipment and enteral and parenteral nutrients from the permissible in-office ancillary services,[6] CMS is precluded from making any subsequent exclusion in the exercise of its regulatory authority. [7] This argument is wholly unconvincing. It suggests that because Congress at one time identified a programmatic abuse that required statutory action, the agency charged with administering the statute is thereafter precluded from finding and acting to stem additional related abuses by regulation. As noted above, the Medicare law's express delegation of rulemaking power to the Secretary is considerable, and we are aware of no legal authority that this rulemaking power could be considered limited in this way.

Moreover, the statutory language of the in-office ancillary services exception itself gives the Secretary additional and more specific, authority to exclude services from the permissible in-office ancillary services. After all, the Stark law defines physical therapy as a designated health service, self-referral for which is prohibited unless the service satisfies one of the exceptions. Here, the pertinent exception *only* allows physicians to self-refer for in-office ancillary services

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3 42 U.S.C. § 1395hh(a)(1), SSA 1871(a)(1) ("The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title [XVIII].").

4 Chevron v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984)

5 See Hosp. San Jorge v. Sec'y of Health, Educ., and Welfare, 616 F.2d 580, 590 (1st Cir. 1980) (Campbell, J., concurring).

6 42 U.S.C. § 1395nn(b)(2)(B)

7 This argument might also be viewed as an argument that the agency rule would be arbitrary and capricious because "the agency has relied on factors which Congress has not intended it to consider." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins., 463 U.S. 29, 43 (1983).

"if the ownership or investment interest . . . meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse." [8]

Thus, all that is required for the Secretary to exclude a service from the permissible in-office ancillary services is for the Secretary to conclude that a program abuse exists, and that removing the service is needed to protect against that abuse. Like all agency decisions, this one will be lawful as long as it is not arbitrary, capricious, or contrary to law. As discussed in the *White Paper*, the evidence is more than sufficient to show the abuses with POPTS. In light of that, **a CMS decision to prohibit POPTS under the in-office ancillary exception would be a manifestly reasonable, and therefore lawful, exercise of the Secretary's rulemaking authority.**

Tightening Additional Requirements under the In-Office Ancillary Services Exception

As stated earlier, APTA believes that the in-office ancillary services exception, in its entirety, is problematic and creates significant loopholes for fraud and abuse in the Medicare program, but there are also statutory definitions that must be adhered to under the exception that when examined, individually, should be revised to curb abusive practices created by the exception. In the proposed rule, CMS poses the following question:

> *Whether and how changes should be made to the definitions of same building and centralized building under the in-office ancillary services exception?*

The Agency's interpretation of the "centralized building" requirement creates a significant loophole for fraudulent and abusive behavior. The present definition allows the physician group practice to utilize multiple off-site locations to furnish DHS such as physical therapy. CMS only requires that these off-site locations are exclusively used by the group practice.

As stated earlier, this allows a physician group practice to employ a physical therapist, who has obtained an individual provider number from Medicare, to provide services and reassign benefits to the physician practice for payment. This directly conflicts with the original intent of the in-office ancillary exception which was to provide DHS in the physician's own office to their patients.[9]

We strongly urge CMS tighten the restrictions under the definition of "centralized building" to reflect the original intent of the law in which services under the in-office ancillary exception are only allowed when they are delivered in the physician's own office thus eliminating the use of multiple off-site locations. The current definition and interpretation leads to potentially abusive behavior and creates an environment for overutilization of services.

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8 42 U.S.C. § 1395nn(b)(2)(B) (end).

9 CMS, Medicare Program; Physicians' Referrals to Health Care Entities with which They Have Financial Relationships (Phase II): Interim Final Rule, 69 Fed. Reg. 16056 (March 6, 2204)

Unit-of-Service Payments in Space and Equipment Leases

In this proposed rule, CMS expresses its concern with lease arrangements that are structured so that a physician is rewarded for each referral he or she makes for designated health services (DHS). Such arrangements could take the form of physician leasing equipment that he or she owns to a hospital and receiving per-use fee each time a patient is referred by the physician-owner to the hospital for use of the equipment. CMS states that it also concerned about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis.

CMS proposes that space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity. CMS believes that these situations are inherently abusive because of the incentive to profit by the volume of patients referred to the lessee.

We applaud CMS on identifying this potential area for fraud and abuse. We agree that these types of arrangements are inherently abusive due to incentive nature, and APTA urges the Agency to finalize the proposed change in the final rule.

Comprehensive Outpatient Rehabilitation Facility (CORF) Issues

In the proposed rule, CMS discusses several changes to the structure, payment, and administration of comprehensive outpatient rehabilitation facilities (CORFs). The purpose of a CORF is to permit the beneficiary to receive multidisciplinary rehabilitation services at a single location in a coordinated fashion.

Specifically, we would like to highlight the following proposed changes:

1) The proposed rule seeks to revise the CORF regulations to clarify that CORF services are covered only if they relate directly to the rehabilitation of injured, disabled, or sick patients. CMS states that it believes that this is consistent with congressional intent that services provided in a CORF setting be covered as CORF services only if such services relate directly to the rehab of the patient.

   APTA supports this proposed revision. It is directly aligned with the goals and purpose of physical therapy. Physical therapists examine each individual and develop a plan using treatment techniques to promote the ability to move, reduce pain, restore function, and prevent disability. In addition, physical therapists work with individuals to prevent the loss of mobility before it occurs by developing fitness- and wellness-oriented programs for healthier and more active lifestyles.

2) The proposed rule seeks to clarify that physical therapy, occupational therapy, and speech-language pathology services can be furnished in the patient's home when payment for those therapy services is not otherwise covered under the Medicare home health benefit. In addition, the proposed rule seeks to clarify that the patient must be present during the home environment evaluation that is performed by the therapist. CMS states that this necessary to fully evaluate the potential impact of the home situation on the patient's rehabilitation goals.

APTA supports these proposed revisions. We believe that both of these provisions are positive updates that allow physical therapists to provide comprehensive and an improved quality of care to Medicare beneficiaries in the home environment.

The APTA appreciates the opportunity to offer these comments to CMS. If you need further information, please contact Gayle Lee, Director of Regulatory Affairs at 703-706-8549. We look forward to working with you on the issues raised in these comments.

Sincerely,

Dave Mason

G. David Mason
Vice President, Government Affairs

Attachments

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August 28, 2007

Honorable Herbert Huhn
Acting Administration
Centers of Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

RE: CMS 1385-P Mohs Surgery

Dear Sir:

The issue has been well described in the letter by Dr. David G. Brodland, President of the American College of Mohs Surgery. I am in complete support of the position so well articulated.

I am a Mohs surgeon at Brown Medical School in Providence, RI, and work training future Mohs surgeons, 11 Dermatology residents, and am a partner with Raymond G. Dufresne, Jr., M.D.

Our history in Rhode Island is unique in this discussion, however. It was here that the debate over this exact same exemption took place more than 15 ago, from 1989-1991.

At that time, Dr. Dufresne entered into a period of negotiation with Blue Cross Blue Shield of RI, then the Medicare intermediary. The local representatives personally oversaw the Mohs procedure with him or via a step-by-step slide presentation. All of this material was reviewed federally, resulting in the decision to make this procedure exempt.

Nothing has changed in the codes to merit this change in the multiple procedure rules, and no such deliberation or demonstration has taken place on a national level that I am aware of. I cannot believe the review recently by the RUC was anywhere as complete as it was in 1990-1991 that we did here in RI. I do not believe the decision was made with a proper understanding.

We have an evolving situation relating to the numbers of and understanding about skin cancer in the U.S. Make no mistake – there is an epidemic of skin cancer. The obvious, undeniable benefits of Mohs surgery, namely highest cure rates, minimal morbidity, and cost efficiency has translated into more trained physicians and higher utility, with unquestionably enhanced patient care, satisfaction, and success. In fact, Mohs surgery became too successful in some eyes, i.e. rapidly increased utilization, and has been subjected to a 'whack it down' mentality.

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When we in RI were among the last regions to have a significant Mohs surgery presence prior to the change in exemption status, all the dire predications made in reference to these changes were real. People waited 4-6 months or longer for surgery, only had one cancer attended to at a time, despite the presence of multiple cancers. Complex repairs were deferred overnight to a different surgeon or even to the operating room, with enormous increases in expense, time, and resources. These practices were adopted in order for the Mohs units to survive financially. The overhead is huge for Mohs Surgery; it is an office-based procedure, is not billable.

Nationwide, many of the busy units are academic affiliated. Academic Mohs surgeons make a commitment to the residents, fellows, and the community. We accept lower salaries and support the academic programs. In our system, it would have a chilling if not killing effect on the Dermatology program, immediately and in the future. I am also concerned that surgically oriented dermasurgeons will abandon Mohs surgery for cosmetic and more lucrative alternatives. This is a separate disturbing trend, one that will be influenced without a doubt based on the CMS ruling.

The proposed changes will reverse 20 years of progress in treating skin cancers with Mohs surgery. On behalf of the patients in southern New England and the Brown Dermatology Program, I respectfully ask that you reflect on these issues. I request the exemption be made permanent.

Sincerely,

Nathaniel J. Jellinek, MD, FAAD
Assistant Professor
Department of Dermatology, Brown Medical School
Associate Director, Fellowship Training Program, American College of Mohs Surgery

Associate Editor
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August 2, 2007

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

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

Dear Acting Administrator Kuhn:

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

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

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

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

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

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

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

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August 31, 2007

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

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

RE: Physician Self-Referral Issues

Dear Sir:

I am a licensed and practicing physical therapist in the state of New Jersey. I have been practicing for the past six years in various settings with the last two years specifically in a physical therapist owned outpatient orthopedic setting.

I would like to comment on the July 12 proposed 2008 physician fee schedule rule specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. I opposed physician-owned physical therapy practices that refer their Medicare beneficiaries to their own practices because it has a potential for fraud, abuse and conflict of interest. The physicians will tend to refer their patients to their own physical therapy practice because of inherent financial interest. This will leave patients with fewer choices. I encountered an experience with one of my patients that I evaluated and treated who left the physician own physical therapy practice and came to our practice instead. He was unhappy about the care that he received because the hours were inconvenient as well as he stated that "the gym was too small and had less equipment." Therefore, he was unable to receive the full physical therapy benefit. In addition, physicians own physical therapy practices don't offer services that other physical therapist owned practice offer such as aquatic therapy.

I also read in one study that physicians owned physical therapy practices tend to discharge patients later (increase number of sessions= increase cost) compared to physical therapy owned due to financial interest.

Thank you for your kind consideration regarding this matter.

Sincerely,

Franceah R. Palencia, MS PT

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Adel Mohamed, MD, FACS
Robert G. Lippitt, MD, FACS
Board certified urologists

September 4, 2007

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

Dear Mr. Kuhn:

I am a urologist who practices in group setting of two physicians. More than 50% of my practice is Medicare patients with major urological diseases including kidney and ureteral stones which are very predominant in our area (Southeast USA). I am writing to comment on the proposed changes to the physician fee schedule rules that were published on July 12, 2007 that concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules.

"Under Arrangements Contracts"

- The changes proposed in these rules will have a serious impact on the way my group practices medicine and will not lead to the best medical practices. I am an owner in joint venture LLC that provides lithotripsy services. The health care benefits to our patients had been tremendous compared to the pre-venture arrangement. The patient access has improved and the cost has been contained as we share two lithotripsy units "Under Arrangements Contracts" between our LLC and different hospitals.

- The urologists are closer to their patients and the patients stay in their communities avoiding long travel (especially in rural areas such our area) to a central location. If the new proposals are implemented, my Medicare patients have to travel one hundred miles roundtrip to have access to a central location for the lithotripsy. I believe this will restrict access to this service to lot of elderly and sick patients who have no means financially or physically.

- Our LLC has an excellent Quality Assurance program and is continuously updating and maintaining the equipment. If the hospital owns the lithotripsy

equipment (with each hospital low volume per one lithotripsy unit), it will be very expensive to operate, maintain or update it. These extra costs will eventually be passed over to the Medicare program.

- According to *American lithotripsy vs. Thompson* case, the lithotripsy is NOT a designated health service (DHS) under Stark, and thus our LLC cannot be deemed to be performing a DHS or causing a claim to be submitted for a DHS

- Lithotripsy service is therapeutic and objectively verified by the presence of stone on the X-Rays, so there is no risk of over-utilization.

- Stark legislative history indicates Congress clearly intended under arrangement contracting to only require a compensation exception and not an ownership exception.

Per procedure fee prohibition

- Hospitals are risk adverse. Purchasing the best new equipment, or entering into fixed monthly lease over a term of one year or more are capital risks hospitals do not want to take especially if they can not predict the volume.
- Rural hospital procedure volume is usually low to allow for fixed monthly rental of technology thus limiting the access to the latest technology
- Congress clearly wishes to preserve per procedure fees in the Stark legislative history and CMS can not contradict congressional intent through a prohibition of such arrangements
- I am seeking confirmation that the per procedure payment prohibition would not apply to the Stark indirect compensation exemption relied upon by our LLC.

Percentage Fee Prohibition

- I am seeking confirmation that the percentage fee prohibition would not apply to indirect compensation arrangements
- Lithotripsy reimbursement rates may increase or decrease and payer mixes change. Percentage fee prohibitions allow hospitals and equipment vendors to share in these market risks and are often preferred by hospitals. These arrangements ensure that a hospital will never make an equipment rental payment in an amount greater than what it collects fro the service from even the lowest cost insurer

Stand in the Shoes

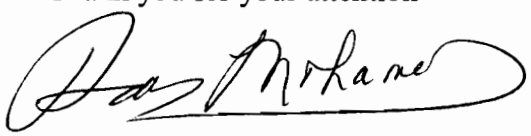
- The Medicare ASC Approved Procedure List does not allow for reimbursement of Stark DHS procedures, so Stark should not be implicated by a physician LLC contracting with an ASC
- ASC are lower cost providers of services. Physician-owned ventures should be encouraged to contract with ASCs regardless of their ownership and control, if it results in saving to the Medicare program.

- This prohibition would deter physicians from joint venturing with hospitals to form ASCs. Instead, physicians would develop only wholly-owned ASCs.

In summary, the proposed rules changes by the CMS would restrict access of Medicare patients to very important services in our area (Kidney stone treatment) which is very prevalent disease, would increase the cost of delivering this service to the Medicare program and is not in compliance of the intent of Congress.

I would propose to stop these rule changes from being implemented.

Thank you for your attention



Adel Mohamed, MD, FACS

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VIA FED-EX

August 30, 2007

223 North Van Dien Avenue
Ridgewood, NJ 07450-2736

Mr. Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore MD. 21244-1850

Dear Mr. Kuhn:

On behalf of Valley Hospital, a 451 bed licensed acute care facility in Ridgewood New Jersey; I would like to comment on the Centers for Medicare and Medicaid Services (CMS) proposed 2008 Medicare Physician Fee Schedule. We appreciate CMS' effort to clarify its position on "under arrangements" and concur with its assertion that these agreements are questionable under Stark regulations. We further agree that lease and per-click arrangements between hospitals and physicians are grounds for potential abuse and support CMS' efforts to revise Stark to prohibit this activity.

Under arrangements have proliferated in recent years because the Stark Law allows a physician-owned entity to provide services to hospitals as long as the services are provided under contract. As such, revenue generated from these arrangements is considered under the indirect compensation exception. We support a clarification that would cause these transactions to more appropriately be considered ownership relationships. As a result, the indirect compensation exception would no longer be available to physician owners of the under arrangements entities.

New Jersey has witnessed an increase in the number ventures involving, by way of example, cardiac catheterization laboratories, and the New Jersey Attorney General's Office is currently considering whether these arrangements violate applicable state laws. The proposed rule will clarify CMS' position by removing any ambiguity surrounding the use of under arrangements and per click ventures. Valley Hospital supports this effort and agrees with CMS' statement that "there appears to be no legitimate reason for these arranged services other than to allow referring physicians an opportunity to make money on referrals for separately payable services."

While we are sympathetic to the economic situation that physicians' face in light of declining reimbursement and escalating practice expenses, we do not believe that augmenting income through questionable ventures represents good public policy or medical practice. A better alternative would be to raise fees paid to physicians for services legitimately rendered.

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

Very truly yours,

Gail Callandrillo

Gail Callandrillo
Vice President, Planning
The Valley Hospital

724

Heart Center
MOUNTAIN WEST CARDIOVASCULAR ASSOCIATES, PC

RECEIVED - CMS

2007 AUG 31 P 1:56

August 29, 2007

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

Re: Physician Fee Schedule Proposed Rule
File Code [CMS–1385–P]
Issue Area: Physician Self-Referral Provisions -- Under Arrangement Services

To Whom It May Concern:

I am a practicing physician in Salt Lake City, and I am writing to express my objection to CMS's proposed changes to the Stark regulation related to under arrangement services. I have read and support the positions taken in the submission written by Tom Crane of the law firm, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. In my experience, under arrangement services by cardiologists are cost effective and improve quality of care. CMS should treat these services like other similar extension of practice services. There are numerous bona fide reasons for physicians to own and operate service providers furnishing arranged-for services, among them including:

- The physicians can provide the service more efficiently and with higher quality.
- The arranged-for service avoids duplication of services.
- The physicians desire and achieve a greater level of excellence by becoming involved.
- A physician-run service has more streamlined management and decision-making.
- The service is not a priority for the hospital, but is a priority for the physicians.

CMS would advance no legal or policy interests if it implements the changes it proposes, and so I urge CMS to retain its existing policies

Respectfully submitted,

James Zebrack

James Zebrack, MD, FACC, FASE

CC: Tom Crane

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August 31, 2007

VIA HAND DELIVERY AND ELECTRONIC MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building --Room 445–G
200 Independence Avenue, SW.
Washington, DC 20201

Re: Physician Fee Schedule Proposed Rule
File Code [CMS–1385–P]
Issue Area: Physician Self-Referral Provisions -- Under Arrangement Services

To Whom It May Concern:

This letter is submitted on behalf of the 105 providers and other interested parties listed in Attachment A[1/] to comment on the Notice of Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, specifically the physician self-referral provisions ("Stark Law") related to under arrangement services.

Because of CMS's stated concerns about physician-owned entities providing services under arrangement to hospitals, it proposes to change the definition of the term "Entity" in section 411.351 to the following:

> ". . . A person or entity is considered to be furnishing [designated health services (DHS)] if it—
> "(i) Is the person or entity that has performed the DHS, or
> "(ii) Presented a claim or caused a claim to be presented for Medicare benefits for the DHS."

Although CMS does not say so directly, CMS is adopting the novel interpretation that such physicians who cause the hospital to present claims, through their ownership interest in the under arrangement service provider, would have an ownership interest in

1/ Several of the signatories to this letter will write CMS directly with additional comments.

the DHS service itself, thereby creating an impermissible ownership interest under the Stark Law if revised by regulation. In short, CMS proposes to ban physician-owned under arrangement service providers meeting the above definition of Entity.[2/] For the following reasons, we believe CMS's proposal is an impermissible interpretation of the Medicare statute, identifies no regulatory loopholes in need of closing, and is ill-considered policy. Consequently, CMS should retain existing policy in this area and take no further regulatory action.

I. EXECUTIVE SUMMARY

Congress has spoken clearly that arranged-for services should be regulated under the Stark Law as compensation arrangements. Prior to the proposed rule, CMS's long-standing interpretations and policy statements had been entirely consistent with this congressional intent. Moreover, CMS's proposed standard of "causing to present" claims is not a clear, bright-line rule and will not enable providers to know if they are in compliance with the law. As a result, CMS's approach in the proposed rule will likely not withstand judicial scrutiny.

CMS identified a number of potentially abusive arrangements as its rationale to propose banning all physician-owned under arrangement services. Yet such arrangements clearly violate the existing Stark Law, Anti-Kickback statute or CMS's under arrangement rules. Consequently, CMS has identified no loopholes that need to be closed. Rather, CMS should enforce the existing Stark Law and under arrangement rules.

The proposed rule is based on unsupportable policy objectives. If CMS implements these changes, it will require significant restructuring of existing arrangements causing disruption in patient care, with little commensurate benefit. In its consideration of the appropriate treatment of arranged-for services, CMS should consider the following policies:

- Cardiac catheterization is a personally performed service, and therefore should be afforded the same protection as other extension-of-practice services, like ASCs.
- Congress has accepted the concepts of mandated referrals and per-service payment methodologies with arranged-for services.
- Inpatient and outpatient hospital services furnished under arrangement should be treated in the same manner.

2/ We understand that sections 1877(c) and (d) provide ownership exceptions, which could apply, for example for services furnished in rural areas.

- The location of the arranged-for service in or near the hospital should be viewed as a positive factor, not a signpost of abuse.
- CMS should explicitly recognize the many positive reasons for hospitals and physicians to enter into clinically-driven, cost-effective under arrangement agreements.

II. THE PROPOSED RULE IS AN IMPERMISSIBLE INTERPRETATION OF THE STARK LAW

The proposed rule will not withstand judicial scrutiny because it is an irrational interpretation of the Stark Law and other Medicare principles and departs from long-standing CMS interpretations without adequate support.

1. Congress Has Determined That Under Arrangement Services Do Not Create An Ownership Interest, But Only A Compensation Arrangement

a. Statutory Under Arrangements Exception

In enacting Stark II in 1993, Congress carefully considered the issue of the provision of services furnished under arrangement by physician-owned entities to hospitals. Congress determined that such service arrangements with group practices[3/] should be protected as compensation arrangements meeting certain standards ("Under Arrangements Exception"). *See* § 1877(e)(7). Among the standards Congress set out include the following:

- Substantially all of the DHS furnished to patients of the hospital that are covered under the arrangement must be furnished by the group under the arrangement.
- The compensation arrangements with the hospital may be on a per-unit of service basis.
- The compensation must be --
    - consistent with fair market value,

3/ It is of no legal significance that the exception is limited to group practice arrangements. Physician ownership of and compensation arrangements with group practices furnishing DHS is addressed in the Stark Law no differently than physician ownership of other DHS entities. Such relationships create financial arrangements under the charging part of the statute (1877(a)) that must meet an exception. Congress created three exceptions specifically addressing group practices. The first two are under section 1877(b) for physician ownership and compensation arrangements for physician services and in-office ancillary services; and the third is the compensation exception for under arrangement services.

  - fixed in advance and
  - not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

- The agreement must be commercially reasonable even if no referrals were made to the entity. And
- The Secretary may, by regulation, impose such other requirements as needed to protect against program or patient abuse.

This statutory exception demonstrates congressional determinations in the following key areas related to arranged-for services provided by physician-owned entities. One, Congress unequivocally decided that the physicians' ownership interest in the under arrangement service provider is not an ownership interest in an entity furnishing DHS services, but rather the only financial arrangement that triggers the Stark law is the service agreement between the hospital and that entity. This interpretation is supported by the exception's plain meaning and other sources. It is striking the care Congress used in placing the exception for group practice arrangements with hospitals as a compensation-only exception. If Congress thought there was any ownership interest created under the Stark Law with these types of arrangements, it would have placed such an exception in the same place as all the other group practice exceptions that protect both ownership and compensation. Additionally, Congress's approach is entirely consistent with CMS's historic treatment of under arrangement services.[4/] There is simply nothing in any CMS guidance that would suggest a service provider that contracts with a hospital for under arrangement services has an ownership interest in that hospital service. Such contracts are exclusively service agreements.

Two, the inescapable logic of the Under Arrangements Exception is that the applicable physician referral triggering the Stark Law is the referral for inpatient and outpatient hospital services. Inherent in this logic is that it is the hospital that is the entity furnishing DHS. This contrasts with the proposed rule that attempts to invoke Stark Law jurisdiction on the under arrangement service provider by declaring it is an entity furnishing DHS.

Three, Congress made a striking policy statement in imposing a referral requirement. To meet the Under Arrangements Exception, physicians participating in the arrangement must refer substantially all of their similar cases through the arrangement. CMS's stated concern about the abusive incentives it sees with arranged-for services cannot be reconciled with Congress's comfort in requiring a high level of self-referral.

4/ CMS has identified consistency with other Medicare principles as one of its five criteria in drafting the Stark rules. 66 Fed. Reg. 855, 860 (January 4, 2001).

Finally, Congress also spoke to the question of payment methodologies, and permitted under arrangement service providers to be paid on a per-unit of service methodology. Again, CMS's stated concern in the preamble about "per-service" payment arrangements contradicts clear congressional intent permitting such payments.

b. CMS's Long-Standing Agency Interpretation From Which It Proposes To Depart Is Consistent With The Statutory Under Arrangements Exception

CMS has addressed the Under Arrangements Exception in each of the Stark I rule, Stark II Phase I rule, and Phase II rule.[5/] Until the proposed rule, all of CMS's legal interpretations of the Stark Law and policy statements on under arrangement services are consistent with this congressional intent as described above.

CMS first implemented this provision in 1995 as part of the Stark I, confining the reach of this provision to clinical laboratory services, but otherwise generally implementing this exception as written. § 411.357(h). In Stark II, Phase I, CMS faithfully followed the Congressional dictates of the Under Arrangements Exception and interpreted under arrangement services as not creating an ownership interest by physician investors in a DHS entity, but rather only a compensation arrangement. In so doing, CMS made an important legal interpretation of the Under Arrangements Exception:

> ". . . [W]e believe there is precedent in the statute for treating this situation solely as a compensation arrangement. In section 1877(e)(7) of the Act, the Congress created a specific compensation exception for certain hospital services provided by physician groups 'under arrangements.' Since, by definition, all services protected under section 1877(e)(7) of the Act--and the resources used to produce them--were "owned" by the physician groups, the Congress would not have created a protected compensation relationship unless it had first determined that these arrangements did not create a prohibited ownership or investment interest in the hospitals. Simply stated, the Congress would not have excepted these relationships from the compensation arrangement restriction, if they were prohibited as an ownership or investment interest."

66 Fed. Reg. 855, 942 (January 4, 2001).[6/]

5/ CMS also intends to address this exception in the Phase III rule to be published on September 5, 2007. *See* fn 8 below.

6/ We recognize that this passage of the Phase I preamble asserted that the Stark Law could be interpreted to prohibit under arrangement services, but CMS provided no support for this assertion, and

In 2004 in Phase II, CMS implemented this exception for all DHS.[7/] Despite CMS's broad authority under 1877(e)(7)(A)(vii) to impose additional requirements to protect against program or patient abuse, as with the Stark I rule in 1995, CMS determined close to a decade later that no additional protections, such as anti-kickback statute compliance, were needed.[8/]

While the proposed rule represents a radical departure from these past interpretations, CMS offers no reasons why past interpretations are wrong. As recently as last year, the United States Court of Appeals for the Second Circuit addressed the standard under which a court will review an agency's reversal of prior interpretations and practice. In *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71 (2nd Cir. 2006), the court exhaustively reviewed the Supreme Court's standard of review in *Motor Vehicle Mfr's Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983) and other existing precedent, and invalidated a CMS change in interpretation of coverage rules for investigational cardiac devices.

> "A settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress; therefore, an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance. As we have explained, when an agency reverses its course, a court must satisfy itself that the agency knows it is changing course, has given sound reasons for the change, and has shown that the rule is consistent with the law that gives the agency its authority to act. In addition, the agency must consider reasonably obvious alternatives and, if it rejects those alternatives, it must give reasons for the rejection, sufficient to allow for meaningful judicial review.... [A]n agency is free to change course after reweighing the competing statutory policies. But such a flip-flop must be accompanied by a reasoned explanation of why the new rule effectuates the statute as well as or better than the old rule."

---

the quoted section clearly expresses a contrary interpretation, i.e., that under arrangement services are only to be treated as compensation arrangements.

7/ Consistent with its other interpretations of the "substantially all" requirements for group practices, this rule utilized a 75 percent test. § 411.357(h)(3).

8/ The combined commentaries from the Phase II and III (Federal Register public display version) rules reveal that CMS has received no formal comments about this exception since 1998. As a result, CMS's views about this exception as expressed in the Phase III rule remain unchanged.

(Internal quotations and citations omitted) 470 F.3d at 79-80. A reviewing court will likely follow this well-established precedent and find CMS's flip-flop to be arbitrary and capricious.

2. CMS's Standard -- Causing To File Claims -- Is Inconsistent With Congressional Intent To Utilize Clear, Bright-Line Rules

In introducing his legislation in 1988, Rep. Fortney ("Pete") Stark stated:

> "[W]hat is needed is what lawyers call a bright-line rule to give providers and physicians unequivocal guidance as to the types of arrangements that are permissible and the types that are prohibited. If the law is clear and the penalties are severe, we can rely on self-enforcement in the great majority of cases. [My bill] provides this bright-line rule."

134 Cong. Rec. E2724-02 (daily ed. Aug. 11, 1988). CMS has consistently followed this congressional intent that clear, bright-line rules be utilized in its Stark regulations. *See, e.g.*, 66 Fed. Reg. at 860. Alluding to this requirement, CMS states in the proposed rule that it has developed a "straightforward approach" by defining an entity furnishing DHS as one that "caused a claim to be presented for Medicare benefits for the DHS." In reality, this standard is anything but straightforward and fails to provide a workable test so that providers will know if they are complying with the law.

The "causes to be presented" language appears to have been adopted from the charging language of the Stark Law (§ 1877(a)(1)(B)), which in turn was adopted from other false claims statutes such as the False Claims Act ("FCA"). 31 U.S.C. § 3729(a)(1). Thus, our comments in this section are derived from our review of the FCA case law. These decisions analyzing what it means to "cause" a claim to be presented are instructive because they reveal that the use of a "causation" standard requires a highly fact-intensive inquiry into the peculiar facts of individual cases -- the farthest thing from a "bright-line" rule.

The courts have generally found causation when (1) the conduct in question was a *substantial factor* in bringing about the filing of the false claim at issue, and (2) the defendant could have *foreseen* that the false claim would be filed, even with any intervening links in the causal chain. *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-45 (3rd Cir. 2004); *United States ex rel. Franklin v. Parke-Davis*, No. Civ.A. 96-11651PBS, 2003 WL 22048255, at *4-5 (D. Mass. Aug. 22, 2003). The court in *Parke-Davis* specifically noted that the substantial factor issue is a question of fact. *Parke-Davis*, 2003 WL 22048255, at *5.

As courts have attempted to apply these concepts to varying FCA fact patterns, they have further looked to multiple and varied factors to assess whether the requisite causation was present. These factors have included, among other things:

- Whether the potential defendant possessed only "mere awareness" that another might make a false claim; *Zimmer*, 386 F.3d at 245;

- Whether an intermediary served as "merely a conduit to the submission of a false or fraudulent claim"; United States ex rel. Drescher v. Highmark, Inc. 305 F. Supp. 2d 451, 460 (E.D. Pa. 2004);

- Whether the potential defendant specifically "direct[ed] the provider to submit the claim to Medicare" or "suggest[ed] to the provider that Medicare should be the primary payer"; *Id.* at 461; and

- Whether the potential defendant "delegated" the authority to submit claims, had "control over the content of the claims," had a "right to review" the claims, or "instructed" the intermediary to use a particular code. United States ex rel. Kinney v. Hennepin County Med. Ctr., No. CIV. 971680, 2001 WL 964011, at * 9-10 (D. Minn. Aug. 22, 2001).

This case law strongly suggests that most agreements for under arrangement services do not permit a showing that the service provider in any way causes the hospital to submit any claims. While it is certainly true that the service provider expects to be paid by the hospital, and understands that the hospital will submit claims for reimbursement, such mere awareness and expectations fall far short of causing the hospital to submit a claim. This is because the service provider doesn't in any way direct or control the hospital's billing function. Even a determination as basic as whether a cardiac catheterization patient is an outpatient or inpatient is exclusively the responsibility of hospital personnel.

III. CMS IDENTIFIED NO REGULATORY LOOPHOLES THAT NEED TO BE FIXED

CMS identified a number of potentially abusive arrangements as its rationale to propose banning all physician-owned under arrangement services. For example, CMS identified arrangements that have "no legitimate reason" or that are "little more than a method to share hospital revenues."[9/] While such arrangements are indeed troubling,

9/ We do not understand the relevance of CMS's concerns about physician joint ventures with hospitals for ambulatory surgery centers or independent diagnostic treatment facilities, or MEDPAC's recommendations regarding physician ownership of companies that rent or lease equipment to imaging centers. Whatever issues arise with these ownership interests, on their face, they have nothing to do with

they do not demonstrate any regulatory loopholes that need to be closed because they clearly violate the existing Stark Law, Anti-Kickback statute or CMS's under arrangement rules.

The most applicable Stark Law exception is the fair market value exception. To be in compliance the arrangement must, among other things, be commercially reasonable but for referrals, with the compensation consistent with fair market value. The arrangements described by CMS fail these tests. CMS should use the final rule to make this point clear.

Determining a violation of the anti-kickback statute is more difficult and can only be determined by a review of all relevant facts. But the arrangements CMS described in the proposed rule would likely be investigated aggressively by the Office of Inspector General and the Department of Justice as they appear to be driven by referrals without any clinical bona fides.

Perhaps most striking is that CMS gave readers the impression that its own Medicare under arrangement rules have no substance. CMS seems to imply that these rules actually permit a hospital to unbundle its services, and without any substance to the arrangement flip those services to a contracted vendor-services model. We view CMS's under arrangement services rules differently, and think CMS should have sent a clear message that the types of arrangements about which it is concerned violate such rules. For example, the CMS Internet-Only Manual (IOM), publication 100–01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 5, section 10.3 states: "In permitting providers to furnish services under arrangements, it was not intended that the provider merely serve as a billing mechanism for the other party. Accordingly, for services provided under arrangements to be covered, the provider must exercise professional responsibility over the arranged-for services." CMS guidance goes on to reiterate that the hospital's policies regarding quality controls, admissions, medical records apply equally to the under arranged-for service. We cannot see how the scenarios described by CMS in the proposed rule comply with these under arrangement rules, and we recommend that CMS use the final rule to make this point crystal clear.

In summary, CMS should enforce the Stark Law and under arrangement rules and not create more regulations where no loopholes have been identified that need to be closed.

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under arrangement services, and therefore we respectfully request that CMS should ignore these comments in its consideration of under arrangement services.

IV. THE PROPOSED RULE REPRESENTS ILL-CONSIDERED POLICY BECAUSE IT THREATENS TO SWEEP ASIDE CLINICALLY-DRIVEN COST-EFFECTIVE UNDER ARRANGEMENT SERVICES

In contrast to past policy statements, CMS did not in any way recognize the positive role of arranged-for services in today's health care system, instead it seems to condemn them all with one-size-fits-all sweeping claims.

In the Phase I regulation, CMS recognized that under arrangement "relationships are pervasive in the hospital industry" and that many help "avoid unnecessary duplication of costs and underutilization of expensive equipment." 66 Fed. Reg. at 942. At the same time, CMS established two rulemaking decision criteria: (a) "be cautious in interpreting [the rule's] reach so broadly as to prohibit potentially beneficial financial arrangements;" and (b) make sure the rule does "not adversely impact the medical care of Federal health care beneficiaries or other patients." *Id.* at 860. As a result of these criteria, CMS found: "[G]iven the sheer number of these arrangements, we think prohibiting these arrangements would seriously disrupt patient care." *Id.* at 942. It appears CMS has lost track of its own wisdom from the recent past.

We suggest the following are important policy considerations for CMS to consider in its decisions about how to regulate under arrangement services:

1. Personally Performed Services -- Extension Of Practice

The proposed rule makes no attempt to distinguish under arrangement services involving personally performed services as opposed to other services.[10/] Although CMS does appear to focus on potential abuses related to imaging services, it should weigh heavily the historical fundamentally different treatment in the fraud and abuse laws afforded to referrals where the service is essentially an extension of the physicians' practice. An example is cardiac catheterization services. But for CMS's policy decision not to include these services on Medicare's approved list of ambulatory surgery center procedures, outpatient cardiac cath would be exempt from the Stark Law. Yet with physician-owned ASCs, the type of incentives present with and protected for ASC referrals is identical to cardiac cath. Simply put, when a procedure like cardiac cath is part of the physician's personal professional treatment of a patient, the physician uses great care in determining the need for that service, and so the likelihood for over-utilization is minimal.

10/ We do not in any way mean to imply that our legal analysis is any different for referrals for under arranged-for services not requiring hands-on care of the physician.

2. Congress Has Accepted The Concepts Of Mandated Referrals And Per-Service Payment Methodologies

In the proposed rule CMS expressed several concerns about the incentives present with arranged-for services. But these concerns are directly contrary to congressional policies contained in the Under Arrangements Exception. As discussed in section I.1 above, Congress made two important policy decisions directly related to physician incentives: (1) it required that substantially all of the DHS furnished to patients of the hospital that are covered under the arrangement must be furnished by the group under the arrangement; and (2) per-service payment methodologies are permitted. The combination of these two policy statements powerfully demonstrates congressional comfort with the incentives present with arranged-for services. CMS cannot reconcile its stated concerns in the proposed rule with this clear congressional intent.

3. Inpatient And Outpatient Hospital Services Furnished Under Arrangement Should Be Treated In The Same Manner

In several places CMS expressed a higher level of concern about the incentives inherent with arranged-for outpatient hospital services. We infer that CMS may decide to regulate such outpatient hospital services differently from inpatient services. Any such differentiation would be misguided.

This approach could result in the use of different patient service-teams being utilized for outpatient versus inpatient care. Yet this flies-in-the-face of clinical practice to provide a seamless transition of care between these two modalities and settings. In addition, it is impractical to regulate inpatient and outpatient arranged-for services differently because many arrangements -- including cardiac cath arrangements -- cover both types of services.

Also, the determination of whether a patient should be held at the hospital and admitted as an inpatient in many cases may either be made during the course of treatment or on a retroactive basis. For example, a retroactive determination of outpatient status could be made by a reviewing team if they determine the patient's clinical condition does not meet the payment rules governing inpatients. Another example of a retroactive determination of outpatient vs. inpatient status for payment purposes is the 72-hour rule, which dictates that diagnostic tests, including cardiac cath, originally made when the patient has not yet been admitted are to be reclassified as part of the DRG payment if the tests were made by the same entity and within 72 hours of admission. Along these lines, we note that driving physician-owned outpatient care away from the hospital could cost Medicare more money because such

services may become provided by two different entities and thereby not subject to the 72-hour rule.

Any attempt to regulate inpatient arranged-for services differently than outpatient hospital services also runs counter to the Congressional determination to treat them both as a single DHS: "inpatient and outpatient hospital services."

4. Location Of The Service

We do not understand CMS's criticism of the provision of arranged-for services provided in space leased by the hospital in a hospital building. This is a good thing. Because of the desire to have stand-by surgical capacity in case of complications with a cardiac cath procedure, we would have thought CMS would actually have made such close proximity to the hospital a mandated criteria.

5. Other Criteria

CMS cites as examples of abusive arranged-for services those that the hospital already provides or that the hospital could continue to perform. Although these facts may raise questions calling for further inquiry, it would be inappropriate for CMS to utilize these parameters as decision rules because there are many non-abusive reasons for hospitals and physicians to enter into under arrangement agreements where either or both of these factors are present. Without presenting an exhaustive list, the following are examples of legitimate reasons, many of which are often present with physician-owned under arrangement service agreements:

- The physicians can provide the service at a lower cost than the hospital.
- The physicians can provide the service more efficiently.
- The physicians can provide the service with higher quality.
- The arranged-for service avoids duplication of services.
- The hospital has problems raising the necessary capital.
- The physicians desire a greater level of clinical excellence by becoming more involved in the management of the service.
- A physician-run service has more streamlined management and decision-making.
- The service is not a priority for the hospital, but is a priority for the physicians.

V. CONCLUSION

For the foregoing reasons, CMS should retain existing policy in this area and take no further regulatory action. If it determines further additional protections are warranted in the form of a stronger compensation exception, it should consider creating a specific under arrangements exception modeled after the statutory Under Arrangements Exception.

In closing, we appreciate this opportunity to comment on this important policy initiative.

Respectfully submitted,

Thomas S. Crane

Thomas S. Crane

4114215v.8

ATTACHMENT A

Aurora Denver Cardiology Associates, PC
Cardiac Partners, LLC
Colorado Heart Institute, LLC
Colorado Springs Cardiology, PC
Four Corners Heart Clinic, PC
Four Corners Regional Heart Institute, LLC
Parkside Cardiology, PC
Pueblo Cardiology Associates, PC
Sierra Nevada Cardiology Associates, PC
Vascular Center of Colorado, LLC
Vascular Center of Pueblo, LLC
Western Slope Cardiology, PC

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Kosta M. Arger, M.D.
Renae Avery
David M. Baker, M.D.
Michael J Barber, MD FACC
William L Barry, MD FACC
Dennis J. Battock, MD FACC
Ronald E. Brown, MD FACC
Chad Bidart, M.D., B.C.
Jack Boerner, MD FACC
Richard H. Bryan, Jr., M.D., FACC
Robert A Cadigan, MD FACC
John S. Carroll
Frank P. Carrea, M.D., FACC
Ram M. Challapalli, M.D., FACC
Sridevi Challapalli, M.D., FACC
Joe Chavez, M.D., F.A.C.C.
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George D Gibson, MD FACC
Clarke C. Godfrey II, MD FACC
Jerry H. Greenberg, MD FACC
Thomas A. Haffey, DO FACC
Ross G. Hoffman, M.D.
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Mark W. Keller, MD FACC
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ATTACHMENT A (cont'd.)

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John A. Prevedel, MD FACC
Joseph O. Rainwater, MD FACC
Velisar L. Rill, M.D.
Arif M.K. Rohilla, MD FACC
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Catherine Winchester, MD FACC
James Zebrack, MD, FACC, FASE

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Four Corners Regional Heart Institute, L.L.C.

1 Mercado Street, Suite120 • Durango, CO 81301-7300 • (970) 375-1710

August 27, 2007

VIA FEDERAL EXPRESS

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

Re: Physician Fee Schedule Proposed Rule
File Code [CMS–1385–P]
Issue Area: Physician Self-Referral Provisions -- Under Arrangement Services

To Whom It May Concern:

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

FCRHI is a Colorado Limited Liability Company owned by five (5) physicians who specialize in cardiology, one (1) cardiology group, and two (2) non-physician managers of the practice and the facility. FCRHI has fourteen (14) non-physician employees including nurses, registered cardiovascular invasive specialists, clerical and administrative workers. FCRHI has a five (5) member Board of Managers (three of whom are cardiologists), a Medical Director, an Administrative Manager, and a Clinical Manager who manage the company on a day-to-day basis.

FCRHI commenced operations in May, 2007 and has operated continuously since that time providing a full range of cardiac catheterization laboratory services to patients of our local hospital under arrangements with the hospital. Services we provide currently include diagnostic cardiac catheterization, percutaneous coronary interventions such as balloon angioplasty and stent, and implantation of permanent pacemakers and implantable cardioverter defibrillators.

FCRHI is located on the campus of the hospital, in a medical office building that is immediately adjacent and connected to the hospital. Patients are transferred between FCRHI and the hospital by gurney. The building that houses FCRHI's clinic space is owned by a real estate development and management company, and rented to FCRHI for its exclusive use by long term lease at market rates. FCRHI has paid significant tenant improvement costs at its own expense, utilizing its own capital.

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

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

Physician ownership and participation in management of FCRHI has resulted in a business focused on clinical excellence. FCRHI participates in routine clinical performance improvement activities of the hospital, such as: 1) FCRHI will be inspected by JCAHO as a part of its review of the hospital; 2) FCRHI and the hospital participate in the American College of Cardiology's Cath and PCI Registries where quality data is routinely reported and benchmarked to national results; and, 3) FCRHI has engaged the local physicians in meaningful Quality review and improvement activities. FCRHI is located in a remote area and it has been hard to recruit and retain cardiologists who can perform therapeutic procedures such as balloon angioplasty and stent services. FCRHI was jointly developed by local cardiologists and a large metropolitan cardiology group that participates in Quality Improvement activities as well as providing coverage to the local cardiologists for weekends and vacations. The patients have benefited from the improved clinical quality in this area.

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

Respectfully submitted.

John S. Carroll
Manager

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Western Slope Cardiology, P.C.

Jacob Webel, M.D
Gary L. Snyder, M.D.
Daniel J. Duffey, M.D.
Donald R. Pacini, M.D.
Paul P. Oupadia, M.D.
William P. Miller, M.D.
Marcus Howell, M.D.
Charlie Brunson, M.D.
Richard Germany, M.D.

Diplomates, American Board of Cardiovascular Disease
American Board of Internal Medicine

August 29, 2007

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

Re Physician Fee Schedule Proposed Rule
File Code CMS-1385-P
Issue Area: Physician Self-Referral Provisions-Under Arrangement Services

To Whom It May Concern

We are a group of 10 cardiologists practicing Grand Junction, Colorado. We would like to express our objection to CMS's proposed changes to the Stark regulations related to under arrangement services. In our experience, physician participation in arrangements such as these leads to a reduction in costs and improve efficiency of care.

Currently we perform noninvasive studies in our office including echocardiography, stress testing and nuclear scanning. The charge to the patient for these services is half of what the hospital charges in their laboratory. We are able to do this more efficiently with better patient through put, lower overhead and less administrative costs.

We would encourage CMS to retain its existing policies as it would continue to allow more cost effective care. We do support the positions taken in the submission written by Tom Crane of the law firm, Mintz, Levin, Cohn, Ferris, Glovasky and Popeo, P.C. and strongly urge CMS to retain its existing policies.

425 Patterson Road, Suite 605 • Grand Junction, Colorado 81506 • (970) 244-2482 • (800) 335-6586 • Fax (970) 255-1701

Sincerely,

WESTERN SLOPE CARDIOLOGY, PC

Dr. Jacob Webel

Dr. Daniel J. Duffey

Dr. Paul Oupadia

Dr. Marcus Howell

Dr. Richard Garmany

Dr. Gary L. Snyder

Dr. Donald R. Pacini

Dr. William Miller

Dr. Charlie Brunson

Dr. Kurt Spriggs

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RICHARD HAMBLEY, M.D.
Dermasurgery • Mohs Micrographic Surgery

2007 SEP -4 PM 1:18

August 31, 2007

The Honorable Herbert Kuhn
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Fax 202 690-6262

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

Dear Herbert Kuhn:

I am a Mohs surgeon in a small town in California. I am deeply concerned about the proposal to make Mohs surgery subject to the Multiple Procedure Reduction Rule.

Mohs micrographic surgery of CPT codes 17311 and 17313 has been proposed to become subject to the Multiple Procedure Reduction Rule (MPRR). I would like to convince you that it is wrong to make Mohs surgery subject to the MPRR. This is because the amount of work to do two Mohs surgeries on the same day or to do Mohs surgery followed by a reconstruction that costs more than the Mohs surgery does not significantly decrease the work of either. Unlike most surgeries, a lot of the payment for Mohs 17311 and 17313 is for work that is done on the tissue after it is removed from the patient and this is not lessened by doing other surgery on the patient. After tissue is excised from the patient I cleanse it, apply ink to the epidermis edge, diagram a map of the tissue and patient, divide the tissue into manageable size pieces, color code the margins, and align the pieces in order. Then each separate piece of tissue is frozen, mounted onto a metal disk, then sectioned in a cryostat. The shavings are mounted on slides, the slides a put through ten steps of staining, the slides are dried and cover slips mounted. I then examine all of every section under the microscope and diagram areas of residual cancer. These steps are time consuming and are the same if I am doing one or two Mohs surgeries or if I later do a reconstruction. It does not make since to cut the reimbursement for Mohs surgeries when other surgery is also done because so much of the work is not reduced.

I am concerned that the proposed cut in payment for multiple Mohs surgeries or Mohs surgeries requiring a reconstruction will make the surgery pay less than it costs me to provide the service. I am not sure how I could deal with the inadequate reimbursement but it would be terrible.

Mohs surgery should continue to be exempt from the Multiple Procedure Reduction Rule because that is fair. Please keep 17311 and 17313 exempt from the MPRR.

Thank you,
Richard Hambley MD
Richard Hambley, MD

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Health Research Associates

HRA

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August 30, 2007

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

Re: RESOURCE-BASED PE RVUs – Photopheresis and Therapeutic Plasma Exchange

Extracorporeal photopheresis (CPT 36522) and therapeutic plasma exchange (TPE; CPT 36514) can be safely provided in a physician-directed clinic, and are each covered by Medicare for a number of serious hematological, neurological and/or autoimmune disorders in this setting.[1,2]

Like many other procedures that began in the hospital setting and have moved to the physician office or clinic, benefits of doing so with photopheresis and TPE include an improved patient treatment experience, reduced nosocomial infection risk in these usually immunocompromised patients, and potentially significant overall cost savings to the Medicare Trust Fund.

Unfortunately, physicians interested in bringing these two historically hospital-based apheresis procedures into the office-based setting are being completely stymied by severe under-valuations of their proposed "fully implemented" practice expense RVUs (PE RVUs). The proposed valuations will yield payment rates that fall far short of actual direct and indirect costs of providing these unusually supply-intensive procedures.

The basis for this undervaluation is driven by CMS' application of a roughly 40% "direct PE budget neutrality adjustment" ("direct adjustment"),[3] which CMS applies equally to clinical labor, supplies and equipment expenses. The impact of this "direct adjuster" then ripples through the entire calculation of PE RVUs: the "adjusted direct RVUs," reduced by about 40%, are fed into the indirect RVU calculation: *Indirect Pct * (Adj. Direct*

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[1] Medicare Coverage Manual Sect. 110.14 (Coverage Issues Manual §35.60).
[2] *Fed Reg.* July 12, 2007; 72(133):38273.
[3] This direct adjuster appears likely to range between the 0.584 value published in the July 12 *Federal Register* and the 0.6186 value used in a sample PE RVU calculation for TPE which was provided to me by CMS.

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[10] Personal communication: Dawson Smith, Director of Sales, Therapeutics Division, North America, Gambro BCT, Inc.

RIVERSIDE UROLOGY, INC.
4845 Knightsbridge Blvd. • Suite 200 • Columbus, Ohio 43214
www.2rui.com

Herbert W. Riemenschneider, M.D.
Board Certified, American Board of Urology
Fellow of the American College of Surgeons

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August 28, 2007

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

To Whom It May Concern:

I am a urologic surgeon and have been in practice for more than 30 years. I believe that my reputation substantiates my interest in delivering quality care, to my patients, which is driven totally by patient need.

There are a number of issues that have come before the individual urologist, as well as the American Urological Association, that relate to restraint of our ability to deliver the quality services referenced above. The main focus of my concern relates to proposed revision of the Stark Laws related to services such as lithotripsy and the availability of laser technology for sophisticated interventions in the urinary tract, from the bladder to smallest recesses of the kidney. Further, I have been one of the pioneers in the development of using extremely cold temperatures to treat malignancies, specifically prostate cancer and renal cancer. This technology is Cryoablation. This technology offers many advantages, which include its minimally invasive characteristics that allow patients to rapidly reengage in full activities shortly following treatment for these potentially devastating diseases.

There are other strategies such as brachytherapy, otherwise known as radioactive seed implant for treatment of prostate and other malignancies. In addition, there are treatments for benign prostatic hypertrophy, driven by various forms of heat delivery including radiofrequency and laser devices.

In many instances institutions do not acquire these technologies because of cost and usage concerns. However physicians, such as urologists have joined together, i.e. joint ventures, and taken the risk to provide this therapy. The fact that a large number of providers are involved makes it probable that the equipment will be appropriately utilized. The method for making this economically feasible is "under arrangement" with institutions such as hospitals. These treatments are and their applications are monitored by the governing bodies of the involved specialty society. These business arrangements, referenced as "under arrangements", should not be prohibited.

The per click fee, is an integral part of delivering these types of technologies. The economic costs can be appropriately assigned and revenues for these services collected based on reasonable economic models used in the free enterprise system.

Further, there is concern about physician owned entities that in part are owned by a hospital being similarly affected. Examples of these are ambulatory surgery centers. Under the proposed rule to ban "under arrangements" and "per click methodology" many of the referenced surgical treatments will not be available to patients who need them as these treatments are an appropriate level of acuity to be treated in such centers.

The most bothersome aspect of the proposed revision of the Stark regulations is that through CMS interpretation the burden of proof, regarding a "violation" under the new rules will fall upon the provider to establish that the service has been delivered in a manner that doesn't violate these regulations.

Simplistically, this interpretation based on my understanding of our jurisprudence system is aberrant in that it appears that the providers, trying to do their jobs would be guilty until proven innocent.

In summary being a member of the Health Policy Council of the American Urological Association has given me access and overview of a great volume of information relevant to these subjects. I would like to say as a practitioner of medicine and urology for over 30 years the proposed regulatory changes if approved will have a significant impact on the quality of healthcare, specifically the accessibility of technology to the consumer, the patient. It will insert regulatory decision making by those non certified or qualified in medicine. This clearly will influence the quality of care which can only be judged by an appropriately certified physician and the patient within the context of **the physician patient relationship.**

I welcome the opportunity to be questioned regarding these perspectives. I look forward to substantiate these positions in a manner that meets formal legal/technical terminology, but request the presence of a knowledgeable healthcare attorney to assist me in doing so.

Sincerely,

Herbert W. Riemenschneider, MD

HWR/mm

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ROBERT W. LUNDY, JR.
PATRIC HOOPER
LLOYD A. BOOKMAN
W. BRADLEY TULLY
JOHN R. HELLOW
LAURENCE D. GETZOFF
JAY N. HARTZ
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FILE NO. 03154-901

August 29, 2007

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

Re: Physician Self-Referral Provisions

Ladies and Gentlemen:

Our firm represents a number of companies that are fully or partially owned by physicians and that supply hospitals and ASCs with implantable medical devices. This letter presents our comments on behalf of one of these companies, Allez Spine, LLC ("Allez Spine"), in response to the proposal of the Centers for Medicare & Medicaid Services ("CMS"), as set forth in connection with its July 12, 2007 proposed revisions to Medicare's physician fee schedule, to modify the Stark law's definition of "entity."

I. Summary Of Allez' Position

As is discussed below, CMS' proposal raises a number of difficult conceptual issues and we are concerned that CMS' proposal could potentially restrict the ability of physicians to hold ownership interests in medical device manufacturing/distribution companies. As is explained below, Allez Spine generates savings for its customers by supplying them with implantable devices at prices that are typically lower than those paid by the customers when they purchase equivalent medical devices from traditional non-physician owned companies. CMS' proposed change, if interpreted to apply to Allez Spine, therefore would be likely to result in unnecessarily decreased competition and in increased costs for hospitals and ASCs in obtaining medical devices.

Accordingly, as is set forth in more detail below, Allez Spine believes that CMS should take one or more of the following actions:

(i) Clarify that CMS' new proposal is limited to formal "under arrangements" relationships with hospitals, whereby an outside provider performs all components of the DHS for the hospital. If this is done, the new rule would not impact Allez Spine since the medical devices that it provides are not covered by Medicare on an "under arrangements" basis.

(ii) Clarify that a company that provides implantable medical devices used by a hospital in the performance of inpatient and outpatient hospital services or by an ASC will not itself be considered to "perform" any DHS, since the provision of an implant device is not the provision of a service. If this is done, the new rule would not impact Allez Spine since, while it provides devices, Allez Spine does not perform any services for hospitals or ASCs at all.

(iii) Clarify that implant devices are not DHS as they are provided by Allez Spine. Because the device company is not a hospital, referrals to it should not be considered to be for inpatient or outpatient hospital services. In addition, the referrals should not be considered to be for other DHS except when the services provided by the company are DHS in their own right (such as, for example, diagnostic imaging services). Allez Spine should not be considered to be providing DME, prosthetics, orthotics or prosthetic devices or supplies that are DHS in their own right under the Stark law, since that is not how the items provided by Allez Spine are characterized for Medicare coverage or payment purposes.

II. Explanation Of The Unique Contribution Of Physician-Owned Medical Device Companies

Before turning to a legal analysis of CMS' proposal, it will be helpful for CMS to understand the motivation underlying the formation of Allez Spine and many other physician-owned medical device manufacturing or distribution companies and the opportunity for savings that such companies create for their customers. To understand the business rationale of Allez Spine for having physician investors, it is important to understand the context of the company's founding by a group of spine surgeons approximately four years ago. These surgeons were frustrated by the extent to which they had become marginalized by the large spine companies. Whereas in years past many surgeons had meaningful interactions with the engineering and product development staff of device manufacturers, many more recently were finding their input and ideas largely ignored or just put on the shelf. At most, they were asked to try out new products or participate in clinical trials, but had no meaningful outlet for their own ideas and innovation.

Moreover, the surgeons saw how much money was being spent on marketing, promotion, and sales fees that were built into product costs, which in turn went up every year. The big companies exercised what was tantamount to oligopolistic sales practices and pricing power.

Sales representatives were making more money on commissions in some cases than the surgeons' fees, and they bore no risk and took no night call. The costs of marketing typically represent in the range of 30% of the total costs incurred by the large national device distribution companies. However, surgeons who own their own company can for the most part avoid these marketing expenses, and it was perceived that the elimination or reduction of the role played by expensive commissioned sales representatives would create substantial savings that could result in hospitals and ASCs ultimately saving money on their purchases of medical devices from surgeon-owned companies.

No single surgeon or small group could devote the time or raise the capital to compete in any meaningful way. The big spine companies were the only game in town. The only possible way to compete against the dominance of the big companies was for physicians to collaborate in a constructive, legal, and innovative manner.

Discussions among colleagues led to extensive analysis of the regulatory issues and the structural options. A physician-led enterprise was conceived that offered the opportunity, but not the guarantee, of a company that could put the surgeons on a more equal footing with the big device companies and create savings opportunities. Allez Spine was guided by the principles of shared intellectual property (IP), rapid product development cycles, lower cost structure, highly competitive pricing at the low end or bottom of the range, donating back to the research community, and continual innovation. Consequently, each surgeon investor committed to:

1) Share and contribute their ideas and innovations in a common enterprise - IP is assigned exclusively to the company;

2) Review and comment on emerging product concepts and designs;

3) Active participation on design teams with rapid turnaround of prototypes;

4) Place a substantial amount of money at risk with no promise of a return;

5) Equal ownership with no consulting fees, royalties, stipends, sponsored CME, etc;

6) Keep development costs low by combining surgeon-generated IP with in-house engineering and rapid prototyping capability;

7) Keep product costs low by controlling development costs, competitive outsourced manufacturing, and reduced marketing and cost of sales and distribution;

8) Provide full disclosure to patients in writing;

9) Donate each year to established, non-profit spine research foundations.

In summary, surgeons have always been essential to the progress and success of the medical device industry - as both sources of ideas and as end users of the products. As the spine industry has matured, several companies have come to dominate the sales and distribution of products, marginalizing the role of the individual surgeon. The "consulting" practices of these companies are under intense scrutiny. Any viable, competitive response to the status quo must find a way to incorporate solo or small groups of surgeons into an entrepreneurial venture in which the physician perceives a sense of ownership, participation, innovation, and influence. Even though each physician investor in Allez Spine holds no more than a fraction of 1%, Allez Spine believes that it has created such a venture, giving the surgeon a voice in the industry. Health system feedback confirms to Allez Spine that it is helping to create downward pressure on prices while providing a high quality product. Many of its surgeons are heavily involved in product development with several projects underway. Time will tell if Allez Spine can stake out a sustainable niche in a highly competitive field dominated by a few big firms, but Allez Spine feels that it has made a compelling start.

III. Background On The CMS Proposal

Absent some exception (and none is available for a small non-publicly traded company of the type that is the subject of this letter), the self-referral restrictions of the federal Stark law prohibit a physician from making a referral of a Medicare patient to an entity in which he or she directly or indirectly holds an ownership interest for the "furnishing" of a "designated health service" ("DHS"). The Stark law's current definition of what it means for an entity to be "furnishing" DHS includes only those persons or entities that directly bill the Medicare program for the DHS.

Allez Spine and similar companies do not themselves bill the Medicare program for the medical devices they provide. Indeed, they cannot bill directly, since their devices are not separately covered by Medicare, but are instead included in the DRG and ASC rates that are paid to their hospital and ASC customers. Therefore, no *per se* prohibition applies to physicians who order devices for their patients that are provided to hospitals and ASCs by companies in which they hold ownership interests. Instead, an indirect compensation relationship is created between the hospital or ASC which purchases the implant devices and the physician owners of the manufacturing/distribution company. Provided that the pricing applicable to the devices is held constant irrespective of the volume or value of the physicians' orders of the devices and is at fair market value, the requirements of the Stark law's exemption for indirect relationships can be satisfied, and, as has been recognized by CMS and MedPAC, the federal self-referral restrictions are not triggered.

However, under CMS' proposal, 42 C.F.R. Section 411.31's definition of when "a person or entity is considered to be furnishing DHS" would be expanded. CMS' proposed expansion of the definition of the entity that furnishes a service would retain the existing definition, which includes the entity that bills, but would add an additional alternative prong to

the definition under which persons and entities that do not themselves bill the Medicare program for any DHS would also be subject to the self-referral limitations if they are "the person or entity that has performed the DHS. . . ."[1] This proposed change would prevent indirect remuneration analysis from being used to permit a physician to have a non-exempt ownership relationship with a company "performing the DHS."

IV. CMS Should Not Throw Out The Baby With The Bath Water By Prohibiting Hospitals From Entering Into Arrangements That Achieve Savings For Them

It does not appear that any formal studies have been conducted by CMS or the GAO of either "under arrangements" relationships with hospitals generally or the specific type of implant device sale arrangement we consider herein. CMS, instead proceeding by its own admission based only on anecdotal evidence, has described its concern with arrangements by which companies perform DHS for other companies as follows:

> We have received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly. There appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. . . . It appears that the use of these arrangements may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and beneficiaries.

It must immediately be noted that, despite superficial similarities, the kind of joint venture we describe herein differs in many material ways from the arrangements over which CMS has expressed concern. First, implant devices are not anything that hospitals directly provide themselves – they invariably purchase them from outside companies. Second, the services would not otherwise be separately payable, since implant devices are not covered by the Medicare program in their own right. Third, since no direct payment is made for implant devices, the arrangements we consider herein are not a scheme for improving reimbursement. Fourth, as described above, there are legitimate reasons for physicians to be involved in the business that are wholly independent of any quest for profit. Fifth, and finally, rather than increasing costs, the type of venture at issue here will typically reduce costs.

When one traces the history of the issue of what entity will be considered to be furnishing DHS, it becomes clear that CMS is now considering a substantial change in policy that may

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[1] 72 Fed. Reg. 38122, 38187, col. 2 (July 12, 2007).

overturn a large number of long established relationships.[2] While overturning the table and starting on this issue afresh is not beyond CMS' power, it should nevertheless give careful consideration to making any such substantial change to already carefully worked ground. There is no necessity for such action by CMS with respect to the type of venture presented here, since the concerns which CMS has expressed do not arise in connection such a venture.

In any case, however, the "indirect" types of arrangements at issue here will still trigger the self-referral prohibition if they are not at fair market value. If CMS is skeptical as to what parties may consider to be fair market value, it appears that the public would be better served by CMS' providing more guidance on that issue and, if necessary, initiating some enforcement actions with respect to arrangements that it does not consider to be at fair market value, as opposed to expanding the scope of the existing prohibition so broadly so as to make the concept of fair market value irrelevant.

In any case, even if CMS concludes that the risks presented by certain arrangements are so great that they must be prohibited through a change in the definition of "entity," CMS should define the scope of such "*per se*" prohibited relationships with a narrow brush, as is discussed below.

V. The Meaning Of "Has Performed The DHS" Under CMS' Proposal Is Unclear And CMS Should Clarify That Its Proposal Applies Only To True "Under Arrangement" Relationships With Hospitals

CMS' proposal to define the person who is "furnishing" DHS to be the person who has "performed" the DHS is hardly illuminating when it comes to understanding what it in fact means to either "furnish" or "perform" DHS. No guidance at all is provided by the commentary for the not uncommon situation in which certain components going into the performance of the DHS are supplied by one company, while others are supplied by another. Instead, the new definition only makes sense when it is viewed simply in the broader context of rejecting the limits of the current definition, which defines "performed" by using the "bright line" test of who has billed Medicare for the DHS.

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[2] For example, without revisiting in detail the long history governing lithotripsy arrangements, it appears that CMS' contemplated change would be inconsistent with the balance that Congress intended to strike in this area with respect to lithotripsy services and which has been reaffirmed by a Court's holding that lithotripsy is neither an outpatient nor an inpatient hospital service. The example of lithotripsy supports the conclusion that services that are not inpatient or outpatient services in their own right should not now be considered in isolation and be deemed to be inpatient or outpatient services simply because they are being billed for by a hospital.

The problem presented when billing is not used to define "furnishing" is that, without further clarification from CMS, there is a danger that arrangements by which several parties are involved in the performance of a DHS may be prohibited when this was the not the intent of either CMS or Congress. Let us use the same example of diagnostic imaging services that is used by CMS in its commentary. Consider, for example, a physician-owned company that owns and operates an independent diagnostic testing facility ("IDTF") that is enrolled as a provider in the Medicare program and that performs services for a hospital on an "under arrangements" basis. That company will own or lease the relevant space and equipment, will employ or contract with the relevant personnel and will have the responsibility for organizing and administering the use of its space, personnel and equipment to conduct diagnostic studies for the hospital's patients. Under those circumstances, the IDTF can be fairly said to be "performing" the diagnostic services. If, as in CMS' example, the diagnostic services are radiology services, the IDTF can reasonably be considered to be performing DHS under the new definition.[3]

Let us consider what happens, however, if the services are not performed in a free-standing IDTF, but are instead radiology services that are provided in the hospital's space by a physician-owned company that is not itself enrolled in the Medicare program, but that will employ or contract with the relevant personnel and will have administrative responsibility for using the hospital's space and its own personnel and equipment to conduct diagnostic studies of patients. The commentary provides the example of a free-standing ASC or IDTF providing services to a hospital "under arrangement," and even goes so far as to address the situation where the joint venture entity leases space from the hospital. However, the commentary does not at any place address a situation where the service is not performed by an independent provider, but is instead performed within the space of the hospital itself. Most obviously (and any broader change would not appear to have been fairly telegraphed to the public by the proposed rule and its commentary), ***CMS should draw this extended line of "furnishing," if there is to be any extension at all, only as broadly as the commentary suggests CMS intended for it to be drawn – at formal "under arrangement" relationships by which free-standing providers that the Stark law would bar from billing Medicare directly for their own services when ordered by their physician owners instead bill their services through hospitals.***

If CMS were to interpret its proposal to apply beyond formal "under arrangement" relationships, it would be sliding down an impossibly slippery slope if it in fact intends for its approach to differ from the one that was proposed by MedPAC. For example, consider the then similar scenario under which radiology services are provided in the hospital's space by a physician-owned company that is not itself enrolled in the Medicare program, and that instead

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[3] The same would appear to be true if the facts were the same, except that the IDTF was not itself enrolled in the Medicare program.

provides the hospital with the personnel (including a radiology department administrator) and equipment to be used in conducting diagnostic studies for the hospital's patients, while the hospital takes the full administrative and regulatory responsibility for ensuring that the personnel and equipment are used to conduct diagnostic studies of the hospital's patients. Isn't this merely an arrangement where indirect remuneration analysis applies to the personnel and equipment relationships? Finally, consider a last scenario under which a physician-owned company merely provides the hospital with the non-supervisory technical personnel and equipment to be used in conducting diagnostic studies for the hospital's patients, while the hospital takes the full supervisory, administrative and regulatory responsibility for ensuring that the personnel and equipment are used to conduct diagnostic studies for the hospital's patients. Again, wouldn't this then be an arrangement where indirect remuneration analysis applies to the personnel and equipment relationships?

Drawing the line at formal "under arrangement" relationships is also consistent with the commentary's discussion of MedPAC's 2005 report to Congress. As CMS is aware, MedPAC recommended that CMS "should expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial portion of its revenue from a provider of designated health services." The CMS commentary makes it clear that CMS believes that the MedPAC proposal would impact "leasing, staffing, and similar entities." However, CMS chose not to make the same proposal that MedPAC had made. This clearly suggests that CMS believes that the reach of the MedPAC proposal would be broader than its own and, accordingly, that the CMS proposal was not intended to reach leasing, staffing or similar relationships. The most significant difference between the CMS and MedPAC approaches therefore appears to be that CMS' approach would only affect companies that perform DHS in its own right, while the MedPAC approach would also affect companies that only provide "inputs" to DHS or, indeed, services that have no relationship to DHS at all.

Unless the present definition of entity that is based on billing is retained unchanged or an "under arrangements" standard is used, whatever lines are ultimately drawn by CMS in the above scenarios will be arbitrary, since a flat out prohibition will apply on one side of the line (since there are no applicable ownership exemptions) and arrangements on the other side of the line will be permitted under the favorable analysis that applies to indirect remuneration. In any case, however, turning our attention to the physician-owned medical device manufacturing and distribution companies that are the subject of this letter, it seems manifestly clear that a company that merely sells an implantable medical device to a hospital or to an ASC cannot be considered to have performed a hospital inpatient or outpatient service or ASC service when performing the patient's "service" is the operational and regulatory responsibility of the hospital or ASC and the patient's physician who performs the surgery procedure in which the medical device is in fact implanted into the patient. Thus, ***if CMS does not limit its proposed change to true "under arrangement" relationships with hospitals, it should nevertheless clarify that its proposal would apply only where a completed "service" is being sold to a billing entity, and that the***

proposal was not intended to affect a medical device joint venture of the type at issue here which does not perform any services at all.[4]

VI. Even If CMS Extends "Entity" To Cover A Company That Provides Implantable Devices To Hospitals And ASCs, CMS Should Clarify That Implant Devices So Provided Are Not DHS.

Our final comment is that if CMS extends its definition of "entity" so as to include a physician-owned company that provides implantable medical devices to hospitals and ASCs, CMS should at the same time clarify that the self-referral ban still then will not apply to the situation at hand, since implant devices are not DHS when they are so provided. Because the device company is not a hospital, referrals to it should not be considered to be for inpatient or outpatient hospital services.

Similarly, the referral should not be considered to be for other DHS except when the services provided by the company are DHS in their own right (such as, for example, diagnostic imaging services). In addressing this issue, CMS should therefore also clarify that implantable medical devices provided to hospitals or ASCs which are paid for by Medicare under DRGs or ASC flat rates will not be considered to be DME or prosthetics, orthotics or prosthetic devices or supplies that are DHS in their own right under the Stark law.

Instead, as CMS has noted in its Phase III commentary in connection with its discussion of the whole hospital exemption, hospitals (and the same is true of ASCs as well), as such, are not authorized by Medicare to provide DME, prosthetics, orthotics or prosthetic devices or supplies. They instead only provide implant devices as components of their broader hospital or ASC services. A separate enrollment as a DMEPOS supplier would be required in order for a hospital or ASC (or for Allez Spine for that matter) to provide DME, prosthetics, orthotics or prosthetic devices or supplies. The hospitals and ASCs either will not have such enrollments or, if they do, such enrollments will not be the basis of the Medicare coverage for the implantable devices that are at issue here.

Moreover, the physician-owned company neither needs nor will it have any such enrollment, and it therefore cannot be considered to be providing items in those categories. This is because implantable medical devices simply do not fall within the Stark law's definitions of DME, prosthetics, orthotics or prosthetic devices or supplies. Implanted medical devices do not fit within the applicable definitions and therefore are not covered in their own right by Medicare as DME (as defined by SSA Section 1861(n)) or as prosthetics, orthotics or prosthetic devices or

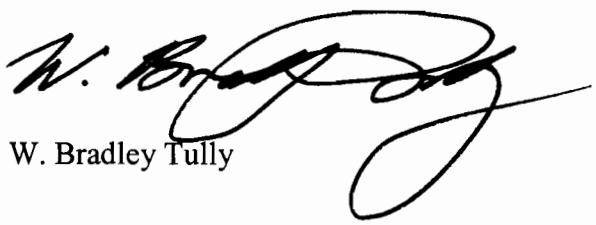
[4] For the reasons set forth herein, Allez Spine also believes that CMS should not adopt the MedPAC proposal.

supplies (as defined by SSA Sections 1861(s)(8) and (9).) They are instead simply supplies that are used in connection with surgeries.[5]

* * * * *

Allez Spine very much appreciates CMS' review of the issues discussed herein that impact physician-owned medical device manufacturing and distribution companies. Please feel free to call me if you have any comments or questions regarding the discussion herein.

Very truly yours,



W. Bradley Tully

WBT/ng
cc: Ed Geehr

[5] CMS' discussion of implants at 66 Fed. Reg. 935, January 4, 2001, which could be read to suggest that implanted knee joints are prosthetics, should not be considered to be relevant here. The comment was based on the completely specious contention that artificial legs, which are prosthetics, contain knee joints, and that implanted knee joints are therefore also prosthetics. While that might make sense where a joint is provided as part of an artificial leg, it makes absolutely no sense in the context presented here, where the joint is implanted, and no artificial leg is being used.

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

August 31, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphery Building
200 Independence Ave. SW
Washington, D.C. 20201

Dear Mr. Kuhn:

RE: CMS-1385-P, Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

On behalf of nearly 500 hospitals and health systems, and ancillary providers in the state of California, the California Hospital Association (CHA) is pleased to comment on' proposed policy and payment changes to the calendar year (CY) 2008 physician fee schedule final rule. In addition to offering the comments below, CHA supports the comments and recommendations of the American Hospital Association.

Physician Self-Referral Provisions

Hospitals in California have a strong interest in the policy changes to self-referral and anti-kickback provisions because of a unique state statute forbidding the "corporate" practice of medicine, effectively prohibiting most hospitals in the state from directly employing physicians. With this option expressly forbidden in the California, hospitals in the state must rely upon other remunerative relationships with community physicians, many of whom have the potential to be affected by statutory and regulatory changes to self-referral and anti-kickback law.

CHA commends the Centers for Medicare & Medicaid Services (CMS) for reconsidering several self-referral provisions, and is generally in favor of regulatory changes that we feel help contribute to the close professional and collaborative relationships between physicians and hospitals that are required for high-quality health care delivery. We encourage CMS to consider in this and future rulemakings ways in which collaboration between hospitals and their physician partners can be enhanced without exposing federal payment systems to fraud and abuse, and are happy to assist with this effort in any way we can.

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Obstetrical Malpractice Insurance Subsidies
CHA is supportive of CMS' efforts to expand access to obstetric services through incorporating additional flexibility to the anti-kickback exception for obstetric malpractice premiums. We believe that this program provides hospitals and health systems with an important option for expanding availability of obstetric services in rural and underserved areas.

California is uniquely affected by this particular exception to self-referral regulations for several reasons. First, California has a high number of hospitals that are in health provider shortage areas (165), and in medically underserved areas (79). Second, although California has several of the nation's largest urban centers, it also has vast expanses of rural areas. Indeed, 66 hospitals (about one-fifth of CHA member hospitals) are in designated rural areas, and as of December 2006, 24 were certified as Critical Access Hospitals (CAHs). Finally, as previously noted, California state law generally prohibits the "corporate" practice of medicine, effectively prohibiting hospitals in the state from employing physicians directly, and thereby increasing our interest in alternate remunerative arrangements, such as those allowed under the anti-kickback safe harbor provisions in CFR 1001.952(o).

In general, CHA is supportive of CMS' efforts to expand the availability of obstetric care to health professional shortage areas (HPSAs) and medically underserved areas (MUAs), and commends CMS for its efforts. However, we recognize that while this exception can provide an incentive for obstetricians to practice in HPSAs and MUAs, we note that in areas with high proportions of patients who are either uninsured or who are covered only by Medicaid (as is the case in many HPSAs and MUAs), remuneration for malpractice insurance premiums may be insufficient to attract providers who face otherwise poor reimbursement. In California, for example, the cost of providing care to Medi-Cal (California's state Medicaid program) patients exceeds the payment from the state program, and the state's uninsured rate has risen to about 18 percent, according to the U.S. Census Bureau. Moreover, since 1975 California has had caps for non-economic damages in medical malpractice, and has also instituted price controls on malpractice premiums, thus constraining malpractice premiums considerably. The net effect of these factors is the diminution of the incentive structure envisioned by the safe harbor for obstetric malpractice premiums contained in CFR 1001.952(o).

Consequently, we believe that some of CMS' documentation requirements in the proposed rule would have a chilling effect on the availability of this type of permitted remuneration being offered by hospitals and/or the willingness of obstetricians to take advantage of the exception. given the increased administrative burden of these requirements. Of particular concern to CHA is the provision that would require physician certification and (in subsequent years) data indicating that a set proportion of the physician's patient panel reside in a HPSA or MUA. CHA is concerned that this will place substantial administrative burden on providers, whose systems are currently not configured for abstracting HPSA or MUA status in patient records. Moreover, HPSA and MUA data are typically coded by census tract, which correlates poorly with zip code, the most granular captured data in most providers' record system. Consequently, census tract would have to be hand-correlated by address, which would place substantial administrative burden on providers and would equate to an extremely strong disincentive for providers to take advantage of the safe harbor for obstetric malpractice premium subsidies.

We believe that it is also important for CMS to consider that the Health Resources and Services Administration (HRSA) designations for HPSAs and MUAs generally distinguish between shortage and underserved areas for primary medical care, for dental care, and for mental health care. Although there may be overlap between shortage and underserved areas for primary health care and actual shortage areas for obstetricians, the data aren't sufficiently granular enough to make this distinction, and consequently there are no designated shortage areas for obstetric care. On the other hand, providers located in communities in the state, irrespective of the community's HPSA or MUA status are acutely aware of the availability of obstetric services in their local community. Hospitals are particularly cognizant of this availability, as their obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA) compel them to have emergency services available for obstetrics.

Consequently, we propose that CMS loosen the requirements for the safe harbor contained in CFR 1001.952, to include providers in non-HPSAs and non-MUAs as well as those practicing in and receiving patients from those areas. We believe that hospital executives, providers, and patients in California's diverse communities are the best judges of actual availability of obstetric care and that HRSA data regarding HPSA and MUA status and its applicability to obstetric coverage is imprecise. CMS should consider dropping the HPSA/MUA requirement from the regulations at CFR 1001.952(o)(2)(i) and finalize an expanded anti-kickback safe harbor provision for obstetric malpractice subsidies. So long as the malpractice premium subsidy is not contingent upon volume or conduct of referrals; is documented in a written agreement; does not restrict staff privileges; the practitioner agrees to treat all federally-funded patients; and the insurance is *bona fide* as described in regulation; CHA believes that adequate program safeguards are in place to curb abuse. Further, some of the documentation requirements described in the proposed rule, in particular the written agreement requirement, and requirements regarding the location and names of involved parties, are legitimate exercises of CMS' oversight authority, and would help provide additional safeguards against program abuse were the HPSA/MUA requirement lifted.

Ownership of Investment Interest in Retirement Plans

CHA represents nearly 450 hospital and health system members throughout the state of California, and counts sole community hospitals, small rural hospitals and CAHs as full members alongside some of the largest and most clinically sophisticated health systems in the nation. Because of California's unique diversity of communities, health system delivery models, and wide geographic variation, we have a particular interest in CMS' proposal to revise CFR 411.354(b)(3)(i) to provide that physicians' or their immediate family members' ownership interests in retirement plans do not count as self-referral when the physician refers patients to a hospital providing such benefits.

In many rural communities in California, the local hospital is the largest single employer, and especially in the case of rural referral hospitals, can employ a considerable proportion of the population in a rural center or a small town. In addition, CHA's largest urban health system members directly employ hundreds of thousands of California workers. In either case, it is possible, and in some cases quite likely, that members of physicians' families may be employed by and thus receiving an interest in retirement plans provided by a California hospital. We

therefore believe that the regulation as it currently stands is impractical and unreasonable, and we strongly support CMS' proposed revisions to CFR 411.354(b)(3)(i).

Alternative Criteria for Satisfying Certain Exceptions
CHA is cognizant of the fact that, in today's complex health care marketplace, many providers and hospitals in particular must maintain a variety of contracts at a given point in time in order to provide services to patients in a timely, effective, and efficient manner. In California, the contracting issue becomes of particular importance, as state law prohibiting the "corporate practice of medicine" effectively prohibits hospitals in the state from employing physicians directly, and so they frequently must rely upon a constellation of contracts with individual physicians and group practices to provide certain services such as emergency department coverage.

Given the complex nature of health care generally, and the unique position of California hospitals relative to their community physicians, CHA acknowledges that some members may have a number of contracts that may be out of technical compliance on occasion, and appreciates CMS' efforts towards providing alternative criteria. Further, we acknowledge that CMS does not have the authority to waive violations altogether, even when a violation occurs in error and presents no program risk. CHA appreciates the inherent utility of establishing alternative criteria in lieu of enforcement through civil monetary penalties.

In general, we are supportive of CMS' proposed changes to applicable portions of CFR sections 411.355 through 411.357, but are concerned that hospitals will be hesitant to self-report their violations unless CMS clarifies certain issues, including:

- The circumstances under which CMS would allow hospitals to correct their violations (per the proposed rule), versus be subjected to civil monetary penalties. CHA is concerned that if an institution were to have multiple technical violations or have violations over a sustained period of time, CMS could find it operating in "reckless disregard," and thus subject it to civil monetary penalties. This would have the net effect of hospitals self-reporting in good faith and being penalized for doing so. Additional guidance from CMS regarding the specific circumstances under which the institution could make an allowed technical correction would help clarify this aspect of the proposed regulation.
- The proposed rule language regarding whether hospitals may continue to bill for services performed under the auspices of the contract while it is under review with CMS. Specifically, hospitals would need further guidance about what is permitted during three time intervals: 1) the time from when the technical violation is discovered and when it is reported to CMS; 2) the time from when it is reported to CMS and when CMS issues a determination; 3) the time from when the determination is issued and when the contract is brought back into compliance. Without clearer guidance regarding CMS' expectations of hospitals during these intervals, it is difficult to conceive of many hospitals self-reporting if the act of self-reporting would introduce a high degree of uncertainty into the revenue stream related to the contract in question.

Therapy Standards and Requirements

Revisions to Personnel Qualification Standards for Therapy Services

CMS is proposing to revise the personnel qualifications for physical therapists, physical therapy assistants, occupational therapists, and occupational therapist assistants. If they are finalized, these revisions should culminate in revisions to the Medicare *Benefit Policy Manual*, chapter 15, sections 220 and 230. This section, which regulates the qualifications of physical therapy assistants who provide services to Medicare beneficiaries, reads:

> A qualified physical therapy assistant... is someone who is licensed by the state in which practicing, and:
> - Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or
> - Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that **these determinations of proficiency do not apply with respect to persons licensed by a State or seeking initial qualifications after December 31, 1977.** *(emphasis added)*

Though the heading for this section of the benefit manual applies explicitly to rehabilitation services furnished in an outpatient setting, in prior communication (Change Request 5405/Transmittal 65), CMS sought to expand this definition to therapy staff providing Part A hospital based therapy services.

CHA is very appreciative of the responsiveness of CMS to the concerns raised by Change Request 5405/Transmittal 65, as evidenced by the proposals outlined in the current proposed physician payment rule.

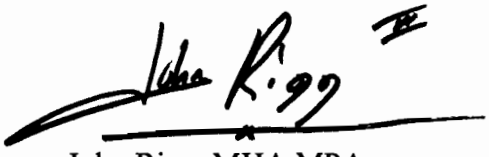
CHA strongly supports CMS' proposed change to recognize practicing physical therapists, physical therapy assistants, occupational therapists and occupational therapy assistants who have been licensed, certified, registered or otherwise regulated in the state in which they practice before January 1, 2008, provided the practitioner continues to work at least part time and does not have an interruption in clinical practice of more than two years. If CMS does not finalize these regulations, CHA is concerned that California's hospitals and skilled-nursing facilities may experience a high degree of operational disruption as physical therapy assistants who have worked under their state guidelines for their entire career would find themselves suddenly unable to treat Medicare patients.

In the proposed rule, CMS also proposes to recognize "comparable" training programs in addition to programs accredited by the Commission on Accreditation of Physical Therapy Education (CAPTE). CHA supports this change and notes that many of the affected staff in California hold degrees from training programs in foreign countries, or received training through the United States military. The majority of affected physical therapy assistants became certified in California through "challenging" the California state exam after becoming eligible through some combination of college coursework and work experience. In many California hospitals and skilled-nursing facilities, these staff are among the most seasoned therapy personnel.

There are several possible likely outcomes if the proposed rule is not finalized. The state's facilities will be forced either to change terms of employment or terminate employment with the affected staff, or they will create a stratified system where the affected staff would only treat non-Medicare patients. At best, the results would make caring for Medicare patients less efficient and more administratively burdensome; at worst, beneficiaries' access to therapy services would be harmed through diminished access to experienced staff.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions, please contact me at (202) 488-4688 or jrigg@calhospital.org.

Sincerely,



John Rigg, MHA MPA
Vice President, Federal Regulatory Affairs

JR:

733

SMDC
HEALTH SYSTEM

MEMO

To: CMS

From: Claire Smith, RHIA

Date: Friday, August 31, 2007

Re: CMS-1385-P
Document ID: CMS-2007-0118-001
CORF Issues

To Whom It May Concern:

This memorandum is in response to the recently published Federal Register, dated July 12, 2007, proposed rule changes for a Comprehensive Outpatient Rehabilitation Facility (CORF) beginning in Part K, page 38171.

Through the last year and a half we have experienced Medicare coverage changes, which created havoc with our CORF provider services. It appeared that rule changes were made, but the scope and intent of these changes were not published. Therefore, it has been difficult to ascertain the direction CMS was going with CORF services. We were particularly interested to read the proposed rule of July 12th to see what the changes were to be. Here are our responses to the proposed rule.

The Proposed Rule states in #3 Physician services (Sec. 410100(a):

- **A.** "We are proposing to revise Sec 410.100(a) to clarify that only those physician services required and provided by the CORF facility physician that are administrative in nature are considered CORF services, whereas diagnostic and therapeutic services provided by a physician to CORF patients are considered physician services under section 1861(q) of that Act".

  - We found there was little information on the scope and intent of the physician diagnostic services for changes throughout the past year. After numerous calls, our Carrier told us of the connection between the physician diagnostic services and psychological and neuropsychological testing. This change seemed unusual to us since the Medicare Benefit Policy Manual, Chapter 12 states the required services includes diagnostic services as well as therapeutic and restorative services to outpatients, etc. (Medicare Benefit Policy Manual, Chap.12, Section 20.1).

SMDC
HEALTH SYSTEM

Psychological testing and neuropsychological testing services are important elements in the diagnostic evaluation that determines the patients psychological issues related to their medical problems and are not typical physician services. . The psychological testing *is* an important element of the "Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility." (July 12th Proposed Rule Section K, #5. Social and Psychological Services)

- Traditionally, our master's level psychologists have provided their own psychological testing for their CORF patients, and our PhD level psychologist has performed the neuropsychological testing within the CORF.

- **B.** "Physician bills the carrier in the same manner as if the services were provided in the physician office setting and notes the CORF as the place of service." (Federal Register Proposed Rule #3 Physician Services (Sec. 410.100(a).

  - B. Our carrier does *not* recognize the CORF place of service "62" for psychological and neuropsychological diagnostic services. Therefore we are *not able to* bill Part B for our psychological testing or neuropsychological testing from our CORF site. These services will need to be moved to one of our clinics.

Summary:

Historically, psychologists have always performed psychological testing services within the CORF. Therefore it made sense to bill from the CORF. Our patients have experienced positive psychological care along with their physical, occupational, and speech therapies. This new requirement to place these diagnostic testing services under Part B to a clinical facility is inefficient, inconvenient and disrupts the continuity of patient care. We would like to see psychological testing services remain a billable service within a CORF.

Respectfully submitted by:

Claire Smith, RHIA
Payor & Provider Research Analyst
St. Mary's/Duluth Clinic
400 E. 3rd Street
Duluth, Minnesota 55805
Csmith1@smdc.org

SMDC
HEALTH SYSTEM

(218) 786-6309

1234

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August 30, 2007

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

Re: CMS-1385-P: "Geographical Price Cost Indices"

Dear Mr. Kuhn:

This letter serves as our comments on the "Geographical Price Cost Indices" section of the Proposed Rule (CMS-1385-P). Our organization strongly opposes any reductions in Medicare reimbursement for ambulance service providers that would have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The Proposed Rule would unfortunately cause that exact effect in areas where providers would receive lower reimbursement as a result of the updated Geographical Price Cost Index (GPC) figures.

While we recognize the statutory requirement for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled "Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly" (GAO-07-383) which determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services particularly in super rural areas. We believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affected by the changes in the GPCI. We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers while ensuring that those providers who would benefit from the changes receive the proposed increases that are desperately needed.

Thank you for your consideration of these comments.

Sincerely,

William McCarthy
President/CEO

486 Gus Hipp Boulevard
Rockledge, FL 32955
Visit us at: www.coastalhealth.org

Administration: *(321) 633-7050*
Communications: *(321) 631-1448*
Fax: *(321) 632-3005*

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Taney County Ambulance District

2003 Missouri State EMS Service of the Year

Mailing: P.O. Box 460 Branson, MO 65615-0460
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Business: (417) 334-6586 Fax: (417) 337-5519
EMERGENCY: 9-1-1

August 30, 2007

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

Re: CMS-1385-P: "Geographical Price Cost Indices"

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Thank you for your consideration of these comments

Sincerely,

Melissa Stiffler
Office Manager
Taney County Ambulance District

August 30, 2007.

The business is located in New Jersey.

I own a business that rents to hospitals, surgery centers etc. laser equipment in the urology field. We charge on a per case basis, supplying the laser, a certified tech. to run the equipment, various disposables needed for the case etc. It is really a turn key operation. We have some state of the art lasers that were just released a year ago for the treatment of BPH. These are newer technology which shortens the procedure time, gives improved clinical results to the patient, and has other benefits as well over the older laser technology. We find ourselves sometimes presenting this new technology to a doctor and his first question is, "what is in it for me?" We have situations, including Northern Virginia, where a doctor refuses to order the device to be brought into a hospital because he has no ownership interest so he does not tell his patient about this option and uses older technology on his patient. Mind you, the hospital has no problem bringing the newer equipment in, if the doctor would just ask for it. Since it is on a rental basis, there is no huge capital outlay. This doctor ownership can color a doctor's mind as well as shade his judgment when it comes to what he uses in his office, since that is a lump sum versus his smaller physicians fee with procedures done at hospitals. All of this adds up to the patient losing out and CMS paying more and getting less. It is time for the doctors to go back to the practice of medicine and stop their world revolving around dividend checks.

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August 27, 2007

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

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

Dear Mr. Weems:

I recently broke my shoulder and the surgeon had to replace the ball with a titanium one. While in the hospital, I contracted a staph infection and required a second surgery within three weeks time. As a result of these surgeries being so close together, my therapy was delayed and thus I am having a much more difficult time regaining the use of my right arm and shoulder.

Since a therapy unit was located down the hall from the surgeon's office and I thought I would receive special care by utilizing their services and I am extremely disappointed that I chose to do so after spending the first four weeks of therapy with them. I do not believe they took a personal interest in me and my health needs. Also, I am not sure that there was much communication between the therapist and my surgeon to insure that I was receiving the best care possible.

Therefore, I switched to Fernandez, Scaia, and Renner where I have been given excellent treatment by the entire staff. They never rush my therapy, and are always monitoring each of the movements I am required to do in order to be able to use my right arm and shoulder, once again. I am extremely grateful for their care and concern for my welfare.

Thank you.

Sincerely,

Mrs. Laura G. Mottice
2555 Trillium Circle NE
Massillon, OH 44646

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

Regarding: Self referral issues, Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems,

My name is Bonnie M. Black, LPTA, CWT, 2744 Coffee Rd, Lynchburg, VA 24503, bonnie.black@racva.com .

I am writing to express my concerns regarding the self-referral issues that are coming up for review in 2008. Self referral by physicians leads to the potential for abuse by physicians owning their own Physical Therapy practices and affecting their profitability. These "in-house ancillary services" give the physicians an unfair advantage in that in the State of Virginia we work from physician referrals for Physical Therapy. There is limited direct access but it also requires that a patient see a physician within a given time frame. We have had numerous patients express their concerns that they are not free to go to the PT of their choice.
I am asking that you remove Physical Therapy as a designated health service under the "in-house ancillary" exception to the Federal physician self referral laws.

Thank you for serving the best interests of the patients and the profession of Physical Therapy in this matter by removing Physical Therapy as a designated health service under the "in-house ancillary" exception to the Federal physician self referral laws.

Sincerely,

Bonnie M. Black, LPTA, CWT

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REHAB ASSOCIATES
OF CENTRAL VIRGINIA

September 30, 2007

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Lynchburg, VA 24501
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Hurt Practice
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P:434.324.9750
F:434.324.9796

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

Reference: Physican Self-Referral Issues

Dear Mr. Weems,

My name is Connie Slusher. I graduated in 2001 from the College of Health Science Physical Therapy Assistant Program. I am employed by Rehab Associates of Central Virginia, Lynchburg, Virginia and am a member of the APTA.

I am writing to express my concerns for the proposed July 12 physician fee schedule rule relating to physician self-referral and "in-office ancillary services" exception.

The proposed rule creates the opportunity for physicians to refer patients to their physician owned practices resulting in their own financial gain. This rule will open the door for abuse because the physicians have an investment in their practices and will refer their patients there for physical therapy. Thus, resulting in over utilization of those services solely for their profit.

In regards to the patients, it is not a matter of convenience to receive therapy from a physician-owned facility. It should be a matter of choice. I feel this rule creates potential for patients to feel obligated to the physicians and lose their freedom to choose.

Thank you, Mr. Weems, for your attention to my concerns.

Sincerely,

Connie N. Slusher, LPTA

Connie N. Slusher
Licenced Physical Therapy Assistant

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REHAB ASSOCIATES
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8/27/2007

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

RE: Physician Self-Referral Issues

Dear Mr. Weems,

My name is Joe Spagnolo. I am a licensed physical therapist practicing in the state of Virginia for the past 10 years. I am currently working on my doctoral degree at the University of Saint Augustine and I am certified as manual therapist through the university and I am also a certified orthopedic specialist through the American Physical Therapy Association.

I am writing to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue regarding physician self-referral and the "in-office ancillary services" exception. I am asking CMS to seriously consider the removal of physical therapy as designated health service permissible under the in-office ancillary exception of the federal physician self-referral laws. The potential for fraud and abuse in a physician owned physical therapy practice is apparent. With the elimination of physical therapy as a DHS under the in-office ancillary services exception, the risk of over utilization of physical therapy services under a referral for profit system would greatly be reduced. It appears that physicians are supporting this arrangement as a way that they can directly supervise physical therapy services. However, more and more physician owned physical therapy practices are using reassignment of benefits laws to collect payment and avoid "incident-to" requirements. In addition, with Medicare guidelines requiring a physician referral for physical therapy treatment, obviously the potential for a monopoly, if you will, in regards to the physical therapy care of those patients exists.

REHAB ASSOCIATES
OF CENTRAL VIRGINIA

Thank you for taking the time to consider these comments.

Sincerely,

Joseph W. Spagnolo MSPT, MTC, OCS
Site Director, Co-Owner
Forest Practice - RACV

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INTEGRITY PHYSICAL THERAPY

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(260) 482-7712 FAX

5050 North Clinton Street
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(260) 471-4272 FAX

7563 West Jefferson Boulevard
Fort Wayne, Indiana 46804
(260) 432-2668
(260) 436-2976 FAX

August 30, 2007

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

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

Dear Mr. Weems,

I am a registered nurse and have practiced in the Midwest for 30 years. My first year was spent as a firefighter / paramedic for a paid fire department. The next 17 years were in a large acute care hospital where I worked in the Emergency Room, Cardiac Catheterization, Endoscopy, and Preadmission Testing. For the next 3 years, I worked in a referral-based Rehabilitation Hospital. I deviated a bit from my medical career and spent 2 years in a Steel Mill, until I returned 7 years ago to an Outpatient Physical Therapy practice, where I serve as practice manager. During this time I have seen a lot of changes in health care.

One major downfall occurring is physician ownership of virtually every ancillary service of medicine. They are partners in ownership with manufacturers of orthopaedic implants and co-owners of specialty hospitals Now, despite Peter Stark's efforts, lobbyists have been able to convince CMS that it is OK for physicians to own, operate, and make a profit from physical therapy. I emphatically disagree. What is interesting about this is the fact that I am a nurse, and not a therapist.

Prior to my most recent employment, my knowledge about physical therapy was pretty miniscule – until I became a patient. Had I not received adequate physical therapy in 1998 for a back problem (bulging disc with pain in the back and leg) I would have most assuredly had surgery. At one time, surgery was thought to be the cure-all, and in some medical disciplines still is the first choice to correct problems. Time and again, it has been proven wrong.

At one time, our state and others required CONs (Certificates of Need) if anyone wanted to duplicate a medical service which was already provided in the area. Unfortunately, those disappeared, but the void was soon filled by the Stark Legislation. As you well know, the Stark Legislation has lost its punch.

In 1986, while running the Cardiac Cath Lab at the hospital, I oversaw the creation of a second lab at a cost of $1.2 million – the physicians mandated equipment and ancillary supplies. Within the year, they built their own catheterization lab in their office a block

away from the hospital and took a large portion of the elective business away from the hospital. This was on the heels of another 'take-away' in the form of a large EKG system that allowed them to provided treadmill services in the office. I witnessed it again as ophthalmology demanded the purchase of therapeutic lasers for eye conditions, then duplicated the systems in their offices and took the business with them.

I would like to provide the following arguments against POPTs:

- I believe we have some anti-monopoly laws in the U.S. Isn't total control of patients by one faction of the total medical community considered a monopoly? Think about it – a physician may already determine which hospital you go to, tests and lab work performed, surgery performed and now what therapy is performed. They even have ownership in convalescent homes in which they are medical directors

- I must also cite the OIG Report to Leslie Norwalk, dated May 1, 2006: This report outlines the problems found in POPTs in 2002.

  'Based on a simple random sample of 70 physical therapy line items billed by physicians and rendered in the first 6 months of 2002, we found that 91 percent of physical therapy billed by physicians and
  allowed by Medicare during the first 6 months of 2002 did not meet program requirements, resulting in $136 million in improper payments.'

  'The total allowed for physical therapy claims has increased from $353 million in 2002 to $509 million in 2004, and the number of physicians who billed for more than $1 million in physical therapy has more than doubled, from 15 to 38 in the same 2-year period.'

- Current rules allow physicians an unlimited license to practice medicine. This allows them to place personnel in their physician-owned physical therapy practices who are not licensed to practice physical therapy. This provides for the potential to provide substandard care to the patient. Allow me to illustrate:

  Imagine that you have had neck pain and go to see your doctor, an orthopaedic surgeon, who has his own MRI which he orders for your problem. HE interprets the film and orders therapy at his POPT. Because he uses a tech who doesn't understand the concepts of therapy, you don't get better. Of course the next step is cervical fusion – an expensive option. A few years later, you have another fusion because the first problem has now transferred to the segment above the fused one because it was never properly rehabed

Physical therapists have generally tried to stop POPTs, but lack the financial resources to fight the AMA and other physician groups (David vs. Goliath). Now out of frustration and financial need, some therapists are defecting to POPTs in order to provide for their families financially and pay back the student loans (most PT schools now require doctoral programs).

With these thoughts in mind, I sincerely hope strong consideration will be given to removing Physical Therapy Services from the 'permitted services' under the 'in-office ancillary exception' currently in effect. You, in your position, are 'David' and the physician special-interest groups are 'Goliath'. It is time to act.

For obvious reasons, please keep my letter CONFIDENTIAL between you and me. Feel free to contact me at (260) 483-2422.

Respectfully Yours,

James H. Dougal, RN, BS

Metro
HAND REHABILITATION
Specialists in Hand & Upper Extremity

August 20, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-801

Re: Physician Office PT/OT Services

Dear Mr. Weems,

I am writing this letter to express my concern regarding the in-office ancillary service arrangements that have impacted the delivery of quality Physical and Occupational Therapy.

Over the past decade, I have observed a dramatic increase in the formation of corporations in which physicians own interest in physical therapy/occupational practices. In the current loophole that exists with the "in-office ancillary services" exception, this allows physicians to make money from their referrals to their own therapists.....this is **not** viewed as a *kickback....**why**?* They are directly benefiting financially from their referral which then encourages them to over-utilize. The more they send their patients to their clinic, the more money they make from their referral....why is this considered legal?

I am partners in three clinics in the Oklahoma City area that employ Certified Hand Therapists who are physical and occupational therapists with specialized training and certification through national examination in the field of hand therapy. Physicians that own their own therapy clinics often forego sending their upper extremity patients to Certified Hand Therapists to send them to their clinics without specialists. This is not in the best interest of the patient, only the physician who is making money from their own referral...***why*** is this **not** considered a conflict?

I recently had an orthopaedic surgeon tell me he would refer his patient to his therapists in downtown Oklahoma City rather than allow them to be seen in Edmond, the location of my clinic which is a suburb of Oklahoma City. When I inquired as to whether he was unhappy with our services, he responded "no, we were the best in town, but every time he sent us a patient, that was money out of his pocket". This requires his patients to drive 20 miles to receive care when they

can receive care within 2 miles of where they live. When a patient asks if they can receive care closer to home, the physician presents it in a manner that they work together as a team and he can keep a closer eye on their progress. The teamwork in the process is between the physician and his accountant...***why*** is this considered ethical behavior in the referral process.

Finally, I had another orthopaedic surgeon tell me recently he was puzzled by this loophole. He summed it up better than I have ever heard it done....he said he did not understand....if I approached a physician and offered $25 for every referral he made to me, it would be called a kickback and fraud because the physician would be receiving financial benefit from his referral. I could lose my license for doing so and receive huge fines. BUT, if a physician sends a patient to his own clinic he receives the full financial benefit of his referral and he is considered to be a good business man. Obviously, this particular physician saw it as unethical for physicians to direct their patients to their own therapy practices. ***Why*** does this loophole exist to allow such unethical referral practices?

I have practiced physical therapy for over 30 years. Seeing the change of my profession as it is impacted by the physician owned practices makes me fear for the future of my profession. It is not considered ethical by my professional organization for therapists to practice in physician owned practices, but often therapists are placed in the situation in which they want security in their jobs.....what is more secure than working for the physician who drives the referrals to your clinic? Some states are now beginning to mandate through their practice acts that therapists not be allowed to maintain their license if they practice in physician owned practices. That is how serious the problem is viewed. I would love to see this as a nationwide edict, but therapists have little money for lobbying in comparison to large medical lobbying groups who do not want to see this practice changed. I have been told that state medical associations have been told to block any changes in therapy practice acts that come into their states with such license restrictions. The issue revolves totally around physicians making money from their referrals. It is common for presentations to be made at orthopaedic meetings that promote physician owned therapy practices as a means of passive income for the physicians.

Please change this practice. As therapists we are being increasingly monitored for proper behavior, but the fox is coming in the front door without any chicken wire to stop them. It is time to stop this stop this. If CMS will make changes in the exception, then other payors will be quick to follow. I would be happy to

Metro
HAND REHABILITATION
Specialists in Hand & Upper Extremity

discuss this with you if you have any questions. Please call my office at (405) 359-7575. I would look forward to the opportunity to speak with you.

Sincerely,

Patricia A. Taylor, PT, CHT

Patricia A. Taylor, PT, CHT

☐ **NW Oklahoma City Location**
3613 NW 56th Street, Suite 202
Oklahoma City, OK 73112
Tel 405.948.8686 | Fax 405.948.8603

☐ **Edmond Location**
Building 300 | 501 E. 15th Street, Suite B
Edmond, OK 73013
Tel 405.359.7575 | Fax 405.359.7589

☐ **SW Oklahoma City Location**
9356 S. Western, Suite C
Oklahoma City, OK 73139
Tel 405.691.5742 | Fax 405.691.5862

743

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

Mr. Weems,

The purpose of my letter is regarding **Physician Self-Referral Issues**. I am a Physical Therapist currently working in a privately owned outpatient facility.

I wanted to touch base with you on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. These new rules open the door for the potential of considerable physician abuse of self-referral of physical therapy services. I've heard some refer to it as *just a little healthy competition.* This tactic ruins the autonomy of our practice. In addition, there is the concern that these physicians will inappropriately mislead their patients into believing that it is necessary for them to be treated at the physician's office and not inform them that they have the choice of which clinic they choose to go to.

The clinic that I work at is located in a small town with limited access to therapy facilities. A number of our patients greatly appreciate the close proximity of our clinic to their homes. Unfortunately, a number of physicians have not made it clear to a number of patients that they are free to go to any clinic they choose. As a result a number of patients have had to drive at least 30-60 minutes to either Kalamazoo or Grand Rapids for treatment, and some end up not going to therapy at all because of this. Not only is the long drive to physician owned physical therapy clinics inconvenient, it is often unsafe for a number of our injured and elderly patients.

Please consider eliminating Physical Therapy as a designated health service furnished under the in-office ancillary services exception. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, the Centers for Medicare & Medicaid Services would reduce a significant amount of programmatic abuse, over-utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

Thank you for your consideration.

Regards,

Michael Brossman, MSPT

744

Hazel Hawkins
MEMORIAL HOSPITAL
CONVALESCENT HOSPITAL
HOME HEALTH AGENCY

San Benito Health Care District
A Public Agency
911 Sunset Drive
Hollister, CA 95023-5695
(831) 637-5711

August 31, 2007

RE: CMS Rule for 2008 Physician Fee Schedule

While San Benito County is a beautiful area with outstanding weather and an attractive location, it is one of the least desirable places in California for physicians to practice medicine. Housing and other cost of living indicators are well above California averages. Medicare classifies this area as "rural" with associated lower reimbursements than "urban" area physicians receive, and Blue Cross, the other major payor here, recently slashed twenty percent off its fee schedule to physicians and will pay less than Medicare rates for office visits.

A physician in Gilroy, in Santa Clara County, 11 miles away, will on average, receive from Medicare between fifteen and twenty percent higher reimbursement for the same services than a physician in San Benito County.

We may soon be surrounded by urban classified counties – Santa Clara, Santa Cruz, and Monterey.

As CEO of the only hospital in San Benito County, I desperately am seeking your assistance with stabilizing sufficient physician coverage in this area. This can be accomplished by adopting the GAO June 2007 Report; July 12 Federal Register GAO – 07-466 "Geographic Areas Used to Adjust Physician Payments for Variations Practice Costs Should be Revised". Specific areas of the report for adoption include proposed rules on pages 38138-38143, 38234–39364, 39365-66, and 39367-68. Option 3 sets forth the most reasonable appropriate designation for our area.

Thank you for your consideration.

Sincerely,

Ken Underwood
Chief Executive Officer

August 27, 2007

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

Subject: **Tempting Physician Self-Referral Issues**

Dear Mr. Kerry Weems,

I am writing to you to express my **strong support** of the efforts **to remove physical, occupational and speech therapy from the designated health service exception.** As an employee of a physical therapist owned therapy clinic, I urge you to take a closer look at this issue. I believe that removing the exception, the way that many other ancillary services have been, will help potential therapy patients to receive the best care, from the right place, only when it is needed. The current exception makes the likelihood for abuse is too great.

As you know, checks and balances are an essential part of every facet of governmental affairs. When a physician is able to own their office, see a patient, and refer them to a therapy clinic they own, the checks and balances are gone. Regardless of the quality of therapy at the physician-owned therapy clinic, the physician will refer their patients to it. This develops the potential for patients to go to a sub par therapy clinic that does not make them any better. It would be much like a physician profiting from the prescriptions they write- **there is too much of a profit incentive.**

Thank you for your time and consideration in this matter.

Danielle Baker

Danielle Baker

746

39202

August 30, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare & Medicaid Services
U.S. Dept of Health & Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Subject: Medicare Program: Proposed Revision to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY2008; Proposed Rule

Dear Mr. Weems:

I am contacting you regarding the Physician Self-Referral Issues, specifically the July 12, 2008 physician fee schedule rules regarding self-referral and "in-office ancillary services."

I believe that physicians who own Physical Therapy practices are inherently incentivized (if not coerced) to refer excessively to their own physical therapy practice.

My partner and I have operated a private physical therapy practice in the Mid-Mississippi area since 1985. We have worked and marketed the Mid- Mississippi area for over 20 years, often calling on physicians who traditionally do not utilize physical therapy. They become regular P.T. referrers once they invest in a P.T. practice.

A large orthopaedic practice has been our main referral source during these 22 years. In 2006 they opened their own P.T. practice in a building addition designed to fit the Stark II "loopholes". We refused to become their employees and offered to lease their P.T. space for fair market value. (We are located next door to them).

Their ownership of a P.T. practice was not required to provide patient convenience or any supervision on their part. As we were their initial choice for employees, obviously they were satisfied with our services.

Please consider the American Physical Therapy Association's position to eliminate any abusive and for profit financial arrangements as allowed by the existing Stark Law. I strongly urge you to remove Physical Therapy as a designated health service (DHS)

permissible under the in-office ancillary exception of the federal physician self-referral laws.

Thank you very much for your consideration.

Sincerely,

Mississippi Private Practice PT 39202

PTSIR

PHYSICAL THERAPY AND SPORTS INJURY REHABILITATION

August 23, 2007

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

Subject: Physician Self-Referral issues
Medicare program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and other part B payment policies for CY 2008; proposed rule
Dear Mr. Weems:

My name is James LoPiccolo and I am a licensed physical therapist practicing in Lansing, Illinois. I have been working in private practice outpatient orthopedic physical therapy for the past 6 years. I work for a company that has been in business for 30 years and is owned and operated by physical therapists.

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

Physician-owned physical therapy arrangements have had a negative impact on my patients and my practice. Over the years, our company has formed good working relationships with local orthopedic surgeons. Patients were referred to one of our 5 locations based on convenience for the patient. We have found that physicians are establishing their own physical therapy services in their offices. Patients have had to drive further distances to get physical therapy and often times have to wait to start their therapy because there are no available appointments. At our facilities we schedule new patients within 24-48 hours, with documentation if that standard is not met. The result is often patients starting therapy later and missing appointments because of increased commute times, making compliance more difficult. Referrals have decreased and in some cases, stopped completely from referral sources that we have worked with for decades. Competition in outpatient physical therapy is at an all-time high, and the physician-owned physical therapy situations have made it harder for private clinics to remain viable.
The "in-office ancillary services" exception has created a loophole that has resulted in the expansion of physician-owned arrangements that provide physical therapy services. If this loophole could be closed, patients would benefit from highly skilled, competitive physical therapists in the market that are conveniently located near them.

Thank you for your consideration of my comments,
Sincerely,

James LoPiccolo MPT, ATC

2 RIVER PLACE ▪ SUITE B ▪ LANSING, ILLINOIS 60438 ▪ PHONE (708) 895-9860 ▪ FAX (708) 895-9866

748

CLAUSEN CHIROPRACTIC

Anna M. Clausen, D.C.
217 Gilman St
P.O. Box 520
Sheffield, IA 50475
#641-892-4008

08-27-07

Dear Shirley,

I am writing to you because you have benefits under Medicare, Medicaid, or both. I have just received notification from the Iowa Chiropractic Society that the Centers for Medicare and Medicaid Services are attempting to adopt a new ruling that will exclude some x-ray benefits. Currently, Medicare and Medicaid will pay for x-rays taken at a hospital or clinic when ordered by a Doctor of Chiropractic. The new ruling states that they will no longer pay for these services. If you need x-rays, you would need to be referred to another provider (orthopedist, rheumatologist, etc) for another or duplicate examination before being referred to a radiologist for x-rays or you would pay for them out of your own pocket.

In an attempt to override this new ruling that will eliminate current x-ray benefits, I urge you to read, sign, and mail the enclosed letter in the stamped, addressed envelope I have included. **The letter must reach Medicare and Medicaid no later than Friday Aug. 31st.**

If you have any questions, please call us at the office at #641-892-4008. Thank you for your time.

Sincerely,

Anna M. Clausen, DC

Urology birmingham
CENTERS OF ALABAMA, P.C.

(205) 930-0920 800-452-1464

3485 Independence Drive
Homewood, AL 35209

7419

August 27, 2007

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

Dear Mr. Kuhn:

I am a practicing Urologist in Birmingham, Alabama, with Urology Centers of Alabama, P.C. There are 14 Urologists in this group and we have a large Medicare patient population. In order to provide the most up-to-date and quality controlled services to our patients, both Medicare and non-Medicare, we have developed in-office ancillary services. These services include pathologic evaluation of biopsy material, radiation therapy for urologic cancers, urine cultures and PSA levels. We also have the ability to provide microwave thermotherapy for obstructive BPH symptoms.

The proposed changes to the physician fee schedule rules that were published on July 12, 2007, that concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules, will have a serious impact on the way that I and my partners are able to practice medicine and, more importantly, will have a detrimental effect on the quality of care available to my patients.

I am also associated with a large group of non-urologic physicians who have developed a joint venture with a local hospital in order to keep this hospital from going bankrupt. This is a hospital in an area that services a large Medicare/Medicaid population and patients who cannot afford to travel very far for their medical care. This joint venture has allowed this hospital to remain in service and also to continue to provide employment to a large number of employees.

I feel strongly that the regulations on physician joint ventures and our ability to provide in-office ancillary services greatly improve our ability to provide state of the art and quality care for our patients. I firmly believe that the Medicare program should be protected from fraud and abuse. However, the current drastic changes to the Stark regulations and the reassignment and purchased diagnostic test rules should be revised only to prohibit those specific arrangements that are not beneficial to quality patient care.

I very much appreciate your consideration of these thoughts.

Sincerely,

Rodney Dennis MD

Rodney L. Dennis, M.D.

RLD/br
Cc: Mr. David Sorrells, Administrator
Urology Centers of Alabama, P.C.

750

Physician Self-Referral Issues

August 28th, 2007

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

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

Dear Mr. Weems:

I would like to take this opportunity to voice my opposition to the practice of physician self-referral for physical therapy. I have been practicing as a physical therapist in the Birmingham area for the past six years. I am currently self-employed and direct an outpatient orthopedic clinic. It has been difficult to obtain referrals over the past year due to the prevalence of physician owned physical therapy clinics. Some of my colleagues have had to close their practices secondary to the lack of referrals. As physical therapists in the state of Alabama, we can only evaluate and treat patients by referral. In other words, we are dependent on physician referrals. The practice of self-referral completely undermines this system.

I have personally had patients who wanted to see me for their therapy, but were forced to go elsewhere by their physician. In some cases, patients are forced to travel up to 60 miles to have therapy. Imagine a patient driving 60 miles to be treated for low back pain because he was not told he could go where he wanted to for physical therapy. Patients should be allowed to receive care in the most convenient location, by the practitioner of their choice. Instead, they are being pressured to go to therapy where their physician has a financial incentive.

CMS should eliminate physical therapy as a designated health service under the in-office ancillary services exception. If the current practice of self-referral is continued, our patients will suffer and the system will most assuredly be abused.

I appreciate your consideration on this very important matter.

Sincerely,

Paul
35080

751

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

29 August 2007

I will like to know is there is any regulation that explain the payment procedure for the anesthesia service. For Puerto Rico hospitals, maybe something in the web or www.

And also like to know if there is and difference between hospital in USA and Puerto Rico for Payment, and also for US Virgin Islands.

This is for an investigation purpose only.

Also maybe there is a difference in pay for a Nurse provider and a Physician provider, also. In the states.

Respecfully

Orlando Rodriguez
P.O. Box 141137
Arecibo, P.R. 00614-1137

752

August 29, 2007

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

Dear Sir;

As a Registered and Licensed Occupational Therapist and Certified Hand Therapist with 25 years of experience, I am writing because of my concern regarding the Physician Self Referral Issue. I strongly urge and back the APTA in the removal of Physical Therapy, Occupational Therapy and Speech Therapy from the designated health service exception that allows physicians to own and refer to their own clinics. I feel that the physician's monetary gains outweigh the patient's best interest and lead to fraudulent practices.

I have personally known patients who had to drive over one hour to attend the physician's owned therapy clinic 2-3 times a week to see "His Therapists" instead of a local clinic with qualified therapists just minutes from their home or work. Not only was this a financial burden but additional time commitment that took valuable time away from their jobs and family. Patients have the right to choose the clinic of their own choice.

Thank you for your continued efforts in keeping fraud at a minimum and supporting OT, PT, and ST in becoming independent or physician practices.

Sincerely,

Debbie Bartrow

Debbie Bartrow OTR/L,CHT
Conway Regional Therapy Center
550 Club Lane, Suite 2
Conway, AR 72034

August 27, 2007

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

Subject: Eliminating PT as a DHS

To Whom It May Concern:

My name is Ramona Deen, and I have been a physical therapist for 10 years. I practice at Conway Regional Medical Center, mostly seeing inpatient, and some outpatient wound care patients. I am writing you to comment on the July 12th proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

As a physical therapist, I feel that allowing PT as a designated health service creates an opportunity for fraud and abuse of those services. The physicians who own a therapy clinic have a financial incentive to recommend PT for their patients. Eliminating PT as a DHS would reduce the chance of fraud and ensure the best and proper referral for PT services, which is what Medicare and Medicaid beneficiaries deserve.

Thank you for your consideration in this matter.

Sincerely,

Ramona Deen, PT
Conway Regional Health System
2302 College Ave
Conway, AR 72034

In regards to: Physician Self-Referral Issues

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

Subject:

Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY2008; Proposed Rule

Dear Mr. Weems:

I have been practicing physical therapist since getting my doctorate degree in May 2005. I have been involved with my professional organization the American Physical Therapy Association since beginning my training five years ago. I am very proud of my profession and of the work that our association does to protect our rights as licensed physical therapists. I would wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

I just recently made a job switch from a corporate outpatient physical provider to a private practice for outpatient orthopedics. In doing so, I had the opportunity to interview with different companies and a POPTS since they growing quickly in the Denver, Colorado region (80230). The particular orthopedic physician group had physical therapy as an "in-office ancillary service" in which they would refer all their patients to unless the patient was educated enough to know they had a choice therapy physical therapy provider. This would in turn allow the doctors to write scripts for therapy 6-8wks for 3 times a week and provide the service in-house in which they would make financial gains on. These services were provided on diagnoses in which over utilized and used as a way to have more financial success. After going through all of my training and learning how health care costs are soaring and learning evidence based techniques to regain our patient's functional independence as quickly and safely as possible this experience was contradictive. My personal beliefs and ethics led me away from this type of setting and into private practice. By being exposed to this type of setting, I am concerned for the patients whom might feel the need to follow their physician's orders and get themselves in a situation where the quality of patient care is not the first priority.

This example I have given is where the potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, over utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

I would like to thank your for time and consideration of my comments.

Kim Weber, M.D.
1118 Greenoak Ct.
Springfield, Ohio 45503-6200

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

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

Dear Ms. Norwalk:

I would like to express my support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. Thank you for both recognizing the gross undervaluation of anesthesia services, and taking steps necessary to address this complicated issue.

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

Kim Weber, MD

Kim Weber, M.D.

I would like to comment in the Stark Rule, and referral for profit. I am in practice in Patchogue, NY since May of 2005. It's been very difficult to get MD's to refer to me on a regular basis. This is mostly due to the big orthopedic practices in my area have their own PT offices. I have done all the usual things to increase my referral base, from doing expensive lunches, to mailing thousands of postcards to MD's. At the end of 2005, one of the orthopedic offices nearby closed their PT office. I then started getting some regular referrals. At the end of 2006, they moved their offices, and reopened their PT office. I have not gotten one referral in 2007. I would also like to comment on one of my patients. This man is a school teacher, and has worked for a doctor as a PT for several years. He states he's done ultrasound, electrical stimulation, cervical stretching and traction. When I asked him if he does a vertebral artery test before stretching a person's neck, he said "what's that"? He also told me that the doctor would see the patient and send them in to see him. He would ask the patient what they wanted treated that day and they would tell him what hurt, and he would apply a hot pack, e-stim, and send them home. He was very surprised when in the course of his treatment in my office, that he had to do exercise after his modalities. He said "no one in the office I worked at ever did any exercise". This is some of the quality of care people are receiving when treated at a doctor's office. My referral base has increased only due to my patients recommending me. It's becoming very difficult to keep my doors open at this rate. Everyone says to be patient and things will pick up. I want to continue to help people in my office, and I'm sure if doctors could not refer to themselves, things would be better for all therapists involved. I hope the federal government closes the loophole in the Stark physician self-referral law, and protects physical therapy services as Congress originally intended.

Zip Code 11772

GALILEO SURGERY CENTER

757

1001 Foothill Blvd. ** P.O. Box 5458 ** San Luis Obispo, CA 93403
(805) 782-8222 ** FAX (805) 782-8220

August 29, 2007

Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Implantation of Spinal Neurostimulators

I am writing to express my concern over the proposed changes to CMS' OPPS and ASC reimbursement methodologies. In particular, my concern over the proposed rule which I believe will limit patient access to a beneficial technology.

CMS has proposed the elimination of a separate APC for rechargeable neurostimulators, which will directly impact hospital financial considerations, and the corresponding ASC reimbursement methodology. For the past two years, CMS has allowed reimbursement for this new technology, the rechargeable spinal cord stimulator. The additional reimbursement has been available either through a new technology pass-through in the hospital setting, or via the DMEPOS fee schedule in the ASC. The proposed rule to eliminate the pas-through, and group rechargeable stimulators and non-rechargeable neurostimulators into APC 0222, despite a documented significant cost differential, will change the decision process from a clinical decision to an economic decision process.

As a provider in a community in which a hospital has made a financial decision to eliminate this beneficial therapy, I am very concerned that the alternative site of service ASC will be forced to eliminate the therapy as well. The decision will be a direct result of CMS decision to only allow one APC for both rechargeable and non-rechargeable stimulators. Medicare and private payer patients will no longer have access to this valuable therapy.

We recommend that CMS create separate APC's for the rechargeable and non-rechargeable neurostimulators on the basis of the substantial cost differential. We believe that there is a substantial clinical improvement provided by rechargeable neurostimulators, and the therapy is worthy, clinically effective therapy.

Thank you for your consideration.

Cordially,

Boris Pilch, M.D.
BP/cm

August 28, 2007

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

Subject: **Physician Therapy Referrals**

Dear Mr. Kerry Weems,

I am writing in response to the concerns that CMS has on abuse of self referrals to physician owned physical therapy clinics. **I strongly urge you to support the APTA's position that supports the removal of physical therapy from the designated health service exception that allows physicians to own and refer to their own clinics.**

I feel that **patients have the right to choose the clinic of their choice**. I believe physician owned clinics refer to themselves for monetary gains at the expense of the patient and do not have the patient's best interest in mind.

Thank you for your continued efforts in keeping **fraud to a minimum** and supporting physical therapy in becoming independent of physician practices.

Sincerely,

Don Clark, PTA
Conway Regional Therapy Center- Greenbrier
Greenbrier, AR

759

CONWAY THERAPY SERVICES

1500 Museum, Suite #104 • Conway, Arkansas 72032
(501) 329-3804 • 800-737-9736

To Kerry N Weems
Administrator – Designate
Centers for Medicare and Medicaid Services

Dear Mr. Weems

I wish to comment on the July 12 proposed 2008 physician fee schedule, specifically physician self referral and the " in-office ancillary services".

1. Abuse is a potential when physicians can refer Medicare beneficiaries to a facility to which they own.
2. Most all patients will go to where their physicians send them without question.
3. I know of patients who have driven 30 or more miles to receive therapy in their physician's office and actually pass by another Physical Therapy center within several blocks of their home.
4. I have had physicians tell me that when they open their own facility that all there referral will be to that facility.
5. It is not more convenient to be seen in the physician's office because of the repetitive nature of Physical Therapy.
6. The Quality of the therapy treatment is not superior because it is performed in a physician's office and physician supervision is not required.
7. I know of a Therapist in Arkansas who's practice decreased by 80% when physicians opened their own therapy center in his community, patients didn't get a choice.
8. I have been in practice as a Physical Therapist since 1971 in a small community and I know of numerous patient s have been told that the only place they should receive Physical Therapy is in the referring physicians office.
9. I believe allowing this practice of physician referral to their own facility opens the door for abuse. Patients are seen for a longer period of time and it cost the system more.

Thank you for considering my comments

Sincerely

Greg Wren PT

160

CONWAY REGIONAL
THERAPY CENTER

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

August 29, 2007

Mr. Weems,

I am writing to you as a concerned physical therapist regarding the regulation of physician owned physical therapy practices. In situations such as these, the potential for fraud and abuse exists. Patients' personal choice for health care provider is taken away by these physicians and financial incentives may be gained by them. Often it has been reported to me by my patients that services were billed as physical therapy and not provided by a licensed physical therapist. These situations do not allow for a standard of care and discredit the licensed physical therapist and therapist assistant as the sole providers of care for physical therapy.

In this day and age, physical therapy clinics are readily accessible to patients and communication between various health care providers is enhanced through technology. As a result, it is no more "convenient" for a patient to visit a therapy clinic that is in the physician's office. Test results, progress reports and questions can be shared easily through fax, e-mail, computer server systems and telephone.

Physical therapists have been educated to be the experts in the treatment of movement dysfunctions. It is not necessary for these practitioners to be directly supervised by physicians. In fact, many states do allow for direct access to the physical therapist without a physician referral. In our code of ethics, it is our responsibility to refer to another practitioner if the need arises.

In closing, thank you for your consideration in this matter. I truly feel that allowing physician owned physical therapy practices to continue will be a detriment to the quality of care that is provided to our patients.

Sincerely,

Julie Shock, PT

Julie Shock, PT
Conway Regional Therapy Center Salem

700 SALEM ROAD CONWAY, ARKANSAS 72032 (501) 327 - 9944 PHONE (501) 450 - 9085 FAX

761

Jessica Michelle Iams
1727 Jupiter Avenue
Hilliard, Ohio 43026

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

August 31, 2007

SUBJECT: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule **PHYSICIAN SELF-REFERRAL ISSUES: Comments pertain to the July 12 proposed 2008 physician fee schedule rule**

Dear Mr. Weems:

I am a concerned physical therapist in Ohio writing to urge you to consider removing physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws. These laws, as you know, are in place to protect Medicare beneficiaries from situations where medical decisions are made on the basis of financial interest on the part of the physician or other referring body. Many arguments have been made against self referral. That which is most important to CMS:

> Abuse/over-utilization of Medicare and Medicaid services for the purposes of financial gain= **greater cost**

Physical therapists in private practice will argue that the quality is less in physician owned physical therapy groups. This is due in part to the ability to bill "incident to the physician" and delegate physical therapy care. This billing "incident to the physician" was removed by CMS, but still is allowed by law and therefore is not sanctioned in any other arena, allowing private insurance and cash patients to be treated in this way. As you know, billing "incident to the physician" allows unlicensed persons to provide care that should be provided only by licensed physical therapists, licensed physical therapy assistants, and qualified persons under their supervision following the plan of care written by the physical therapist. In my opinion, the quality is less in physician owned physical therapy clinics due to the type of professionals you will find working in those situations. Physical therapists now hold Master's Degrees and Doctoral Degrees. We are capable of making diagnoses and decisions about our patients within our scope. In the majority of

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Aug. 27, 2007

To whom it may concern:

I am writing to comment on the CMS-1385-P issue. I am a medical rep. and believe that the current arrangement regarding this issue should be changed because:

- I have seen hospitals use "physician-owned" vendors instead of other vendors simply because of the physicians' ownership. The other companies competing for the business had better service, equipment, and pricing than the doc owned group. In the end competition is stifled because a physician's investment is taken into account when deciding a service issue.

- Patients are also losing out because of the current arrangement allowing "physician owned vendors." I have witnessed situations where patients are not able to get the best technology and service available simply because a physician will only use his company he's invested. The patient than suffers because of doctors' financial motivations.

- How should it be legal for doctors to rent from their own company or use their own company's products? Good medicine and the patients' well being should be the only factors that come into play when making medical care decisions. That is unless a hospital has financial issues as well that they need to tend to.

Thank you for your consideration and attention to this issue.

-Eric Lehmann

764

Aug. 27, 2007

To whom it may concern:

I am writing to comment on the CMS-1385-P issue. I am a medical rep. and believe that the current arrangement regarding this issue should be changed because:

- I have seen hospitals use "physician-owned" vendors instead of other vendors simply because of the physicians' ownership. The other companies competing for the business had better service, equipment, and pricing than the doc owned group. In the end competition is stifled because a physician's investment is taken into account when deciding a service issue.

- Patients are also losing out because of the current arrangement allowing "physician owned vendors." I have witnessed situations where patients are not able to get the best technology and service available simply because a physician will only use his company he's invested. The patient than suffers because of doctors' financial motivations.

- How should it be legal for doctors to rent from their own company or use their own company's products? Good medicine and the patients' well being should be the only factors that come into play when making medical care decisions. That is unless a hospital has financial issues as well that they need to tend to.

Thank you for your consideration and attention to this issue.

-Eric Lehmann

765

August 30, 2007

Physician Self-Referral Issues

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

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

Dear Mr. Weems,

I have practiced physical therapy for over 20 years and have owned my own independent outpatient practice for the past 15 years. We have multiple offices in our area and have built a solid reputation in the community over the years. I am writing you anonymously to express my concern with the practice of physician self-referral of physical therapy services. My anonymity is due to my fear of backlash from local physicians.

Two large physician groups in this area have adopted a POPTs (physician owned physical therapy service) approach and it has severely damaged my practice and that of many of my independent colleagues – to the point that many of us may have to sell our practices to survive. Practicing in the area for such a long period has allowed me to get to know many physicians personally. In both cases when these respective groups created a POPTs, I received apologetic calls from physicians that I had worked with for years who candidly told me that it was "just a business decision – it's about the money."

While I will admit that being located in a physician office can help with the communication process between therapist and physician, ownership is certainly not a prerequisite. We had an office located in a physician group office for over a decade and it worked great. Ironically, the reason we no longer operate in this office is because they were one of the physician groups identified above that started a POPTs.

Why does Medicare pay more for physical therapy services provided under a physician's roof? The treatment is exactly the same and in fact, in one of the physician offices noted above is conducted by one of our former therapists. There is no difference.

Allowing physicians to self refer entices over utilization. We have seen scripts written for weeks of PT for patients that we would have discharged after only a few visits. Numerous studies have documented the over utilization and higher costs associated with POPTs.

Recently we received a script from a local POPTs for daily PT for a wrist fracture. The patient had seen us before for another issue but had been told by the POPTs that they would not give

them a script unless they saw *their* therapist. The patient was knowledgeable of their rights and demanded to see us – otherwise they would have just conformed. This situation has happened many times with several patients. How can this not be a restriction of trade?

Patients trust their doctors. When a physician requires a patient to see *their* PT and the patient becomes aware of the monetary connection, it compromises the doctor/patient relationship of trust. It hurts the physician's reputation as well and if allowed to continue could result in the unfortunate stigma that chiropractors developed when rogue practitioners claimed the ability to cure the common cold and other ailments unrelated to the spine.

With higher reimbursement, POPTs are also able to pay higher salaries to PT staff. This is yet another unfair advantage and a double edged sword as independent practices must not only operate on less reimbursement but also pay higher wages to compete with the POPTs for staff.

As a taxpayer, I personally want my government to operate in the most efficient manner possible taking care to manage these assets responsibly. As a governmental agency, I would hope Medicare would consider the physician self-referral laws and eliminate abusive practices of POPTs.

To put it in perspective, just knowing that even though I am writing this letter anonymously it will be posted publicly and I am terrified that there will be a backlash from physicians in my area because of my comments. As medical professionals we should first be concerned with the well being of our patients and not on the financial leverage that we can gain at detriment of another.

Please consider restructuring the physician self-referral laws as the Start Phase III regulations are being reconsidered.

Thank you,

An independent physical therapy practice owner.

766-1

ALABAMA
ORTHOPAEDIC
CLINIC, P.C.

3610 Springhill Memorial Drive N
Mobile, Alabama 36608
Phone: (251) 410-3600
Fax: (251) 410-3700
Toll Free: (888) 878-1999
E-mail: information@alortho.com
www.alortho.com

August 27, 2007

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

Dear Sir:

I am writing to you as a licensed physician in the State of Alabama regarding the proposed revisions to the Medicare Physician Fee Schedule for 2008. While I appreciate the opportunity to review the proposed revisions, I would like to submit the comments listed below.

In regard to the Anti-Markup Provision, CMS' decision to focus on the billing of diagnostic tests of one physician or group where the diagnostic test is performed by someone other than a full time employee is appropriate. CMS' approach of paying the less of the Medicare fee schedule amount, actual charges, or the charges of the physician performing the diagnostic test is inherently reasonable. However, I do request that CMS ensure that the calculation of payment level under the "anti-markup" provision place no new administrative burdens on the billing physician or group.

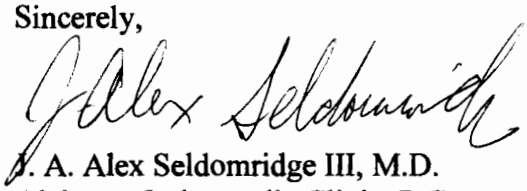
I strongly challenge some the characterizations articulated in the In-Office Ancillary Exception section of the proposed rule. CMS refers to "hundreds of letters from physical therapists and occupational therapists that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices." CMS does not elaborate any further on the propriety or harm of this activity. The advantages of physician owned physical and occupational therapy practices to physicians, therapists and, most importantly, patients are well understood. These practices give patients more places to choose from to get physical therapy services. In some cases, it may be more convenient for patients to obtain therapy at their physicians' offices rather than have to travel somewhere else to get them. In addition, some patients may feel more comfortable knowing that their therapists and physicians are working together at the same location. I request that CMS elaborate on its concerns in this area, acknowledging that the number of letters received on a subject is not always indicative of the gravity of the issue or need for correction. I also request that CMS engage in discussions with stakeholders on this issue given the obvious importance

of physician expertise, patient needs, clinical quality, and the appropriate use of Medicare resources in the area of physical therapy.

The last issue in which I would like to comment is regarding the Alternative Criteria for Satisfying Certain Exceptions. I commend CMS on its attempt to bring rationality to the strict enforcement of inadvertent violations of the self-referral regulations. However, I also believe that CMS should amend the proposal so as not to be so unilateral on the part of CMS. Surely CMS can preserve its authority, while simultaneously ensuring that those that are subjected to this rule and exception are able to access the benefits of it.

I look forward to hearing from you regarding these issues. Thank you in advance for your consideration.

Sincerely,



J. A. Alex Seldomridge III, M.D.
Alabama Orthopaedic Clinic, P.C.

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3325 N. Willow Dr
Zanesville, Ohio 43701
August 29, 2007

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

Dear Sirs:

This is a letter in reference to the pending Stark revision re: Physician Self-referral Provisions. As a Urologist I have been involved with providing my patients lithotripsy and other cutting edge therapies for urological diseases. These include Holmium laser treatment for benign prostate disease, Cryotherapy for cancer of the prostate, and Brachytherapy.

Extra corporal lithotripsy was becoming available in the United States during the 1980s. The original lithotripsy units were very expensive and hospitals were reluctant to purchase the equipment due to cost and to quantity of use. Fortunately, the area urologists, under the direction of Dr. Henry Wise, were able to finance the cost of the equipment. The benefit to the patients was they did not require open surgery. This was the standard procedure of care before the availability of the lithotripsy. Use of the lithotripsy lowered the cost for the patient insurance and medicare cost. This has been a substantial savings over the years.

There has been no abusive diagnostic ventures during this time for the urologists and should not be considered under the Stark revisions as such. It has proven itself over time to be a much needed technology for patients as well a cost saving procedure for the health care market.

Sincerely yours,

Edward J. Booth, M.D.

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August 27, 2007

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

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

Dear Mr. Kerry Weems,

I am writing to you to express my **strong support** of the efforts **to remove physical therapy from the designated health service exception.** As a practicing, licensed Physical Therapist for the last 14 years, I believe that removing the exception would greatly assist the public in receiving the best and unbiased health care. I feel this measure would reduce the potential for fraud and programmatic abuse.

Thank you for your time and consideration in this matter.

Cendey Roberts

Cendey Roberts, PT

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August 28, 2007

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

Subject: **Physician Self-Referral Issues**

Dear Mr. Kerry Weems,

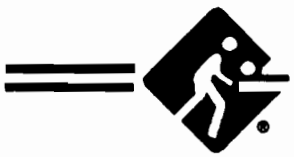
I am writing in response to the concerns that CMS has on abuse of self-referrals to physician owned physical therapy clinics. **I strongly urge you to support the APTA in the efforts to remove physical therapy from the designated health service exception that allows physicians to won and refer to their own clinics.** I am a physical therapist in a rural area, and I have had several patients tell me that they had to drive more than 1 hour to the physical therapist 3 days a week because their doctor wanted them to be seen by "HIS THERAPIST." This type of referral causes hardship on family members and unnecessary monetary inconvenience due to travel time and distance. After all, these people are in pain in the first place. Couple that pain with a 2.5 hour car ride, and then they have a real problem.

There was no reason that these people could not have been seen and treated in this clinic that was only minutes away from their home. I am a Doctor of Physical Therapy, and I believe that I am just as qualified in patient care as any other therapist. **I believe physician owned clinics refer to themselves for monetary gains at the expense of the patient and do not have the patient's best interest in mind.**

Thank you for your continued efforts in keeping fraud to a minimum, supporting physical therapy, and our dedication to become independent of physician practices. **Please remove physical therapy from the DHS exception.**

Sincerely,

Holly Hardy, DPT, PT
Supervisor
Conway Regional Therapy Center- Greenbrier



August 29, 2007

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

Dear Centers for Medicare and Medicaid Services,

Metropolitan E.M.S. commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements of 42 C.F.R. §424.36. Ambulance services are atypical among Medicare covered services to the extent that, for a large percentage of encounters, the beneficiary is not in a condition to sign a claims authorization during the entire time the we are treating and/or transporting the beneficiary. Many beneficiaries are in physical distress, unconscious, or of diminished mental capacity due to age or illness. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

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

Current Requirement

When the beneficiary is physically or mentally incapable of signing, we have been following the requirements listed in the CMS Internet Only Manual, Pub. 100-02, Chapter 10, Section 20.1.2 and Pub. 100-04, Chapter 1, Section 50.1.6(A)(3)(c). These sections require the ambulance provider or supplier to document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary.

Summary of New Exception Contained in Proposed Rule

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

Metropolitan Emergency Medical Services (MEMS)
P.O. Box 2452, Little Rock, AR 72203-2452
Administrative Office (501) 301-1400 / Fax (501) 301-1401

1. The beneficiary was physically or mentally incapable of signing the claim at the time of service;
2. None of the individuals listed in 42 C.F.R. §424.36(b)(1) – (5) was available or willing to sign the claim on the beneficiary's behalf at the time the service was provided; and
3. The ambulance provider maintains specific information and documentation for at least 4 years from the date of service. The required information and documentation includes:
    a. A contemporaneous statement from an ambulance employee present during the transport, stating that the beneficiary was physically or mentally incapable of signing, and that no other authorized person was available or willing to sign the claim on the beneficiary's behalf.
    b. Documentation providing the date and time of the transport, and the name and location of the receiving facility.
    c. A contemporaneous statement from a representative of the receiving facility, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility.

While the intent of the proposed exception is to give ambulance providers explicit relief from the beneficiary signature requirements where certain conditions are met, we note that the proposed exception does not grant ambulance providers any greater flexibility than that currently offered by existing regulations. Specifically, 42 C.F.R. §424.36(b)(5) currently permits an ambulance provider to submit a claim signed by its own representative, when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf. If "provider" in this context was intended to mean a facility or entity that bills a Part A Intermediary, the language should be changed to also include "ambulance supplier". The proposed exception essentially mirrors the existing requirements that the beneficiary be unable to sign and that no authorized person was available or willing to sign on their behalf, while adding additional documentation requirements.

Therefore, we believe that the new exception for emergency ambulance services set forth in proposed 42 C.F.R. §424.36(b)(6) should be amended to include only subsection (i), i.e. that no authorized person is available or willing to sign on the beneficiary's behalf.

It is important for CMS to realize that the first two requirements in the proposed sub-division (ii) are always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. For this reason, we do not object to the requirements that an ambulance provider obtain (1) a contemporaneous statement by the ambulance employee or (2) documentation of the date, time and destination of the transport. Nor do we object to the requirement that these items be maintained for 4 years

from the date of service. However, we do not see any reason to include these in the Regulation, as they are already required and standard practice.

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

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

We also strongly object to the requirement that ambulance providers or suppliers obtain this statement from a representative of the receiving facility *at the time of transport.* Since the proposed rule makes no allowances for the inevitable situations where the ambulance provider makes a good faith effort to comply, but is ultimately unable to obtain the statement, we believe this requirement imposes an excessive compliance burden on ambulance providers and on the receiving hospitals. Consider what this rule requires—the ambulance has just taken an emergency patient to the ER, often overcrowded with patients, and would have to ask the receiving hospital to take precious time away from patient care to sign or provide a form. Forms such as an admission record will become available at a later time, if CMS wants them for auditing purposes.

<u>Difficulty in Obtaining Hospital Records</u>

The PCS requirement is an excellent analogy for the difficulty ambulance providers and suppliers have in obtaining forms signed by facilities, and how CMS has adopted acceptable alternatives.

Medicare requires ambulance providers and suppliers to obtain a physician certification statement (PCS) from the facility for most <u>non-emergency</u> transports. CMS understood the problem experienced in trying to obtain PCS forms – and that was for non-

emergencies. For non-repetitive patients, Medicare regulations provide the ambulance provider with up to 21 days *after* the date of transport to obtain this PCS. Where the

ambulance provider is unable to obtain the PCS within this extended period of time, the regulations still permit a claim to be submitted, provided the ambulance provider documented its attempts to obtain the PCS and uses the alternative permitted, i.e. proof of the attempt to obtain the PCS, e.g. by Certified Mail or Proof of Mailing.

In other words, Medicare regulations recognize that obtaining the PCS is, to some extent, outside the control of the ambulance provider, and, accordingly, permit claims to be submitted so long as the ambulance provider takes reasonable steps to comply with the PCS requirement. We believe that, at a minimum, a similar exception should apply to medical emergencies. Treatment and care of the beneficiary should be the overriding focus of all parties, not another form signed by already overburdened ER personnel.

Purpose of Beneficiary Signature

a. Assignment of Benefits – The signature of the beneficiary is required for two reasons. The first purpose of the beneficiary signature is to authorize the assignment of Medicare benefits to the health care provider or supplier. However, assignment of covered ambulance services has been mandatory since April 2002. Furthermore, 42 C.F.R. §424.55(c), adopted November 15, 2004 as part of the Final Rule on the Physician Fee Schedule (67 Fed. Reg. 6236), eliminated the requirement that beneficiaries assign claims to the health care provider or supplier in those situations where payment can only be made on an assignment-related basis. Therefore, the beneficiary's signature is no longer required to effect an assignment of benefits to the ambulance provider or supplier.

CMS recognized this in the Internet Only Manual via Transmittal 643, by adding Section 30.3.2 to Pub. 100-04, Chapter 1. As a result, the beneficiary signature is no longer needed to assign benefits of covered ambulance services.

b. Authorization to Release Records – The second purpose of the beneficiary signature is to authorize the release of medical records to CMS and its contractors. However, the regulations implementing the HIPAA Privacy Rule, specifically 45 C.F.R. §164.506(c)(3), permit a covered entity (e.g. an ambulance provider or supplier) to use or disclose a patient's protected health information for the covered entity's payment purposes, without a patient's consent (i.e. his or her signature). Therefore, federal law already permits the disclosure of medical records to CMS or its contractors, regardless of whether or not the beneficiary's signature has been obtained.

Signature Already on File

Almost every covered ambulance transport is to or from a facility, i.e. a hospital or a skilled nursing facility. In the case of emergency ambulance transports, the ultimate destination will always be a hospital. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. The term "related services", when used by hospitals and SNFs, can mean more than only entities owned by or part of the facility. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service", since the ambulance transports the patient to or from that facility for treatment or admission. Therefore, we believe a valid signature will be on file with the facility. Additionally, for those transports provided to patients eligible for both Medicare and Medicaid, a valid signature is on file at the State Medicaid Office as a product of the beneficiary enrollment process.

Electronic Claims

It is also important to note that, as a result of section 3 of the Administrative Simplification Compliance Act and the implementing regulations at 42 C.F.R. §424.32, with very limited exceptions (e.g. providers or suppliers with less than 10 claims per month), ambulance suppliers must submit claims electronically. Thus, the beneficiary does not even sign a claim form. When submitting claims electronically, the choices for beneficiary signature are "Y" or "N". An "N" response could result in a denial, from some Carriers. That would require appeals to show that, while the signature has not been obtained, an alternative is accepted. As a result, many Carriers allow a "Y", even though the signature was not actually obtained, if one of the exceptions is met.

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

Program Integrity

It is important for CMS to realize that, for every transport of a Medicare beneficiary, the ambulance crew completes a trip report listing the condition of the patient, treatment, origin/destination, etc. AND the origin and destination facilities complete their own records documenting the patient was sent via ambulance or arrived via ambulance, with the date.

Thus, the issue of the beneficiary signature should not be a program integrity issue.

Conclusion

Based on the above comments, it is respectfully requested that CMS:

- Amend 42 C.F.R. §424.36 and/or Pub. 100-02, Chapter 10, Section 20.1.1 and Pub. 100-04, Chapter 1, Section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambulance provider or supplier has documented that the beneficiary could not sign and no one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".
- Amend 42 C.F.R. §424.36 to add an exception stating that ambulance providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.
- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

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

Sincerely,
Metropolitan E.M.S.
Little Rock, Arkansas

771

THE UNIVERSITY OF
CENTRAL ARKANSAS

CONWAY, ARKANSAS 72035-5003

August 27, 2007

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

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

Mr. Kerry Weems:

I am a physical therapist presently working in Conway, Arkansas as an assistant professor for a doctorate in PT program at the University of Central Arkansas. I have been practicing as a physical therapist in since 1979 in outpatient settings in Florida and Georgia and as a health care consultant. I have had numerous occasions to experience care, fraud and abuse problems with the Medicare patients receiving services through physician owned Physical Therapy services (POPTS) and welcome the opportunity to relate some of these experiences to your department for use in your most recent request for comments.

EXAMPLE #1: As an outpatient physical therapist in independent practice, service to the insurers and the patients are the means to develop a thriving and successful practice. These service points would include being cost effective, being efficient in delivery and quantity of care, and having the highest quality services. By performing above the standards of Medicare, most patients and providers are pleased and the quality of intervention is usually high. My practice in Gainesville, Florida enjoyed this success and I received many referrals from the orthopedic surgeons in my area. The comments from the surgeons included comments that my practice was the "best" for treatment and outcomes of multiple entities and diagnoses. After the exception rule of Stark II was implemented and tested by others in the orthopedic profession, the surgeons I worked with decided they needed to have an ancillary PT service in their office. They offered me the opportunity to negotiate a contract to provide this service. They wished to have a profit margin for their referral services and wanted to provide the services with minimal equipment and supplies. They ended up hiring a new graduate physical therapist and not using my services. Of course all referrals to my

practice dried up from these physicians. They stated that I was the "best" but that this was just a "business" decision.

EXAMPLE #2: As a consultant, I helped to set up a private clinic in the St. Augustine, Florida area that was going to rely on referrals from the major orthopedic clinic in that geographical area. This clinic opened and was very successful was honored as the "BEST REHAB CLINIC" through a consumer poll from the area. The orthopedic doctors decided they wanted to have a clinic ancillary in their office instead of across the street. They stopped all referrals to this clinic and hired a new graduate therapist. I have since been called into service as a consultant with the new practice and found many problems with billing, intervention, and documentation. These problems did not exist with the previous practice. Profit margin on the in-house services was amazing and this was the reason for the physicians change.

EXAMPLE #3: I was hired as a consultant to start up a physician owned PT service in Savannah, Georgia in the height of the boom in these services. I was out of practice at the time and needed to make a living with my skill set so, I reluctantly took on this opportunity. I set up the practice to the wishes of the orthopedic surgeons. They were told, by an outside National physician consulting agency, they would make $100,000 a year in net profit just by bringing PT in-house and wanted me to set up the clinic to make this money. They felt their income was not as strong due to certain Medicare revisions in payments and jumped at this opportunity. When comments were made by me to patients and the MD to attempt to decrease the amount of care originally prescribed, I was released from service. The physicians referring the most patients to the clinic received the largest bonuses at the end of the year.

Because of my role in consultation, I am constantly bombarded with advertisements offered to orthopedic and other specialty physicians to increase their passive income through the addition of ancillary services. After being in both the private and the consultation environments, I can see no advantage to the Medicare patient by having PT offered in the MD offices. There is no incentive for the PT in this arrangement to supply highest quality care as there are no competitors and insurance pays readily. There is no need for MD supervision of the services rendered by the PT and in most instances the physicians never look at these services (they just collect the profits from their referrals). I find documentation to be poor (for the same reasons) and interventions to be excessive to increase the profit margin of the referring physicians. Referrals have a tendency to increase dramatically after the start up of one of the ancillary clinics. Finally, the ability of the patient to have choices in providers is eliminated as many of the private clinics close their doors when the MD ancillary services are offered. In private practice, I was never able to generate as much profit or income as the MD practices where I consulted. I see the only means of restricting abuse would be to revert to the original intent of the Stark Laws and restrict all self-referral relationships in medicine.

I thank you for the opportunity to relate my personal experiences to this investigation. Please feel free to contact me at any time if more information is needed to answer these research questions. You can reach me at (501) 366-7014 or through e-mail at sforbush@uca.edu.

Sincerely,

Steven W. Forbush, PT, MS
Assistant Professor of PT
University of Central Arkansas
Conway, Arkansas
(501) 450-5554

772

Triangle Urological Group

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August 29, 2007

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

Dear Mr. Kuhn:

I am a urologist in the Triangle Urological group. We are a single specialty practice comprising 10 urologists and five physician extenders covering a large area of Western Pennsylvania. I am writing to comment on the proposed changes to the physician fee schedule rules that were published in the federal register on July 12, 2007. Specifically the changes that concern the Stark self referral rule and the reassignment and purchased diagnostic test rules. It is my and my partners opinion that these changes are excessive and far more than is needed to protect Medicare from fraud and abuse.

One of the strengths of our group which covers a large geographic area with numerous smaller community hospitals is that we have been able to provide tertiary type care to our patients. In particular, we pride ourselves in being at the cutting edge of the urologic field, particularly as it pertains to technology. We are therefore particularly concerned about the proposed "under arrangement" rule. This will limit or prohibit the provision of prostate and renal cryosurgery services, as well as some laser services. We have found that by using the same technicians and the same equipment and by having some control over their hours and availability that we have been able to provide to our Medicare and other patients the ability to offer high quality standardized and immediate care to patients with BPH issues, prostate cancer and kidney cancer. This is particularly so in some of the more rural hospitals that we serve. Not being able to provide these services to these patients amounts to restricted access of services and will force patients to either travel or accept alternative therapies. Therefore we ask you to please strongly reconsider some of these proposed rule changes.

We thank you for your time and consideration.

Sincerely,

JCL/vam

J. Christopher Lyne, M.D.

Ralph J. Miller, Jr., M.D.

Jeffrey K. Cohen, M.D.

773

CareFlite
North Central Texas Services

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Grand Prairie, Texas 75052
972-339-4200
972-988-3144 Fax

August 21, 2007

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

RE: File code CMS–1385–P
BENEFICIARY SIGNATURE

Dear Ms. Norwalk:

CareFlite would like to take this opportunity to offer comments on the recent rule change proposed by the Centers for Medicare and Medicaid Services (CMS). CareFlite provides over 40,000 patient transports each year and close to 50% of these patients are Medicare recipients. The proposed rule would have a direct impact on the operation of our services. We therefore greatly appreciate this opportunity to submit comments on the proposed rule.

We believe that it is impractical to require additional paperwork be generated and maintained when a Medicare recipient is unable to sign an assignment of benefits form. When these patients are transferred non-emergently we request a PCS (physician certification statement) form which documents that the transfer is medically necessary according to the sending physician. When the patient is unable to sign, which is frequently the case in emergent situations; the medical record has a documented reason for the missing signature. Then when the patient is delivered to the receiving facility the accepting staff, usually a nurse or doctor, signs the medical record saying they are accepting the patient and have received adequate report on the patient. All of this documentation is kept, as part of the patient's medical record, indefinitely. Requesting additional signatures from accepting facilities, usually emergency departments (ED), puts additional burdens on the ambulance crews but also slows the process in the already overcrowded ED.

We believe that all the information you are proposing with a "signed contemporaneous statement" is currently available in the patient medical record and that it is unnecessary to generate additional paperwork to document this information. CareFlite urges CMS to eliminate the beneficiary signature requirement for ambulance services entirely.

Thank you for your consideration of these comments and our recommendation.

Sincerely,

Jan Cody, RN, LP
VP of Clinical Services

WWW.ENCOREANESTHESIA.COM

Encore ANESTHESIA

A HARD ACT TO FOLLOW

August 29, 2007

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

Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS' proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS' proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services. This increase in Medicare payment is important for several reasons. First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.

Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers' services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.

Third, CMS' proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments. Additionally, if CMS' proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation). America's 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency's acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely,

Stephen M. Carrier, CRNA, President

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August 27, 2007

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

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

Dear Sir:

My name is Linda Cullum, PTA. I am a practicing Physical Therapist Assistant in the State of Arkansas. I have been a Physical Therapist Assistant in Arkansas for 18 years. I graduated from the PTA program at the University of Central Arkansas. I have practiced in the Acute Care Physical Therapy Department at Conway Regional Health System up to this point.

I am very concerned regarding **Physician Self referral Issue.** I have serious concerns regarding the potential for future and the current abuse that occurs in the profession regarding Physician referrals for Physical Therapy services in Physician owned practices. I would strongly encourage CMS to support the removal of PT services from the in-office ancillary exception to reduce fraud and abuse that is occurring in the PT profession in these type clinical settings.

Thank you for your consideration of this very serious matter.

Linda Cullum PTA

Linda Cullum, PTA
PT Dept
Conway Regional Health System
2302 College Ave
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776

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JOHN T. GIANIS, JR., M.D.*
THOMAS J. GIANIS, M.D., F.A.C.S.*
*DIPLOMATE-AMERICAN BOARD OF UROLOGY

TELEPHONE (908) 273-8854
FAX (908) 273-4585

August 27, 2007

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

To Whom It May Concern:

I am writing to express my concern regarding certain proposals in the recently released 2008 proposed Physician Fee schedule. As a physician practicing in Summit, New Jersey, I fear that several of the proposed changes to the Physican self-referral rules will needlessly and unjustifiably harm Medicare patients and providers. As an urologist, I have seen first-hand the beneficial affects that Joint Ventures have had for the healthcare system. I have been involved with providing my patients lithotripsy and other cutting-edge therapy for urologic disease that would not have been widely available to my patients, including Medicare beneficiaries unless physician Joint Ventures had provided the services. By accepting the risk of providing these costly services when hospitals refused to do so, Urology Joint Ventures have greatly expanded patient access to worthwhile and effective treatments.

CMS provides that a provider should bear the burden of proof that referrals were not made in violation of Stark and any appeal of a denial of payment on this basis. This appears to me to require providers to provide a negative which would be difficult, if not impossible, to accomplish.

As I understand it, it was the intent of Congress, as recognized by CMS in its phase 1 rule making, to permit time based or unit-based payments for space and equipment leases. The proposal to prohibit these arrangements therefore directly contradict Congressional intent. CMS should not prohibit an arrangement that Congress expressly intended to permit. Hospitals are generally unwilling to take risks and are often operating on razor razors and margins. They are adverse to bearing this risk of low-volume usage for newer innovative technologies and services.

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ELIZABETH FALADE, M.D., M.P.H.
HEALTH OFFICER

KATHRYN FLORES
DIRECTOR

HEALTH & HUMAN SERVICES AGENCY

PUBLIC HEALTH SERVICES
Healthy People in Healthy Communities

August 29, 2007

CMS, Dept of HHS,
Attention: CMS-1385-P,
PO Box 8018
Baltimore, MD 21244-8018

RE: CMS Rule 2008 Physician Fee Schedule

Dear Sir or Madame:

As the Health Officer of San Benito County, California, I am writing to comment on the Proposed CMS Rule for the 2008 Physician Fee Schedule issued by CMS in the Federal register, Volume 72, Number 133, July 12, 2007.

The 2000 U.S. Census ranked San Benito County number one in California counties ranked by rate of population growth, with a growth rate of 45.06%. The flawed methodology used by Medicare and resulting inequities for San Benito County providers rate of reimbursement has been a major contributing factor to a crisis of monumental proportions resulting in lack of stability of our health care structure which affects all county residents. Physicians in San Benito County have been unfairly impacted by the miscalculations of the physician fee schedule which unfairly penalizes them with lower reimbursement rates than nearby Santa Clara County (15 minutes away) with a GAF 1.224, compared with San Benito County with a GAF of 1.012. This exceedingly large inequity of 21% unfairly impacts physicians in San Benito County in reimbursement rates and has resulted in the inability of our local medical practitioners to maintain their practices given the current reimbursements options available to them combined with the cost of practicing medicine in our area.

Representative Sam Farr, serving California's 17th District, is proposing relief from falsely low reimbursements for several California counties by seeking to remove them from Locality 99. He introduced into HR 3162 a Section 308 which would revise the fee schedule areas using the county-based geographic adjustment factor as specified in Option 3 (table 9) of the previously referenced proposed CMS Rule.

San Benito County is bordered by Santa Clara County, who is already its own locality with a reimbursement rate in Gilroy (a 15 minute drive) of 21% higher. Historically, our rates have always been linked to those of Monterey and Santa Cruz counties, who would also be affected by any changes. The

not start by looking at the relative cost difference of each county. Instead, it used the localities established in 1967 for Medicare's reasonable charge based physician payment system. The then existing locality costs were established under the 5% threshold, not by comparing individual county costs. In other words, the "charge based localities" were not broken down into their county components. This resulted in the state's Locality 99, which includes four counties with cost differences which exceed 5%. It is my belief that if Medicare had used individual counties instead of the "charged based localities", the counties of San Benito, Santa Cruz and Monterey would be grouped in more appropriate localities or new unique localities. The end result would be that they would not be inappropriately grouped in Locality 99 as they are now.

This inequality in fee schedules has resulted with San Benito County having virtually only a handful of physicians who now accept new Medicare patients. With reimbursement rates 21% higher across the county line in Santa Clara, physicians are choosing to relocate 15 minutes away and are increasingly unwilling to work in San Benito county due to the high cost of living combined with the low federal reimbursement rates for individuals covered by Medicare. The end result is that our community residents are the ones who are facing the brunt of this injustice. I understand the complexities of attempting to resolve these inequities which have not been appropriately updated since the inception of the Medicare program in 1966, and urge you to reconsider the data from the GAO and, within Option 3, remove San Benito County, California from Locality 99 or at least hold the county harmless until the appropriate administrative or legislative corrections can be made. I believe that our exclusion from the increases proposed in Section 308 would certainly adversely impact our ability to retain and recruit physicians to practice in our community. This would place patients in San Benito County access to medical care in jeopardy.

Moreover, the recent June 2007 GAO Report on "*MEDICARE – Geographic Areas Used to Adjust Physician Payments for Variation in Practice Costs Should Be Revised*" includes data which would support the inclusion of San Benito County in the area adjustment process. The inequities in our low Medicare reimbursements have a domino affect and impact physician rates with other insurance companies which are using Medicare rates as their baseline. According to the physicians of San Benito Medical Association, our largest payor, Blue Cross, currently reimburses them at 20 to 30% less than Medicare.

As the population of San Benito County continues to grow, physicians are discovering that it is also an expensive location to relocate their homes and offices to. The increase in home costs and office space coupled with decreases in Medicare reimbursement rates have caused San Benito County to be in a state of crisis as we are unable to retain or recruit new physicians to meet the needs of a growing population.

As Health Officer, I am charged with assuring that the medical needs of the population of San Benito County are being met. At this time, the needs of the residents of San Benito County are not being met due to dwindling numbers of physicians willing to practice in San Benito County due to their inability to make ends meet in my jurisdiction.

I am advocating for a payment structure which supports our physicians and their ability to provide high quality care for all of our residents. There are three current documents under consideration which may impact physician fees in San Benito County:

1. The GAO June 2007 MEDICARE report which offers recommendations for changes in the locality system which demonstrates that San Benito County qualifies for removal from Locality 99. These data and calculations are evidence of the incongruities in the current system and support administrative and/or legislative changes to correct the current discrepancy.
2. The July 12, 2007 proposed CMS Rule Option 3 which sets forth a methodology which would positively impact Medicare reimbursement rates for several California counties and which, ***if correctly calculated*** using current GAO figures, would include San Benito County.
3. Congressman Farr's HR 3162 Section 308 which offers relief from the low reimbursement fees set for some current Locality 99 counties by supporting Option 3 and would provide for future corrections which would qualify San Benito County for the same. This Section would at least hold San Benito County harmless from bearing the brunt of changes to other localities within the State.

San Benito County residents pay equal premiums to support Medicare, yet there are substantial differences in Medicare physician reimbursement rates in our county. The financial losses incurred by physicians have forced many to leave our county. This in turn, has resulted in a crisis situation for residents of San Benito County. The unreasonably low Medicare payments are having any increasingly negative impact on patient care and access in my jurisdiction. I urge you now to take immediate steps to correct this imbalance and protect the future of medical care in San Benito County.

Taken together, the time is right to correct past inequities which do not take into account the high cost of living and practicing medicine in San Benito County. It is unreasonable to assume that residents of San Benito County will have the means to travel to another county for medical care. These inequities have resulted in a threat to the health of local residents.

I urge you to reconsider the data from the GAO and, within Option 3, remove San Benito County, California from Locality 99 or at least hold the county harmless until the appropriate administrative or legislative corrections can be made.

I believe that you must assign a high priority to eliminating Geographic Practice Cost Indices and other components of the Medicare program that result in inequitable reimbursement to physicians. Never before has there been this great a threat to the health care of residents of San Benito County covered by Medicare. I urge to please help us make significant progress toward a goal of restoring equity to Medicare, and leveling the playing field for San Benito County residents.

Sincerely yours,

Elizabeth Falade MD MPH

Elizabeth Falade, MD, M.P.H.
Health Officer
County of San Benito
Heath & Human Services Agency – Public Health Division

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UROLOGY
CENTERS OF OKLAHOMA
A DIVISION OF
SURGICAL SPECIALISTS OF OKLAHOMA, PLLC

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James R. Wendelken, M.D., F.A.C.S.

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August 27, 2007

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

Dear Mr. Kuhn:

I am a urologist who practices in Oklahoma City. We are in a large multi-specialty group that has 15 urologists, as well as general surgeons, neurosurgeon, podiatrists, cardiovascular surgeon, and orthopedic surgeons. Our group treats a large Medicare population. Approximately 40% of our patients are Medicare age. We have the gamut of care for these citizens. We treat cancer of the prostate, bladder, and kidney. We care for patients with renal insufficiency, urinary tract infections, benign prostate disease, and incontinence. Our stone population is great. I am writing to comment on the proposed changes to the physician fee schedule rules that were published on July 12, 2007 that concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules.

The changes proposed in these rules will have a serious impact on the way we practice medicine and provide service to our patients. With respect to the in-office ancillary services exception, the definition should not be limited in any way. It is important for patient care for urologists to have the ability to provide pathology services in their own offices. It is equally important to allow urologists to work with radiation oncologists in a variety of ways to provide radiation therapy to patients. We have developed methodology of diagnostic lab testing and reporting that is accurate and timely. We are particularly proud of our relationship with the radiation oncologist in providing cost effective, prostate specific radiation therapy to our patients.

The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible, for us to provide in-clinic prostate cancer radiation therapy, timely pathology services, and non-invasive prostate therapy.

The proposed "under arrangement" rule will be a detriment to the provision of IMRT/IGRT by a radiation oncologist focusing on these complex technologies. The service will be scattered about the community resulting in the degrading of the quality of the service. We have seen this sort of quality issue occur in the placement of Brachytherapy.

The prohibition of per click payments for space and equipment rentals will prohibit the continued development of disease specific treatment centers. These centers tend to provide high quality, low complication, cost efficient programs when compared to hospital based services.

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

Thank you for your consideration,

James R. Wendelken, M.D.

JRW/emd

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IRA SILVERSTEIN ASSOCIATES
Physical Therapy

August 24, 2007
Mr. Kerry N. Weems
Administrator- Designate
Center for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8018
Baltimore, Maryland 21244-8018

Dear Mr. Weems:

I am writing to you regarding the Physician Self-Referral Issue and how it affects the practice of physical therapy. Being a physical therapist in private practice specializing in orthopedics for the past 27 years in the District of Columbia, I wish to elaborate on how this has had a significant impact on the treatment outcome of my patients.

The most recent case that I'm dealing with is a 75 year old female who had both knees replaced. After being treated at a physician owned facility for 31 visits, the patient finally realized that things were not progressing as they should have. Realizing that she had to take matters into her own hands because she wasn't getting answers from the people involved in her rehabilitation, she pursued other opinions and options. Finally, after going through this unnecessary ordeal a functional outcome was achieved.

A patient I had treated in the past, called me seeking advice on what to do regarding the rehabilitation of her recent fractured hip. Due to her circumstances and the frequency of treatments she could not come to my office so I advised her to seek treatment as an outpatient at the hospital closest to her home. She was unable to be seen in reasonable amount of time and sought treatment at a physician's office where she had seen the physician. I advised her to make sure she was being treated by a licensed physical therapist and that the rehabilitation for this type of injury is pretty straight forward. This patient returned to see me in six weeks ambulating with a walker and in extreme pain. I eventually found out that she was not treated by a physical therapist. She had to have her hip replaced because there was a slippage in the fracture.

Another individual came to see me for a consultation because she did not want to have rotator cuff surgery for numerous reasons. She was being treated by the physical therapist in her orthopedist's office for 4 months and had not made any significant progress. To make a long story short, I evaluated this patient and after 3 months of rehabilitation her arm is pain free and fully functional.

The examples I have cited have put the consumer at risk. Even in this day an age, the patient is reluctant to go against the advice of their physician believing that the

physician is acting in their best interest. Fortunately, for these patients it wasn't too late to produce a functional outcome. Not all patients are as lucky.

Physician owned physical therapy practices have an inherent financial incentive to refer their patients to the practices they have invested in and to over utilize those services for financial reasons. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, CMS would reduce a significant amount of abuse, over utilization of physical therapy services under the Medicare program and enhance the quality of patient care.

The physical therapy profession has evolved academically and professionally into a reputable profession for the treatment of physical dysfunctions. We can practice without referral in 43 states and the prescriptions that physicians write for me to treat their patients say evaluate and treat. I even have physicians calling me up seeking advice on how to resolve their patient's physical dysfunctions. The irony of this situation is that I treat the physicians who have their own physical therapy practices. You have the opportunity to protect the public from this abusive situation by eliminating the physician self referral loop holes.

Please feel free to contact me if you any further questions and thank you for taking the time to consider my comments

Sincerely,

Ira Silverstein, M.S., P.T., ATC

784

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BTULLY@HEALTH-LAW.COM

FILE NO. 14290-901

August 31, 2007

VIA EMAIL & U.S. MAIL

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

Re: Physician Self-Referral Provisions

Ladies and Gentlemen:

This letter presents our comments on behalf of California Cancer Specialists Medical Group, Inc., *d.b.a.* City of Hope Medical Group ("City of Hope") in response to the proposal of the Centers for Medicare & Medicaid Services ("CMS"), as set forth in connection with its July 12, 2007 proposed revisions to Medicare's physician fee schedule, to modify the Stark law's definition of "entity."

As discussed below, CMS' proposal raises a number of difficult conceptual issues and City of Hope is concerned that CMS' proposal could potentially restrict the ability of physicians to directly or indirectly hold ownership interests in a joint venture company that provides the space, personnel and equipment used by their own medical group to perform the technical component of a designated health service.

I. The Contemplated Joint Venture

City of Hope is a medical group specializing in the treatment of cancer which satisfies each of the requirements of the Stark law's definition of a group practice. The joint venture being considered by City of Hope would provide it with the space, personnel and equipment that it would use for the performance of the technical component of radiation oncology services. City of Hope would pay the joint venture for the use of the joint venture's space, personnel and

equipment on a unit of service basis. City of Hope would perform the professional component of the radiation oncology directly.

These radiation oncology services would be covered by Medicare under the "incident to physician services" rules, and the services would be directly supervised by a physician who is a member of the group practice. The radiation oncology services would be performed in space subleased to City of Hope by the joint venture.

In order to meet the joint venture's need for capital, it is intended that the joint venture would not be owned solely by City of Hope's physicians, but would instead be jointly owned by City of Hope with a hospital. However, for purposes of the analysis herein, it would not matter whether there is or is not a hospital participant in the joint venture, or whether the physicians will invest in the joint venture directly or indirectly through the medical group. Moreover, since the specific category of DHS involved is not relevant to analysis under the Stark law, our comments will not focus on radiation oncology, but will instead address DHS generically.

II. Background On The CMS Proposal

Absent some exception (and none is available for a small non-publicly traded company of the type that is the subject of this letter), the self-referral restrictions of the federal Stark law prohibit a physician from making a referral of a Medicare patient to an entity in which he or she directly or indirectly holds an ownership interest for the "furnishing" of a "designated health service" ("DHS"). The Stark law's current definition of what it means for an entity to be "furnishing" DHS includes only those persons or entities that directly bill the Medicare program for the DHS.

Since the joint venture company under consideration would not itself bill the Medicare program for the DHS it would help provide, no *per se* prohibition currently applies to physicians who order DHS for their patients when the space, personnel and equipment used to perform those DHS are provided by such a joint venture company. Instead, an indirect compensation relationship is created between the medical group which purchases the components used in the performance of the DHS from the joint venture and the physician owners of the medical group. Provided that the pricing applicable to the space, personnel and equipment supplied by the joint venture is held constant irrespective of the volume or value of the physicians' orders of the DHS and is at fair market value, the requirements of the Stark law's exemption for indirect relationships can be satisfied, and, as has been recognized by CMS and MedPAC, the federal self-referral restrictions are not triggered. In addition, as it would be the case here, the DHS would also be categorically exempted by the Stark law's in-office ancillary services exemption, regardless of the nature of the physicians' relationships with the joint venture.

However, under CMS' proposal, 42 C.F.R. Section 411.31's definition of when "a person or entity is considered to be furnishing DHS" would be expanded. CMS' proposed expansion of

the definition of the entity that furnishes a service would retain the existing definition, which includes the entity that bills, but would add an additional alternative prong to the definition under which persons and entities that do not themselves bill the Medicare program for any DHS would also be subject to the self-referral limitations if they are "the person or entity that has performed the DHS. . . ."[1] This proposed change would prevent indirect remuneration analysis from being used to permit a physician to have a non-exempt ownership relationship with the entity performing the service (such as a joint venture). The change might impact the availability of the in-office ancillary services exemption as well.

III. Summary Of City Of Hope's Position

As is set forth in more detail below, City of Hope believes that CMS should clarify either that (i) CMS' new proposal is limited to formal "under arrangements" relationships with hospitals, whereby an outside provider performs all components of the DHS for the hospital or (ii) a joint venture company that provides the space, personnel and equipment used by a medical group in the performance of DHS will not itself be considered to "perform" the DHS so long as the supervision of the DHS which is required for Medicare coverage purposes is provided by the medical group, and not by the joint venture.

Alternatively, should CMS be unwilling to take either of the above positions, City of Hope believes that CMS should provide more narrow protection for the particular type of joint venture at issue here (i) by acknowledging that its proposal does not apply to a joint venture that performs all or part of a DHS technical component and then sells that service to a medical group that bills for the DHS in compliance with all of the requirements of the in-office ancillary services exemption or (ii) by creating an exception to its new definition of "furnishing" for situations where the DHS would have been exempted by the in-office ancillary services exemption had it been performed directly by a group practice and all of the physicians having financial relationships with the entity furnishing the DHS and who make referrals to the group practice for the DHS are members of the group practice.

IV. The Meaning Of "Has Performed The DHS" Under CMS' Proposal Is Unclear And CMS Should Clarify That Its Proposal Applies Only To True "Under Arrangement" Relationships With Hospitals

CMS' proposal to define the person who is "furnishing" DHS to be the person who has "performed" the DHS is hardly illuminating when it comes to understanding what it in fact means to either "furnish" or "perform" DHS. No guidance at all is provided by the commentary for the not uncommon situation in which certain components going into the performance of the

[1] 72 Fed. Reg. 38122, 38187, col. 2 (July 12, 2007).

DHS are supplied by one company, while others are supplied by another. Instead, the new definition only makes sense when it is viewed simply in the broader context of rejecting the limits of the current definition, which defines "performed" by using the "bright line" test of who has billed Medicare for the DHS.

The problem presented when billing is not used to define "furnishing" is that, without further clarification from CMS, there is a danger that arrangements by which several parties are involved in the performance of a DHS may be prohibited when this was not the intent of either CMS or Congress. Let us use the same example of diagnostic imaging services that is used by CMS in its commentary. Consider, for example, a physician-owned company that owns and operates an independent diagnostic testing facility ("IDTF") that is enrolled as a provider in the Medicare program and that performs services for a hospital on an "under arrangements" basis. That company will own or lease the relevant space and equipment, will employ or contract with the relevant personnel and will have the responsibility for organizing and administering the use of its space, personnel and equipment to conduct diagnostic studies for the hospital's patients. Under those circumstances, the IDTF can be fairly said to be "performing" the diagnostic services and, if, as in CMS' example, the diagnostic services are radiology services, the IDTF can reasonably be considered to be performing DHS under the new definition.

Let us consider what happens, however, if the services are not performed in a free-standing IDTF, but are instead radiology services that are provided in the hospital's space by a physician-owned company that is not itself enrolled in the Medicare program, but that will employ or contract with the relevant personnel and will have administrative responsibility for using the hospital's space and its own personnel and equipment to conduct diagnostic studies of patients. The commentary provides the example of a free-standing ASC or IDTF providing services to a hospital "under arrangement," and even goes so far as to address the situation where the joint venture entity leases space from the hospital. However, the commentary does not address a situation where the service is not performed by an independent provider, but is instead performed within the hospital itself (or is billed for by an entity other than a hospital). Most obviously (and any broader change would not appear to have been fairly telegraphed to the public by the proposed rule and its commentary), ***CMS should draw this extended line of "furnishing," if there is to be any extension at all, only as broadly as the commentary suggests CMS intended for it to be drawn – at formal "under arrangement" relationships by which free-standing providers that the Stark law would bar from billing Medicare directly for their own services when ordered by their physician owners instead bill their services through hospitals.***[2]

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[2] If CMS were to interpret its proposal to apply beyond formal "under arrangement" relationships, it would be sliding down an impossibly slippery slope. For example, consider the (footnote continued)

Drawing the line at formal "under arrangement" relationships is also consistent with the commentary's discussion of MedPAC's 2005 report to Congress. As CMS is aware, MedPAC recommended that CMS "should expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial portion of its revenue from a provider of designated health services." The CMS commentary makes it clear that CMS believes that the MedPAC proposal would impact "leasing, staffing, and similar entities." However, CMS chose not to make the same proposal that MedPAC had made. This clearly suggests that CMS believes that the reach of the MedPAC proposal would be broader than its own and, accordingly, that the CMS proposal was not intended to reach leasing, staffing or similar relationships. The most significant difference between the CMS and MedPAC approaches therefore appears to be that CMS' approach would only affect companies that perform DHS in its own right, while the MedPAC approach would also affect companies that only provide "inputs" to DHS or, indeed, services that have no relationship to DHS at all. Thus, ***if CMS does not limit its proposed change to true "under arrangement" relationships with hospitals, it should nevertheless clarify that its proposal would apply only where a completed service is being sold to a billing entity, and that the proposal was not intended to affect a space, personnel and equipment leasing joint venture of the type at issue here.***[3]

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scenario under which radiology services are provided in the hospital's space by a physician-owned company that is not itself enrolled in the Medicare program, and that instead provides the hospital with the personnel (including a radiology department administrator) and equipment to be used in conducting diagnostic studies for the hospital's patients, while the hospital takes the full administrative and regulatory responsibility for ensuring that the personnel and equipment are used to conduct diagnostic studies of the hospital's patients. Is this merely an arrangement where indirect remuneration analysis applies to the personnel and equipment relationships? Finally, consider a last scenario under which a physician-owned company merely provides the hospital with the non-supervisory technical personnel and equipment to be used in conducting diagnostic studies for the hospital's patients, while the hospital takes the full supervisory, administrative and regulatory responsibility for ensuring that the personnel and equipment are used to conduct diagnostic studies for the hospital's patients. Would this then be an arrangement where indirect remuneration analysis applies to the personnel and equipment relationships?

[3] Unless CMS clarifies that the MedPAC proposal would not impact services that are otherwise protected by the in-office ancillary services exception (see discussion in Section V), City of Hope also believes that CMS should not adopt the MedPAC proposal.

V. CMS' Newly Proposed Definition Of "Entity" Should Not Affect Services That Are Otherwise Exempt Under The In-Office Ancillary Services Exception

While the Stark law generally prohibits a physician from making referrals of Medicare patients for DHS to an entity with which the physician has a financial relationship, there is, of course, an exception to the prohibition for in-office ancillary services furnished by a group practice.[4] The in-office ancillary services exception will apply to the DHS at issue, since the following conditions will be met:

> (1) The services will be furnished by individuals who are directly supervised by a physician who is a member of the group practice;[5]
>
> (2) The services will be furnished in a centralized building in space that is used exclusively by the group practice for the provision of some of the group practice's DHS;[6] and
>
> (3) The services will be billed for by the group practice under a billing number assigned to the group practice.[7]

Notably, the in-office ancillary service exception does not require the group practice to own the space or equipment it uses to perform DHS or to itself employ the technicians. Therefore, under the current regulations, if a joint venture between a group practice and a hospital sets up a separate service entity (which is not billing Medicare) to hire radiation therapy technicians and to provide the services of those technicians and space and equipment to the group practice, the arrangement will be protected under the in-office ancillary services exception so long as the group practice provides the required supervision of those services.

Nothing in the new definition of "entity" suggests that it was CMS' intent to extend the self-referral ban to services, like in-office ancillary services, that are otherwise excluded from the self-referral restrictions as a category, regardless of the nature of the particular financial

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[4] 42 C.F.R. § 411.355.

[5] 42 U.S.C. § 1395nn(b)(2)(A)(i); 42 C.F.R. § 411.352(b)(1)(ii).

[6] 42 U.S.C. § 1395nn(b)(2)(A)(ii); 42 C.F.R. § 411.352(b)(2)(iii).

[7] 42 U.S.C. § 1395nn(b)(2)(B); 42 C.F.R. § 411.352(b)(3).

relationships. ***City of Hope therefore urges CMS to expressly acknowledge in commentary that services provided under a joint venture arrangement of the type described herein are not impacted by the new definition of "entity," where the DHS are otherwise protected by the in-office ancillary services exception.***

If CMS is unwilling to preserve the existing in-office ancillary service exception in its entirety, it should nevertheless preserve the exception where ***all*** of the physicians who have financial relationships with the intermediary company that "performs" the DHS are members of the group practice that will bill for the services "performed" by the intermediary company. ***A suggestion for a new definition of "entity" that would so preserve the in-office ancillary services exception would be as follows:***

> ***A person or entity is considered to be furnishing DHS if it –***
>
> ***(i) is the person or entity that has performed the DHS (except that this clause shall not apply to an entity performing DHS for a group practice if the DHS would have been exempted by the in-office ancillary services exemption had they been performed entirely by the group practice and all of the physicians making referrals to the group practice for such DHS who have financial relationships with the entity that performed the services for the group practice are members of that group practice.***

This proposed exception will have no negative impact from a policy perspective because the physicians who invest in the intermediary company would have no greater incentive to refer patients for DHS than if the DHS were furnished directly by the physicians' own practice. Moreover, a failure to provide this exception could have unintended adverse policy effects. In states that do not prohibit the corporate practice of medicine, hospitals and other lay entities can directly invest in medical groups, thereby providing capital for the purchase of major medical equipment. The Stark law clearly allows such investment since the in-office ancillary service exception and group practice exception do not prohibit lay investors in medical groups. In those states which prohibit the corporate practice of medicine, hospitals and lay investors typically invest in a separate lay entity, which provides equipment and services to the medical group. As noted above, the Stark law and the CMS regulations have, to date, permitted these arrangements, as have the laws of every state to our knowledge.[8] If the exception proposed above is not allowed under the new definition of "entity", medical groups in states which ban the corporate

[8] States that ban the corporate practice of medicine generally recognize that the intermediary entity that provides services and equipment to the medical group is not "practicing medicine."

practice of medicine would no longer be allowed to attract outside investors, ***even though state law would otherwise permit it***. In essence, the new CMS rule could prohibit medical groups in corporate practice states from obtaining indirect financing from lay investors, while medical groups in non-corporate practice states could continue to raise capital through direct investment. It is difficult to think of a public policy reason to support such disparate treatment among states or among medical groups, or any rational basis for CMS to limit the legitimate raising of capital by outside investors in corporate practice states, especially when state law permits such investment. The City of Hope believes that the aforementioned exception should be adopted to avoid the unnecessary interference by the federal government in legitimate investment arrangements which are permitted under state law.

* * * * *

City of Hope very much appreciates CMS' review of the issues discussed herein that impact joint ventures operating within the in-office ancillary services exception. Please feel free to call me if you have any comments or questions regarding the discussion herein.

Very truly yours,

W. Bradley Tully

WBT/ng
cc: Marc Goldstein, CEO, City of Hope Medical Group, Inc.
Terry Pyle, CFO, City of Hope Medical Group, Inc.
Vince Jensen, COO, City of Hope Medical Group, Inc.
Robert W. Lundy, Jr., Esq.

Docket Management Comment Form

Docket: CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Temporary Comment Number: 209248

Submitter:
Mr. W. Bradley Tully, Esq.

Date: 08/31/07

Organization: Hooper, Lundy

Category: Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions
Physician Self-Referral Provisions
see attachment

Attachments
CMS-1385-P-T209248-Attach-1.doc
CMS-1385-P-T209248-Attach-2.doc

Print | Comment on Another Docket | Exit

Print - Print the comment
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August 31, 2007

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

RE: **Docket Number & Title: CMS-1385-P – Revisions to Payment Policies Under the Physician Fee Schedule**

Dear Ms. Norwalk:

I am writing to you as chairman and the representative of a 70 physician group in the Dallas –Fort Worth area of Texas. As a participant in an " under arrangement" venture our group has specific experience and positive results to report from our situations. Our results are not "anecdotal reports" but are legitimate reasons for having these ventures. We are concerned that CMS would enact reforms in this area on the basis of nothing more than " anecdotal reports". In fact, there exist many sound reasons for hospitals to enter into service contracts with third parties, especially with physicians.

In our venture with our hospital partner we:
1. constructed new facilities;
2. purchased several rooms of all new equipment;
3. negotiated new arrangements with suppliers and vendors;
4. hired staff;
5. and, introduced performance measures for the physicians, staff and hospital.

Our initial results have shown:
1. improved quality outcomes;
2. improved patient satisfaction;
3. establishment of a center of excellence for cardiovascular care;
4. no increased cost to medicare.

We expect continued improvements in our physicians performances and quality of care delivered.

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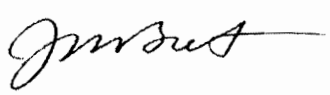
Our experience shows that rather than seeking to validate these partnerships medicare should seek to encourage them. In many instances, it can make financial and clinical sense to enter into a venture with a partner that can provide capital, shared risk, and operational expertise to a hospital striving to improve its specialty services and programs. The fact that physicians can sometimes bring these resources to a hospital should not automatically exclude them as participants in these efforts. In fact, in many ways, physicians are ideal hospital partners and offer benefits to hospitals far beyond mere referral of patients – such as careful cost control and quality improvement expertise. Accordingly, we can see no qualitative difference between a well structured "under arrangement" contract that conforms to all fraud and abuse standards under the anti-kickback statute and other programs that CMS and other government entities are supporting such as the various "gainsharing" and pay-for-performance initiatives. The essential task is to make sure that increased value is being delivered to Medicare beneficiaries in terms of cost and quality

It is clear that throughout the U.S., there are instances of both over and under-utilization of effective care. This is due to the well documented and widespread variation in hospital and physician practice patterns that are often random in nature. It also follows that much can be done to reduce the costs and simultaneously increase the quality of healthcare. However, the mere "risk of overutilization" is not sufficient grounds to enact the policy reform being proposed for "under arrangement" hospital relationships. Based on factual results and outcomes CMS should be able to separate those hospital-physician relationships that are beneficial from those that serve no other purpose other than a transfer of profits from one party to another.

We believe that in order to understand the true impact of "under arrangement" agreements for the provision of certain services, it would be appropriate for CMS to study the issue by availing itself of the actual results described above. This will allow CMS to educate itself on benefits of hospital-physician partnerships before enacting sweeping policy reforms.

Respectfully submitted,



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Physician Self-Referral Issues

Mr. Kerry Weems
Administrator/Designate Centers for Medicare and Medicaid Services
US Department of Health and Human Services
ATTN: CMS-1385
PO Box 8018
Baltimore, MD 21244-8018

RE: Medicare Programs Proposed Revisions to the Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008 Proposed Rule

Dear Administrator/Designate Weems:

My name is Michael P. Miller and I am a physical therapist who has been in private practice for 20 years. Over the past 10 years, our private practice has seen a steady loss of patient referrals from physicians who now have physician-owned physical therapy services in their practice. Our practice has always provided quality and appropriate physical therapy services to these physicians' patients. It has come to our attention that, during the course of loosing these referrals, patients that the physicians would not previously have sent to us because they didn't think therapy services were needed are now being referred to their own practices and insisting that, in fact, therapy services are needed.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer patients to the practices they have invested in and to over-utilize these services for financial reasons.

In addition, it has come to our attention that patients that were previous patients of ours and want to return to our physical therapy services are being aggressively marketed by the physicians and being pressured to come to their own physical therapy services, even going so far as stating to the patient that they don't know whether or not they will be able to see them should something happen to them if they are not receiving physical therapy services from their practices. By eliminating physical therapy services as a designated health service furnished by the in-office ancillary services exception, CMS would reduce a significant amount of problematic abuse, over utilization of physical therapy services under the Medicare program, and enhance the quality of patient care. The not isolated examples that I have stated above describe abusive arrangements you may have observed and the impact of those arrangements have had a deleterious effect on my practice and patients in general.

The in-house ancillary services exception has created a loophole that has resulted in expansion of physician-owned arrangements that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base for physical therapy patients in their office. In addition, due to the repetitive nature of physical therapy services, it is no more convenient for the patient to receive physical therapy services in the physician office than it is in an independent physical therapy clinic. Our clinic is located in an adjacent office to two other physician-owned practices. Physician direct supervision is not needed to administer physical therapy services. In fact, an increase in number of physician-owned clinics are using **their Reassignment of Benefits laws to collect in order to circumvent Incident 2 requirement.**

In closing, I would like to thank you, Mr. Weems for your consideration of my comments.

Sincerely,

Michael P. Miller PT

Michael P. Miller, Physical Therapist

8-28-07

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

Re: CMS-1385-P
Anesthesia Coding

Dear Ms. Norwalk,

I am writing to support the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. When the RBRVS was instituted, anesthesia reimbursement rates were set too low compared to other insurers. Anesthesiologists that work in hospitals with high Medicare populations have either relocated or have become dependent on hospital supplements to maintain a market level income. The correct solution is to raise the anesthesia conversion actor as per RUC's recommendation.

Please feel free to call me at 610 378-2548 with any questions or concerns and thank you for your attention to this matter.

Sincerely,

John G. Goode Jr. MD.

John G. Goode Jr., M.D.

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Edward O. Janosko, MD, FACS*
Benjamin G. Hines, Jr., MD, FACS*
Gregory F. Murphy, MD, FACS*
Dieter Bruno, MD, FACS*
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*Diplomate of the American Board of Urology

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August 20, 2007

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

Dear CMS:

I am writing this letter concerning the July 2, 2007 Medicare fee schedule proposed regulations. I am a urologist who practices in eastern North Carolina at Pitt County Memorial Hospital and have practiced here for 28 years. For the last 19 years I have been an owner and joint venture LLC that provides lithotripsy services to our hospital. Prior to my investment in lithotripsy patients with stone disease underwent open surgical procedures and since that time patients have been treated very well with lithotripsy and have enjoyed the benefits provided by that. Since our lithotripsy partnership is associated by giving care to the hospital and is associated with other urologists we have been able to provide advanced technology and we are actually able to switch from a bath lithotripsy (the original Dornier) to updated Siemen's lithotripters. We have been able to update our lithotripsy equipment because of the volume of services and have provided improved patient access.

Our lithotripsy partnership also has QA and outcome programs and has published in the Journal of Urology. We also have a review at the hospital to assure that patients are appropriately selected and treated for lithotripsy. Therefore there are two areas in which quality control is maintained – at the hospital level and also at the lithotripsy partnership level.

I would like to address the significant concerns that I have concerning the proposed regulations. In regard to arrangements contracting, the LOC that we have contracts with area hospitals in eastern North Carolina and contracts with our hospital. Because of this the physicians who actually see the patients are able to treat their own patients at their own hospital. Since this lithotripsy partnership treats many hospitals we are able to afford the updated quality equipment. I believe that if each hospital had to buy a lithotripsy unit it would soon outdate and the quality would not be as good. I live in a very underserved area and this mobile unit provides access to our patients in underserved areas who cannot afford the latest technology, and many patients in our area cannot even drive to bigger centers. Our mobile units lower hospital costs by sharing expensive equipment among the different hospitals. I would request that the government clarify that because of American Lithotripsy vs. Thompson case lithotripsy not be designated as DHS service under STARK and that our LOC cannot be deemed performing a DHS or a claim submitted for DHS. I would like the government to clarify that these services are not DHS but performed outside the hospital in a lithotripsy center.

CMS is also concerned about the contracting arrangements with physicians. I would like to point out that lithotripsy services are therapeutic and not diagnostic. There is an indication in performing the procedures based on the underlying medical condition that is usually a kidney stone. So there is no risk, and there has never been a risk of over-utilization. I would welcome CMS to look at our lithotripsy partners and to see the indications of our treatment. Lithotripsy is not a diagnostic test. It is therapeutic and can be best run by the urologists who see the patients and perform this on equipment that we know is up to date and of good quality.

Furthermore, STARK legislation indicates Congress intended arrangements of contracts to only require compensation exception and not ownership exception. I can surely state that many of the patients in our practice are very happy with the arrangements that we have and believe that we provide quality care and only under situations of medical necessity.

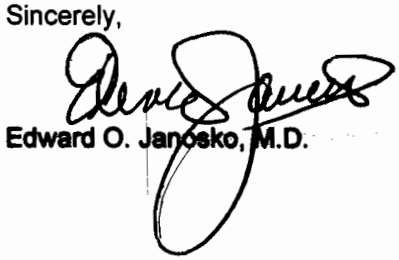
In regard to per procedure fee prohibition they do not often appreciate the benefit of new technology. Purchasing equipment is very difficult to perform and in my experience updated lasers, lithotripsy or whatever are usually leased by the hospitals because they cannot perform enough procedures on their own to justify the purchase of this equipment, nor can they update it because they cannot predict volume. Physicians understand the technology and the risks per se, and these partnerships provide care where a small volume would not allow capital purchases of this equipment, or equipment to be leased on a monthly basis but rather by per procedure. I would seek confirmation of the per procedure fee prohibition and would not apply to the STARK indirect compensation arrangement by our lithotripsy.

I would like to comment on percent fee prohibition. Percent fee prohibition is set in advance and is a requirement of many STARK exceptions but it is not in direct compensation and arrangement with exception relied by our LOC. I would like confirmation that the percent fee prohibition would not apply to indirect compensation arrangements. In addition, lithotripsy reimbursement rates may be increased or decreased and payor mixes may change. Percent fee arrangements allow hospital and the venders to share these marketing risks and are often preferred by the hospitals. This arrangement assures that the hospital will never make an equipment rental payment greater than what it collects for the service, even from the lowest cost insurer.

I would like to comment on the stand in shoes provision. Looking at the approved procedure list it does not allow for reimbursement of STARK DHS procedures so STARK should not be implicated by a physician LOC contracting with an ASC. ASC's are lower cost in providing services. This should encourage them to contract with ASC's regardless of ownership control if the result is saving the Medicare program. This prohibition would deter a physician with hospitals to form ASC's.

I believe that lithotripsy would never have come to the American public were it not for physicians from LOC's to provide this service their patients. I have been in practice long enough to realize that when lithotripsy came along nobody wanted to take a risk and nobody would believe that this machine could crush kidney stones. I believe this is true for other areas in medicine including lasers and thermo-therapies. Our LOC has been very successful in providing care with the least cost to the patients in eastern North Carolina, a very rural area, that I believe would be lost without our lithotripsy partnership. We provide excellent care to patients whether they can pay or not, to Medicaid and Medicare, and all sorts of patients who need to have stones removed by lithotripsy treatment. I strongly encourage the CMS to answer my clarifications and to allow limited partnerships to continue providing this excellent care in the area of our country.

Sincerely,



Edward O. Janosko, M.D.

EOJ/sj

xcs: **Congressman Walter B. Jones**

Senator Elizabeth Dole

Senator Richard Burr

Carolina Lithotripsy
2014 Litho Place
Fayetteville, NC 28304

Ms. Robin Hudson
AUA Manager of Regulatory Affairs

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ENID
THERAPY CENTER
Physical Therapy & Hand Rehabilitation

August 29, 2007

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

RE: Physician Office PT/OT Services

Dear Mr. Weems;

I am writing this letter to express my concern regarding the in-office ancillary service arrangements that have impacted the delivery of quality Physical and Occupational Therapy.

Often, patients are not made aware that they have options regarding which physical therapy clinic to utilize. They are often referred specifically by the physician to the in-office P.T. facility that is owned by the same physician. Since physicians achieve financial gain this way, this practice will likely continue, despite free-standing clinics' attempts to educate the patients on their choices.

Thank you for considering these comments.

Sincerely,

Kayli Means P.T.
Kayli Means, PT

Lynelle E. Fleming P.T., C.H.T.
Kayli Means, P.T.
1900 W. Willow
Enid, Ok. 73703
(580) 233-1667
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792

amcno

2007 AUG 31 AM 10: 04

August 15, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Department of Health and Human Services
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Physician payment localities in Ohio

Dear Ms. Norwalk:

As the Vice President of Legislative Affairs for the Academy of Medicine of Cleveland & Northern Ohio (AMCNO), a regional organization representing more than 4,400 physicians in the Northern Ohio area, I am writing to you on behalf of the organization to provide our comments about the payment localities in Ohio.

Due to the fact that our membership base encompasses mainly the Northern Ohio area, our organization is concerned about the geographic areas used to adjust physician payments in Ohio. The AMCNO physician leadership recently commented on the CMS proposed rule CMS-1385-P (copy enclosed.) As you can see from our letter, the AMCNO is of the opinion that payment locality changes should be considered in Ohio.

As a part of our review of this matter, the AMCNO physician leadership evaluated a copy of the recent GAO Report GAO-07-466. Your response to this report indicated that CMS has looked for support from an impacted state, such as from a State medical association, before proposing to make changes to payment localities in a state. The AMCNO has commented on this and other issues of concern to us in the attached letter to CMS. In addition, your response to the GAO report indicated that CMS "will consider payment locality issues when concerns are raised by interested parties." Please consider this letter and the attached response to the proposed CMS rule as areas of concern raised by an interested party – specifically the physicians from Northern Ohio and the members of the AMCNO. I look forward to your response.

Sincerely,

John A. Bastulli, M.D.
Vice President of Legislative Affairs

Enclosures

Cc: Mr. Herb Kuhn, Director, CMS Center for Medicare Management ✓

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SOUTH CAROLINA
SKIN CANCER CENTER

JAMES R. DEBLOOM II, M.D., P.A.
Associate, American College of
Mohs Micrographic Surgery
& Cutaneous Oncology

MOHS
MICROGRAPHIC SURGERY

August 30, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

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

Dear Acting Administrator Kuhn:

As a fellowship trained Mohs Surgeon who specializes in the treatment of skin cancer in the state of South Carolina I am deeply concerned by the proposed Multiple Payment Reduction for Mohs Surgery. In my opinion this reduction is not justified and will result in a dramatic shift in treatment patterns for skin cancer. This treatment pattern shift will result in substandard care for patients and an increased net cost to Medicare.

Currently when a patient is seen in my office, I have the ability to treat their skin cancer in a single visit while also performing all necessary reconstruction. This allows the patient to have their removal, pathology and repair all performed in a single visit thus saving Medicare the additional costs of pathology fees, additional reconstructive surgeon's consult fees, hospital/facility fees and anesthesia fees. With the proposed Multiple Procedure Reduction I will not be able to justify the cost in time and materials to perform my patient's reconstruction. That is why many surgeons, including myself, will simply refer many reconstructions to hospital based plastic surgeons, thus dramatically increasing the net cost of skin cancer treatment to CMS. In addition, we will be burdening our elderly population with additional office visits and delayed medical care.

Secondly, there is no significant justification for the Multiple Procedure Reduction with Mohs Surgery. Each skin cancer that is treated via the Mohs technique requires complete repeated performance of each aspect of the procedure. When a second skin cancer is treated on a patient there is no less time and cost spent on the second lesion than the first.

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The second cancer requires just as much prep and surgical time. The second skin cancer specimen requires the same amount of time and cost in its laboratory technical processing and the second set of slides produced for the second cancer requires the same amount of time to read and analyze. Essentially the Multiple Procedure Reduction reimburses the Mohs surgeon at 50% for an activity that entails 100% reproduction of their time and their lab's time and costs.

The financial ramifications of this reduction will result in the delay of treatment of skin cancer. Surgeons will be forced to address only one skin cancer with each visit and thus additional cancers will be treated at a later date. This delay in treatment will most importantly put patients at risk, but will also have significant negative financial ramifications for Medicare. The delay in treatment caused by the Multiple Procedure Reduction will result in:

i. larger tumors requiring greater number of layers for tumor clearance and increase in the utilization of the 17312, 17314 and 17315 codes
ii. larger tumors that will require reconstruction with both flaps and grafts rather than less expensive linear closures or "no cost" secondary intention healing.
iii. an increase in the number of secondary referrals for reconstruction resulting in increased hospital, facility and consult fees.

Overall, in my humble opinion, the implementation of the Multiple Procedure Payment Reduction for Mohs Surgery will have a negative impact on patients, physicians and Medicare. I don't see how anyone benefits from this proposal. That is why I would like to ask CMS to reconsider their decision to apply the multiple reduction code to the Mohs codes and instead preserve the long standing exempt status of Mohs Surgery.

Sincerely,

James R. DeBloom, II. M.D.
President, South Carolina Skin Cancer Center

SOUTH CAROLINA SKIN CANCER CENTER
MOHS MICROGRAPHIC SURGERY

SOUTH CAROLINA
SKIN CANCER CENTER
JAMES R. DEBLOOM II, M.D., P.A.
Associate, American College of
Mohs Micrographic Surgery
& Cutaneous Oncology

Fax Cover Sheet

Date: 8.31.07

Time: 1:00 pm

From: James R. DeBloom II, MD

To: Whom it May Concern

Fax Number: 202.690.6262

Number of pages including cover sheet: 3

Regarding: CMS - 1385-P "Multiple Procedure Payment Reduction for Mohs Surgery"

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Gundersen Lutheran

August 30, 2007

Department of Dermatology
James C. Baumgaertner, M.D.
James D. Hogan, M.D.
Jerry J. Miller, M.D.
Kurt K. Mueller, M.D.
Karl R. Noll, M.D.
Alexia M. Passe, M.D.
Darius E. Wampler, M.D.
Stephen B. Webster M.D.

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201

Phone: 202-690-6726
Fax: 202-690-6262

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

Dear Acting Administrator Kuhn

I am a practicing Mohs surgeon serving a large rural population in southwestern Wisconsin. I am writing on behalf of myself, as well as many rural patients who travel as much as 200 miles or more round trip to visit our clinic.

I am certain that you are well aware of the longstanding history of exemption and the rational behind that and will not review that again; although, I certainly do ask that you consider that. On a more human note, I am asking that you consider the needs of skin cancer patients across the country and particularly our rural elderly for whom the expenses as well as logistics of travel create daily difficulties. It is a great benefit for me to be able to treat two, three, or even four or more cancers on these patients on the same day, and it would be disheartening to begin telling them that they have to make multiple trips for something that certainly could be managed more conveniently.

I ask that you consider the time, effort, and support necessary to treat individual cancer separately, whether it be on one visit or multiple visits. Additionally, I would ask that you consider issues facing many of our patients across the country and support their need to have medical care handled in a timely and efficient manner.

Many thanks for your consideration of this issue.

Best wishes.

Sincerely,

Kurt K. Mueller

Kurt K. Mueller, M.D.

KKM:amh

Gundersen Lutheran

Department of Dermatology
James C. Baumgaertner, M.D.
James D. Hogan, M.D.
Jerry J. Miller, M.D.
Kurt K. Mueller, M.D.
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Stephen B. Webster, M.D.

DEPARTMENT OF DERMATOLOGY
FACSIMILE COVER SHEET

DATE: 8-31-07

TO: The Honorable Herbert Kuhn

FAX NUMBER: 202-690-6262

FROM: Kurt K. Mueller MD/Amc

GUNDERSEN LUTHERAN MEDICAL CENTER
DEPARTMENT OF DERMATOLOGY
FOUNDERS BUILDING
(608) 782-7300 OR 1-800-362-9567, EXTENSION 52291
FACSIMILE NUMBER: (608) 775-6361

NUMBER OF COPIES BEING TRANSMITTED, INCLUDING COVER SHEET 2

Remarks or special instructions:

Rajiv Kwatra, M.D.
Mohs Surgery, Dermatologic Surgery
Fellowship Trained, Board Certified

The Honorable Herbert Kuhn
Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

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

Dear Acting Administrator Kuhn

I am writing this letter to express my deep my concern regarding the proposed removal of the Mohs Surgery codes from the MPPR exemption list. I believe this proposed rule change, if allowed to go into affect, will adversely affect the healthcare of U.S. citizens while increasing costs at the same time. I am a Mohs surgeon (Skin Cancer Specialist) and as this will have a very negative impact primarily for my patients I am hoping you can prevent this.

Here in Arizona we have the second highest rate of skin cancer in the world second only to Australia. Mohs micrographic surgery is the gold standard (cure rate of 98-99%) among treatments for skin cancer. As a brief review, these are steps involved in the process to treat **each** skin cancer. The Mohs surgeon removes the obvious skin cancer and the tissue is processed in the lab that is at the office. After it is processed in the lab, the Mohs surgeon examines 100% of the cancer margin. If there is any cancer left, it is carefully mapped and more tissue is removed only where there is still cancer present. This process is repeated until all the cancer has been removed. Once the removal is complete, the area is reconstructed (stitched) or allowed to heal naturally. There is very little overlap between any of the procedures we perform on a single patient. If I treat two skin cancers, it only requires a little extra time if these are located on two different patients. If they are located on the same patient, some time is saved in checking in and checking out the patient but the work required to remove each cancer is more or less the same. Each has to be evaluated and removed in the manner that is best suited for which type of skin cancer it is and where it is located. The Pathology portion of the process has absolutely no overlap at all as each has to be processed and evaluated independently. I allow a very high percentage of areas to heal by secondary intention (heal naturally) because that is the best option for the patient. It also happens to be extremely cost effective. If a reconstruction is performed, it requires the evaluation of the defect as to which way is best, discussing this with the patient., prepping the site for reconstructive surgery, and the setting up of a whole new sterile surgery tray. Frankly, if I referred the patient out to a plastic surgeon for the reconstruction, it would require roughly the same time for them to do all this for the reconstruction. There would be some additional time required to check the patient in and out. However, it would cost at least 3 to 4 times as much as plastic surgeons usually do their reconstructions in the outpatient OR while we do it in the office. The Outpatient OR is a costly environment

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Rajiv Kwatra, M.D.
Mohs Surgery, Dermatologic Surgery
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just by the nature of it. There is a plastic surgeon, an anesthesiologist, and the facility which all will submit their claim.

This rule change will result in many patients having their skin cancers treated one at a time as the reduction will make it prohibitive to treat multiple sites on a single patient. More patients will be referred to plastic surgeons for reconstruction as the reduction will make this prohibitive to do in the office in many patients.

This rule change does not make any sense to me. There is little work overlap in treating each skin cancer or reconstructing a site after the skin cancer is removed. It will inevitably result in unintended increased costs to the healthcare system. Worst of all, it will have the greatest adverse impact on patients who are the most vulnerable in society—seniors with multiple skin cancers with transportation difficulties and transplant patients with multiple aggressive skin cancers.

The exemption of the Mohs codes from the MSRR has been maintained by CMS since 1992 and was not questioned during the CMS mandated five-year review of the Mohs codes undertaken last fall or during presentation of the new Mohs codes to the AMA Relative Value Update Committee (RUC) in October, 2006. Nothing has changed since 1991.

I would ask you to please consider this in your decision making. What you decide will have a tremendous impact on the care of many people. I realize that we live in a time where reducing healthcare costs is critical. However, Mohs Surgery is part of the solution, not the problem. Not only is the cure rate higher with Mohs surgery, It cost approximately 70-75% less to treat a skin cancer at a Mohs Surgeon's office than it does if the patient is treated by a physician in the outpatient OR. Leaving apart the fact that the proposed rule change conflicts with the well known requirements for exemption, this change if allowed to occur will result in decreased quality of care while increasing the costs at the same time. No matter how one looks at it, this proposed change to the application of the Multiple Procedure Rule to Mohs Surgery should be rejected. I hope you will find my letter to be clearly reasoned and of some assistance as you make your decision. We will all of course respect whatever decision you make, but I felt the need to share my thoughts with you as I feel very strongly about this issue. Thank you for taking time to consider my concerns.

Sincerely,

Rajiv Kwatra M.D.

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1331 North 7th Street, Suite 290
Phoenix, Arizona 85006
Phone (602) 230-6744
Fax (602) 230-6746

DATE: 8.31.07

TO: Honorable Herbert Kuhn

FAX: 202 690 6262

RE: MPLR Exception Mohs Surgery

FROM: Dr. R. Kwatra

NUMBER OF PAGES (including transmittal page): 3

MESSAGE:

If you do not receive the above number of pages indicated, or if there is any problem with transmission, please contact us at (602)230-6744.

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August 31, 2007

John K. Geisse, M.D
Diplomate, American Board of Dermatology
Diplomate, American Board of Pathology in Dermatopathology

Serena M. Cruz, M.D.
Diplomate, American Board of Dermatology
Diplomate, American Board of Internal Medicine

Christine Kilcline, M.D.
Diplomate, American Board of Dermatology
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Karl R. Beutner, M.D., Ph.D.
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Terri Nutt, M.D.
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John H. Alexander, PA-C
General Dermatology

Kyle J. Goleno, PA-C
Dermatologic Surgery

Margaret Nonato, PA-C
General Dermatology

Amy Goleno
Practice Administrator

Centers for Medicare and Medicaid Services
Dept. of Human Health and Human Services
Washington, DC 20201

Dear Sirs:

I am writing as the referral-based Mohs surgeon performing numerous important skin cancer surgeries on Medicare beneficiaries daily. This tissue-sparing procedure leads to higher cure rates with smaller wounds resulting in less expense ultimately to Medicare and less morbidity to the patient than standard surgery.

The proposed inclusion of the Mohs surgical codes (17,000 CPT codes) will result in our inability to offer this valuable service to many such patients because it will be reimbursed below our cost to deliver the services.

Please reconsider including the Mohs surgical codes in the multiple procedure payment reduction modifiers as it will only increase the cost of care to your beneficiaries and increase the morbidity of delivering that care.

Sincerely,

John K. Geisse, MD

JKG/ls

PEDIATRIX MEDICAL GROUP OBSTETRIX MEDICAL GROUP

August 29, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave. SW, Room 314G
Washington, DC 20201

RE: CMS–1385–P: CODING – ADDITIONAL CODES FROM FIVE-YEAR REVIEW

Dear Mr. Kuhn:

We want to express our appreciation to CMS for the opportunity provided on August 20, 2007, when representatives from Pediatrix Medical Group and the Department of Pediatrics of the University of Miami met with CMS staff to discuss the proposal to bundle services currently covered by CPT Code 93325 (Color Flow Doppler Echocardiography) into 15 other echocardiography codes. This proposal, should it be implemented as drafted, will have a significant negative impact on the practice of medicine by all pediatric cardiologists regardless of practice setting or affiliation. We are grateful to CMS for the opportunity provided to personally address the concerns shared by the entire pediatric cardiology community regarding this proposal.

At the close of the meeting with CMS staff, we were specifically invited to outline our concerns in writing and further, to outline proposed solutions that will aid in the mitigation and/or resolution of our concerns. We have attached a copy of our initial correspondence to CMS, dated August 1, 2007, which provides our specific concerns as discussed with CMS staff. Please allow today's correspondence to serve as a further statement of our concerns and as a proposal for solutions to this issue.

In developing our recommendations to CMS staff regarding this issue, we considered the extensive efforts by CMS, the interested sub-specialty societies and the CPT Editorial Panel to address an issue specifically associated with utilization of the CPT code combination of 93307, 93320 and 93325 for transthoracic echocardiography services provided to adult patients. We do not believe CMS staff intended the extension of the bundling recommendation that was a result of this process to have the significant adverse impact on the pediatric cardiology community and its patients that will result should the current proposal be implemented.

With this in mind, our recommendations are twofold: (1) Support pediatric cardiology in working through the CPT Editorial Panel for the development of needed new or revised CPT codes for pediatric echocardiography services and (2) Accept the recommendation of the CPT Editorial Panel as the appropriate solution for addressing the issue associated with the to-be-bundled transthoracic echocardiography codes.

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Recommendation No. 1: Support pediatric cardiology in working through the CPT Editorial Panel for the development of needed new or revised codes for pediatric echocardiography services.

In addition to the significant concern within the pediatric cardiology community, it is important to note the strong written objections provided to CMS by the American Academy of Pediatrics and American College of Cardiology to the bundling of CPT Code 93325 as proposed by CMS. When these services are provided in a pediatric population, consideration must be given to the fact that there are no codes that capture the important differences in the work, practice expense and malpractice risk associated with neonates, infants and children and the associated clinical conditions that require additional time, professional expertise and skill.

In addition to the existing codes for patients with congenital heart disease, we believe that new codes should be developed that take these important factors into consideration. Additionally we propose that the codes for congenital heart disease be expanded to include transesophagael and fetal studies in patients with congenital heart disease. Therefore, we will be meeting with the AAP and ACC representatives to discuss new CPT codes that take into consideration patient age, congenital/non-congenital status, and other clinical conditions.

While we understand the role CMS plays in the development of new CPT codes to be primarily one of validation and not formulation, we also feel it is important for CMS to understand our proposed route for bringing the echocardiography codes up to date in light of the significant differences that exist between care provided to the pediatric and adult populations.

Recommendation No. 2: Accept the recommendations of the CPT Editorial Panel and the administrative process currently in progress to address CMS concerns regarding utilization of 93307 with 93325.

During our meeting with CMS, we expressed concern over the variation in administrative due process associated with CMS' greatly expanded proposal. The RUC is scheduled to review the new transthoracic echocardiography code and develop new RVUs for the combined services currently included within CPTs 93307, 93320 and 93325. It would be inappropriate for CMS to bundle CPT Code 93325 into other codes without securing detailed input on clinical practices from the specialty societies and affected physicians. Thus, we recommend that CMS not implement its current proposal and wait to review the results of the RUC's consideration of the bundling of CPT Code 93325 with CPT Codes 93307 and 93320. Care should be taken to ensure that pediatric cardiologists are included in the RUC survey. If they are not included, then any pediatric cardiology application of a new code would, in our opinion, be incorrectly valued.

In summary, we believe the above recommendations address the concerns of CMS staff regarding utilization of the CPT code combination of 93307, 93320 and 93325 while at the same time preventing unnecessary harm to the pediatric cardiology community and its patients' ability to access care. Further, the steps recommended are consistent with the longstanding and effective process for changes to CPT coding and the valuation of services provided.

We respectfully ask you to defer any decision on the current 93325 bundling provision contained in the proposed rule to allow for the development of needed coding revisions in pediatric cardiology that accurately reflect the nature of the additional physician work involved in providing this important service to the pediatric population.

We greatly appreciate your attention to this matter and remain available to you to further discuss these issues.

Sincerely,

Frank M. Galioto, Jr., M.D., FAAP, FACC
Medical Director
Child Cardiology Associates
Fairfax, Virginia
(703) 876-8410

Steven E. Lipshultz, M.D., FAAP, FAHA
Professor and Chairman, Department of Pediatrics
University of Miami Miller School of Medicine
Miami, Florida
(305) 243-3993

Jack Christensen, M.D., M.B.A.
Vice President of Medical Coding
Pediatrix Medical Group
Sunrise, Florida
(954) 384-0175

cc:
Terry Kay, Acting Director of the Hospital and Ambulatory Policy Group
Don Thompson, Deputy Director of the Hospital and Ambulatory Policy Group
Amy Bassano, Director of the Division of Practitioner Services
Edith Hambrick, MD, Medical Officer
Ken Simon, MD, Medical Officer

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PEDIATRIX
MEDICAL GROUP

August 1, 2007

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

Re: CMS–1385–P: CODING - ADDITIONAL CODES FROM 5-YEAR REVIEW

On behalf of Pediatrix Medical Group and its affiliated pediatric cardiology practices, we appreciate the opportunity to comment on CMS' proposed rule "Proposed Revisions to Payment Policies under the Physician Fee Schedule, and other Part B Payment Policies for CY 2008" [CMS-1385-P]. Our comments address the proposed coding change to bundle CPT 93325 (Color Flow Doppler Echocardiography) into codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350, and focus on those aspects of direct concern to pediatric cardiologists and their patients: namely, the lack of administrative due process followed in this instance, the extremely negative impact this regulatory action would have on pediatric cardiology practices, and the potential impact on patient access to care.

Pediatrix is a large national medical group of physicians and advanced nurse practitioners, including over 60 pediatric cardiologists. We provide pediatric subspecialty services, including neonatology, maternal-fetal medicine, as well as cardiology and other services in 32 states and Puerto Rico. Our physicians and other practitioners care for premature and critically ill newborns, sick and injured children, and women with high-risk pregnancies.

First, with regard to the administrative process, we believe it is important to note that the CPT Editorial Panel already recommended earlier this year that a new code be established that would combine 93325 with 93307 and 93320, for implementation in 2009. The RUC is scheduled to evaluate the recommended relevant work and practice expense for this new code at its next upcoming meeting. Importantly, the CPT editorial panel did not recommend bundling 93325 with other echocardiography base codes, other than 93307.

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

However, as a result of this proposed rule to bundle 93325 into CPT codes other than those recommended by the RUC/CPT Editorial Panel, the 93325 bundling issue now directly impacts a distinctly non-Medicare population – namely, pediatric cardiology practices. Further, because the proposed regulation runs contrary to the normal administrative process followed for such changes, specialty societies have not been able to evaluate the proposed change and its impact on pediatric cardiology and develop appropriate new Work and Practice Expense proposals for consideration by the RUC.

Our second concern focuses on this issue: namely, the extremely adverse impact this proposal will have on pediatric cardiology. The surveys performed to set the work RVUs for almost all of the echo codes utilized specifically by pediatric cardiologists and affected by this proposed change were performed more than 10 years ago. As a result, particularly with respect to 93325, the RVUs are reflective of a focus on the cost of the

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technology and not the advances in care that have been developed as a result of the technology. Particularly among pediatric cardiologists, new surveys are needed which we believe would show that the work and risk components of the procedures that involve Doppler Color Flow Mapping have evolved to the point where the relative value of the procedures have shifted to a significantly greater work component and a lesser technology component.

This shift is reflected in the development of national standards such as those present in the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) initiative to develop and implement an echo lab accreditation process. The focus of this initiative is on 'process', meaning work performed, and not on the 'technology' associated with the provision of echocardiography services. This echocardiography accreditation initiative will be mandated by many payors within the next year.

In 1997 there were specific echocardiography codes implemented in CPT for congenital cardiac anomalies to complement the existing CPT codes for echocardiography for non congenital heart disease. "The codes were developed by the CPT Editorial Panel in response to the American Academy of Pediatrics and the American College of Cardiology's request to delineate more distinctively the different services involved in *assessing* and *performing* echocardiography on infants and young children with congenital cardiac anomalies." *(CPT Assistant 1997).*

Consistent with this, we are concerned with proposals that place adult and pediatric patients in the same grouping, as it pertains to evaluation of the work associated with providing care to these significantly different patient populations. Because the adult cardiology population is much larger than the pediatric population, the RVUs for procedures that are common to both are established exclusively using adult patients as the basis. The Work and Practice Expense associated with providing care to pediatric patients is not considered. The inaccuracies that result from this approach can be linked to anatomical differences between pediatric and adult patients (size, development, etc. - see references from the CPT Assistant below) as well as the basic issue of getting a child to be still while performing complex imaging procedures. Examples follow:

CPT Code 93325 describes Doppler color flow velocity mapping. This service is typically performed in *conjunction* with another echocardiography imaging study to define structural and dynamic abnormalities as a clue to flow aberrations and to provide internal anatomic landmarks necessary for positioning the Doppler cursor to record cardiovascular blood flow velocities.

Pediatric echocardiography is unique in that it is frequently necessary to use Doppler flow velocity mapping (93325) for diagnostic purposes and it forms the basis for subsequent clinical management decisions. CPT Assistant in 1997 references the uniqueness of the 93325 for the pediatric population stating that Doppler color flow velocity is "... even more critical in the neonatal period when rapid changes in pressure in the pulmonary circuit can cause significant blood flow changes, reversals of fetal shunts and delayed adaptation to neonatal life." It should also be recognized that Doppler flow velocity mapping is an essential medical service being provided to patients with congenital and non-congenital heart disease in the pediatric population.

The following vignettes will illustrate the importance of the Doppler color flow velocity mapping (93325) remaining as a separate and distinct medical service and as an add-on code (+) for pediatric echocardiography services. These are just a few examples of the many complex anatomic and physiologic issues that we as pediatric cardiologists face on a daily basis when performing echocardiograms on infants, children, and adults with complex congenital or non-congenital heart disease. These are not unusual cases for us.

PEDIATRIX
MEDICAL GROUP

Vignette 1 (*quoted from CPT Assistant 1997*) (example of Congenital Heart Disease)

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

Vignette II (example of non-congenital heart disease)

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

Vignette III (example of congenital heart disease)

An eight year-old child (or a 23-year-old young adult), with complex cyanotic congenital heart disease (functional single ventricle) is post-op completion of a fenestrated Fontan procedure several years ago. He has had a progressive decrease in saturations over the last year. There are several possible explanations and the pediatric cardiologist performs an echocardiogram to help determine the etiology. Color flow Doppler (93325) is essential to help elucidate the postoperative anatomy and blood flow patterns, but the process is complex and time-consuming involving assessment of the surgically constructed lateral tunnel or extracardiac conduit searching for a residual fenestration shunt or obstruction to flow, assessment of flow patterns through the previously surgically constructed Glenn anastomsis between the superior vena cava and pulmonary artery, assessment for obstruction to flow through the bulboventricular foramen, assessment for significant AV valve or semilunar valve insufficiency, and assessment for collateral vessels directing venous (desaturated blood) into the heart that may have developed over time. Any or all of these findings will then help dictate the next step in the care of this patient.

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

1301 Concord Terrace, Sunrise, FL 33323
954.384.0175 800.243.3839

PEDIATRIX
MEDICAL GROUP

On behalf of Pediatrix Medical Group and its 60+ cardiologists, we respectfully urge CMS to withdraw the proposed change with respect to bundling 93325 with other pediatric cardiology echocardiography codes until such time as an appropriate review of all related issues can be completely analyzed. Once this review is completed an appropriate solution can be developed.

Thank you for your consideration of this serious matter.

Sincerely,

Reginald Washington, M.D., FAAP, FACC, FAHA
Rocky Mountain Pediatric Cardiology
Denver, Colorado
(303) 860-9933

Frank M. Galioto, Jr., M.D., FAAP, FACC
Child Cardiology Associates
Fairfax, Virginia
(703) 876-8410

John McCloskey, M.D., FAAP, FACC
Northwest Children's Heart Care
Tacoma, Washington
(253) 396-4868

Ken Shaffer, M.D., FAAP, FACC
Children's Cardiology Associates
Austin, Texas
(512) 454-1110

799

Preparing People to Lead Extraordinary Lives

LOYOLA
UNIVERSITY
CHICAGO

Steven Jay Goulder, M.D.
Chief, Dermatologic Surgery
Assistant Professor, Division of Dermatology
Mohs Surgery and Skin Cancer

Medical Center Campus
2160 S. First Avenue
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18269 Summit Road
Oakbrook Terrace, Illinois 60181
Patient Appointments: (708) 216-8363
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August 27, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201

Dear Acting Administrator Kuhn:

I appreciate this opportunity to offer comment on Section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule. I wish to comment on the proposed rule regarding the explicit withdrawal of the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures as this will have a significant negative impact

STEVEN J. GOULDER, M.D., F.A.A.D.

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Unit 905
Chicago, IL 60610

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FAX COVER SHEET

SEND TO: CMS	FROM: Steve Goulder, MD
ATTENTION: Honorable Herbert Kuhn	OFFICE LOCATION:
OFFICE LOCATION: Centers for Medicare	DATE: 8-29-07
FAX NUMBER: 202 690 6262	PHONE NUMBER: 312 498 4409

☑ URGENT ☐ REPLY ASAP ☐ PLEASE COMMENT ☑ PLEASE REVIEW ☑ FOR YOUR INFORMATION

Total pages, including cover: 4

COMMENTS:

Re.: Proposed changes to the Mohs CPT codes for 2008.

ORGANIZATION

799attachment

Preparing People to Lead Extraordinary Lives

LOYOLA
UNIVERSITY
CHICAGO

Steven Jay Goulder, M.D.
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August 27, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201

Dear Acting Administrator Kuhn:

I appreciate this opportunity to offer comment on Section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule. I wish to comment on the proposed rule regarding the explicit withdrawal of the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures as this will have a significant negative impact on the healthcare of U.S. citizens and potentially add unnecessary cost to the delivery of healthcare in this country.

As you are probably aware, over a million Americans per year are diagnosed with skin cancer, and over the last ten years the rate of new skin cancer diagnoses is growing by what many would call epidemic proportions. Mohs micrographic surgery is a common way of treating some of these cancers and is considered the gold standard among treatments for skin cancer, allowing the physician to examine 100% of the cancer margin to insure complete removal of the cancer with loss of as little normal skin as possible. It also provides the patient with the highest cure rate of any treatment for skin cancer. Mohs surgery is an outpatient procedure that utilizes onsite laboratory analysis of excised tissue while the patient waits for the results.

This proposed change will negatively impact the care of our patients and could add significant cost to an already stressed healthcare budget. This planned change is a departure from a longstanding exemption agreed to by CMS and virtually all private insurance carriers since 1991. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; ***such a decrease in reimbursement would not cover the cost of providing the service*** and possibly lead to the collapse of our institution's ability to provide the most effective care for our skin cancer patients.

If this proposed change is enacted, we will no longer be able to provide the same kind of high-quality, cost-effective services for our patients in need. I predict that skin cancer

surgeons will be forced to change the way they deliver care in order to cover their costs of providing this service.

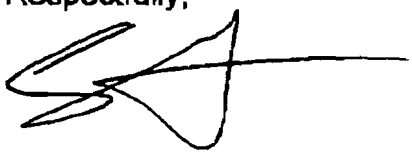
The Final Rule that CMS agreed upon in the 1992 Medicare Fee Schedule that Mohs Surgery for skin cancer removal and subsequent reconstruction of the resultant defect involve, "a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures...They will be paid separately with no multiple surgery reductions." This is still correct and holds true today. **Mohs surgery is not simply an excision of a skin cancer.** Rather it is composed of several processes including: 1 removal of the tumor by the surgeon 2. precise mapping of the removed tissue performed by the Mohs surgeon to accurately trace the roots of the tumor, 3. processing of microscope slides of the removed tissue performed by a Mohs histo-technologist in an on-site Mohs Laboratory and 4. the reading of the microscope slides by the Mohs surgeon and mapping of the tumor roots. Mohs surgeon serves the role of surgeon by removing the cancer *and* the role of pathologist. In this way, Mohs surgery is unique in that it includes the two components of surgery and pathology, both of which are entirely performed by the Mohs surgeon, with the pathology component comprising half of the service. By its very nature, the entire procedure of Mohs surgery (including the processing and interpretation of histology slides) must be completed before any consideration is given to the excision of additional tissue or repair of the resulting defect. RUC acknowledge that the intra-service work for 17311 to be 80% for the total physician work of the procedure including surgery and pathology. When Mohs surgery is performed on two different sites (two different cancers) for a patient on the same date there is no overlap in work, as each requires the components of excision and tissue processing/ interpretation. There is no separate pathology fee - thus part of the Mohs fee must also cover the costs to run the on-site laboratory. The proposed reduction would not cover such costs.

Once the tumor is fully extirpated, the patient is left with a skin defect that typically requires reconstruction. When this is performed on the same day as Mohs Surgery, there again is no overlap. There is an onsite waiting period (often one hour or more) required during Mohs for the pathology component of the procedure. If a repair is required, the patient must return to the operating room, be repositioned, re-anesthetized, and re-prepped before the separate reconstruction can begin. New instrumentation is used for the repair and thus there is zero overlap of work, practice expense, labor time, medical supplies or medical equipment between the Mohs procedure and a repair procedure. They are separate procedures. Thus it is inappropriate to subject 17311 and 17313 to the multiple procedure reduction rules for repairs performed on the same day as Mohs surgery or for Mohs excisions performed on a patient's different skin cancers performed on the same day.

As nearly 10% of skin cancer patients present with more than one skin cancer on the day of surgery, this proposed rule would negatively affect Medicare patients' access to timely and quality care. Application of the proposed rule to a second tumor treated on the same day will mean that the reimbursement for the second procedure does not cover the cost of providing the service. This will most affect the Medicare population as the incidence of skin caner peaks in this age group. It will also pose a significant risk to our immunosuppressed patients (organ transplant patients, patients undergoing chemotherapy, etc) who are not only at a higher risk of skin cancer but who are also at risk for metastases and possibly death from skin cancer.

I am concerned primarily about being able to continue to provide the most optimal, cost-effective care for my patients; if this unexpected change is allowed to take effect that will no longer be possible. I therefore, respectfully request reconsideration of the proposed rule.

Respectfully,



Steven Jay Goulder, M.D., F.A.A.D.
Chief, Dermatologic Surgery
Director, Skin Cancer Program
Loyola University Chicago

800

August 30, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201 FAX (202)690-6262

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

Dear Administrator Kuhn,

I am deeply concerned about the proposed removal of the Mohs micrographic surgery codes from the MPRR exemption list scheduled to occur in January, 2008.

Mohs surgery has a higher cure rate for skin cancer than any other procedure, and has made a huge impact on the well-being of my patients. It is the single most effective procedure in treating skin cancer, but is also very labor-intensive for the physician, who acts as both surgeon and pathologist. It offers many advantages to patients: Besides having the highest cure rate compared to other types of excisions, it sacrifices minimal normal adjacent tissue, which often has significant functional and cosmetic impact for the patient. In addition, once the removal of the cancer is complete, the surgical defect can be repaired the same day, which is much more convenient for the patient than having to go to another doctor or return on a different day for reconstruction.

If the proposed MPRR change goes into effect, there will be a very stong incentive to not repair the defect on the same day. Many patients will probably be referred to other surgeons who would repair the defect the same day, but are not Mohs-trained, and would perform a traditional excision with the associated higher recurrence rate. **This would truly be a great step backwards in our treatment of skin cancer.**

As a fellowship-trained Mohs surgeon, my sole purpose is to eradicate skin cancers as efficiently as possible. If the MPRR change does occur, it will greatly hinder my ability to provide high-quality care to my patients. Over the country as a whole, I know that more patients would end up having traditional excisions and other obsolete treatments for skin cancer and suffer more recurrences, metastases, and even death (squamous cell skin cancer is the third leading cause of death of organ transplant patients – one of the most important groups of patients requiring Mohs surgery for skin cancer). These substitute procedures **would actually result in INCREASED COST** due to the increased recurrence rates and use of operating rooms (where many surgeons perform traditional excisions and reconstructions such as flaps and grafts, in contrast to Mohs surgeons who primarily perform these procedures in the office) and general anesthesia (same reason).

I would like to add my voice to my 800 fellowship-trained colleagues, respectfully requesting that you re-examine this decision, and the impact it will have on all patients with skin cancer and our medical system.

Most Sincerely,

Paul H. Bowman, M.D.
Member, American College of Mohs Surgery

FACSIMILE TRANSMITTAL FORM

Date/Time: **8/31/2007, 4:17:27 PM**

Pages: **2**

Subject:

To: **Administrator Herbert Kuhn**

Fax Number: **12026906262**

From: {Sender's Name}

From: **Paul H. Bowman, MD PA**

Fax Number: **813-977-3886**

Business Phone: **813-977-2040**

Company: **Paul H. Bowman, MD PA**

NOTE: PLEASE CALL **813-977-2040** IF DOCUMENTS ARE INCOMPLETE OR NOT LEGIBLE.

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Lawrence-Douglas County Fire Medical
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Lawrence, KS 66046
Office 785-830-7000
Fax 785-830-7090
lawrencefiremed.org

August 24, 2007

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

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008.

Dear Ms. Norwalk:

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

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

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

We understand that the proposed rule was inspired by the intention to relieve the administrative burden for EMS providers. However, the "relief" being proposed by CMS would have the unintended effect of increasing the administrative and compliance

burden on ambulance services and the hospitals and would result in shifting the payment burden to the patient if they fail to comply with the signature requirements at the time of incident. Accordingly, we urge CMS to abandon this approach and instead eliminate entirely the beneficiary signature requirement for emergency ambulance services.

CURRENT REQUIREMENT

When the beneficiary is physically or mentally incapable of signing, the industry has been following the requirements listed in the CMS Internet Only Manual, Pub. 100-02, Chapter 10, Section 20.1.2 and Pub. 100-04, Chapter 1, Section 50.1.6(A) (3) (c). These sections allow for a representative of the ambulance provider or hospital to sign on behalf of the beneficiary when the patient is unable to sign, document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary.

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

BENEFICIARY UNDER DURESS SHOULD NOT BE REQUIRED TO SIGN ANYTHING

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

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

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

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

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

While the intent of the proposed exception is to give ambulance providers explicit relief from the beneficiary signature requirements where certain conditions are met, we note

that the proposed exception does not grant ambulance providers any greater flexibility than that currently offered by existing regulations. Specifically, 42 C.F.R. §424.36(b)(5) currently permits an ambulance provider to submit a claim signed by its own representative, when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf. The proposed exception essentially mirrors the existing requirements that the beneficiary is unable to sign and that no authorized person was available or willing to sign on their behalf, while adding additional documentation requirements. Therefore, we believe that the new exception for emergency ambulance services set forth in proposed 42 C.F.R. §424.36(b)(6) should be amended to include only subsection (i), i.e. that no authorized person is available or willing to sign on the beneficiary's behalf.

It is important for CMS to realize that the first two requirements in the proposed sub-division (ii) are always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. For this reason, we do not object to the requirement that an ambulance provider obtain documentation of the date, time and destination of the transport. Nor do we object to the requirement that this item be maintained for 4 years from the date of service. However, we do not see any reason to include these in the Regulation, as they are already required and standard practice.

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

- Instead of alleviating the burden on ambulance providers and suppliers, an additional form would have to be signed by hospital personnel.

- Hospital personnel will often refuse to sign any forms when receiving a patient.

- If the hospital refuses to sign the form, it will be the beneficiary that will be responsible for the claim.

- The ambulance provider or supplier would in every situation now have the additional burden in trying to communicate to the beneficiary or their family, at a later date, that a signature form needs to be signed or the beneficiary will be responsible for the ambulance transportation.

- Every hospital already has the information on file that would be required by this Proposed Rule in their existing paperwork, e.g. in the Face Sheet, ER Admitting Record, etc.

We also strongly object to the requirement that ambulance providers or suppliers obtain this statement from a representative of the receiving facility at the time of transport. Since the proposed rule makes no allowances for the inevitable situations where the ambulance provider makes a good faith effort to comply, but is ultimately unable to obtain the statement, we believe this requirement imposes an excessive compliance burden on ambulance providers and on the receiving hospitals. Consider what this rule

requires—the ambulance has just taken an emergency patient to the ER, often overcrowded with patients, and would have to ask the receiving hospital to take precious time away from patient care to sign or provide a form. Forms such as an admission record will become available at a later time, if CMS wants them for auditing purposes in addition to the trip transport that will already include date, time and receiving facility.

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

PURPOSE OF BENEFICIARY SIGNATURE

a. Assignment of Benefits –The first purpose of the beneficiary signature is to authorize the assignment of Medicare benefits to the health care provider or supplier. However, assignment of covered ambulance services has been mandatory since April 2002. Furthermore, 42 C.F.R. §424.55(c), adopted November 15, 2004 as part of the Final Rule on the Physician Fee Schedule (67 Fed. Reg. 6236), eliminated the requirement that beneficiaries assign claims to the health care provider or supplier in those situations where payment can only be made on an assignment-related basis. Therefore, the beneficiary's signature is no longer required to effect an assignment of benefits to the ambulance provider or supplier.

   CMS recognized this in the Internet Only Manual via Transmittal 643, by adding Section 30.3.2 to Pub. 100-04, Chapter 1. As a result, the beneficiary signature is no longer needed to assign benefits of covered ambulance services.

b. Authorization to Release Records – The second purpose of the beneficiary signature is to authorize the release of medical records to CMS and its contractors. However, the regulations implementing the HIPAA Privacy Rule, specifically 45 C.F.R. §164.506(c) (3), permit a covered entity (e.g. an ambulance provider or supplier) to use or disclose a patient's protected health information for the covered entity's payment purposes, without a patient's consent (i.e. his or her signature). Therefore, federal law already permits the disclosure of medical records to CMS or its contractors, regardless of whether or not the beneficiary's signature has been obtained.

SIGNATURES NOT REQUIRED FOR ABN'S FOR EMERGENCY TRANSPORTS

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

Almost every covered ambulance transport is to or from a facility, i.e. a hospital or a skilled nursing facility. In the case of emergency ambulance transports, the ultimate destination will always be a hospital. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services or any related services. The term "related services", when used by hospitals and SNFs, can mean more than only entities owned by or part of the facility. The term already includes physicians providing services at the facility. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service", since the ambulance transports the patient to or from that facility for treatment or admission. Therefore, we believe a valid signature will be on file with the facility. Additionally, for those transports provided to patients eligible for both Medicare and Medicaid, a valid signature is on file at the State Medicaid Office as a product of the beneficiary enrollment process.

ELECTRONIC CLAIMS

It is also important to note that, as a result of section 3 of the Administrative Simplification Compliance Act and the implementing regulations at 42 C.F.R. §424.32, with very limited exceptions (e.g. providers or suppliers with less than 10 claims per month), ambulance suppliers must submit claims electronically. Thus, the beneficiary does not even sign a claim form. When submitting claims electronically, the choices for beneficiary signature are "Y" or "N". An "N" response could result in a denial, from some Carriers. That would require appeals to show that, while the signature has not been obtained, an alternative is accepted. As a result, many Carriers allow a "Y", even though the signature was not actually obtained, if one of the exceptions is met.

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

PROGRAM INTEGRITY

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

Signature authorizations requirement should be waived for emergency encounters.

CONCLUSION

Based on the above comments, it is respectfully requested that CMS:

- Amend 42 C.F.R. §424.36 and/or Pub. 100-02, Chapter 10, Section 20.1.1 and Pub. 100-04, Chapter 1, Section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambulance provider or supplier has documented that the beneficiary could not sign and no

one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".

- Amend 42 C.F.R. §424.36 to add an exception stating that ambulance providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.

- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

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

Thank you for your consideration of these comments.

Sincerely,

Mark F. Bradford
Chief

Cc David Corliss, City Manager

NEWPORT BEACH FIRE DEPARTMENT
P.O. Box 1768, 3300 Newport Blvd., Newport Beach, CA 92658-8915

Steve Lewis, Fire Chief

802

August 30, 2007

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

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Dear Ms. Norwalk:

On behalf of Newport Beach Fire Department (NBFD), please accept our comments on the above mentioned proposed rule. NBFD provides 9-1-1 emergency ambulance services to the City of Newport Beach. The proposed rule would have a direct impact on our operation and the high quality health care we provide to Medicare beneficiaries. We, therefore, greatly appreciate this opportunity for public comment.

BENEFICIARY SIGNATURE

NBFD commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements. Ambulance services are atypical among Medicare covered services to the extent that, for a large percentage of encounters, the beneficiary is not in a condition to sign a claims authorization during the entire time the supplier is treating and/or transporting the beneficiary. Many beneficiaries are in physical distress, unconscious, or of diminished mental capacity due to age or illness. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

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

Current Requirement

When the beneficiary is physically or mentally incapable of signing, the industry has been following the requirements listed in the CMS Internet Only Manual, Pub. 100-02, Chapter 10, Section 20.1.2 and Pub. 100-04, Chapter 1, Section 50.1.6(A)(3)(c). These sections require the ambulance provider or supplier to document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary.

Summary of New Exception Contained in Proposed Rule

While the intent of the proposed exception is to give ambulance providers explicit relief from the beneficiary signature requirements where certain conditions are met, we note that the proposed exception does not grant ambulance providers any greater flexibility than that currently offered by existing regulations. Specifically, 42 C.F.R. §424.36(b)(5) currently permits an ambulance provider to submit a claim signed by its own representative, when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf. If "provider" in this context was intended to mean a facility or entity that bills a Part A Intermediary, the language should be changed to also include "ambulance supplier". The proposed exception essentially mirrors the existing requirements that the beneficiary be unable to sign and that no authorized person was available or willing to sign on their behalf, while adding additional documentation requirements. Therefore, we believe that the new exception for emergency ambulance services set forth in proposed 42 C.F.R. §424.36(b)(6) should be amended to include only subsection (i), i.e. that no authorized person is available or willing to sign on the beneficiary's behalf.

It is important for CMS to realize that the first two requirements in the proposed sub-division (ii) are always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. For this reason, we do not object to the requirements that an ambulance provider obtain (1) a contemporaneous statement by the ambulance employee or (2) documentation of the date, time and destination of the transport. Nor do we object to the requirement that these items be maintained for 4 years from the date of service. However, we do not see any reason to include these in the Regulation, as they are already required and are standard practice.

The Proposed Rule would add a requirement that an employee of the facility, i.e. hospital, sign a form at the time of transport, documenting the name of the patient and

the time and date the patient was received by the facility. Our organization **strongly objects** to this new requirement as:

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

We also strongly object to the requirement that ambulance providers or suppliers obtain this statement from a representative of the receiving facility *at the time of transport*. Since the proposed rule makes no allowances for the inevitable situations where the ambulance provider makes a good faith effort to comply, but is ultimately unable to obtain the statement, we believe this requirement imposes an excessive compliance burden on ambulance providers and on the receiving hospitals. Consider what this rule requires—the ambulance has just taken an emergency patient to the ER, often overcrowded with patients, and would have to ask the receiving hospital to take precious time away from patient care to sign or provide a form. Forms such as an admission record will become available at a later time, if CMS wants them for auditing purposes.

Institute of Medicine Report on Hospital Emergency Department Overcrowding

The Institute of Medicine Committee on the Future of Emergency Care recently released a report citing hospital emergency department overcrowding as one of the biggest issues in emergency health care. According to that report, demand on hospital emergency departments (EDs) increased by 26% between 1993 and 2003. During that same period, the number of EDs fell by 425. Combined with a similar decrease in the number of inpatient hospital beds, this has resulted in serious overcrowding of our nation's ED. A further consequence has been a marked increase in the number of ambulance diversions, with 50% of all hospitals—and nearly 70% of urban hospitals—reporting that they diverted ambulances carrying emergency patients to a more distant hospital at some point during 2003.

The report recommended that hospitals find ways to improve efficiency in order to reduce ED overcrowding. However, the requirement that ambulance providers or suppliers obtain a statement from a representative of the receiving hospital at the time

of transport would only compound the existing problem, by adding an additional paperwork burden. To meet this requirement, ambulance crews would be forced to tie up already overtaxed ED staff with requests for this statement. The Institute of Medicine report makes clear that this time would be more efficiently spent moving patients through the patient care continuum.

Purpose of Beneficiary Signature

a. Assignment of Benefits – The signature of the beneficiary is required for two reasons. The first purpose of the beneficiary signature is to authorize the assignment of Medicare benefits to the health care provider or supplier. However, assignment of covered ambulance services has been mandatory since April 2002. Furthermore, 42 C.F.R. §424.55(c), adopted November 15, 2004 as part of the Final Rule on the Physician Fee Schedule (67 Fed. Reg. 6236), eliminated the requirement that beneficiaries assign claims to the health care provider or supplier in those situations where payment can only be made on an assignment-related basis. Therefore, the beneficiary's signature is no longer required to effect an assignment of benefits to the ambulance provider or supplier.

CMS recognized this in the Internet Only Manual via Transmittal 643, by adding Section 30.3.2 to Pub. 100-04, Chapter 1. As a result, the beneficiary signature is no longer needed to assign benefits of covered ambulance services.

b. Authorization to Release Records – The second purpose of the beneficiary signature is to authorize the release of medical records to CMS and its contractors. However, the regulations implementing the HIPAA Privacy Rule, specifically 45 C.F.R. §164.506(c)(3), permit a covered entity (e.g. an ambulance provider or supplier) to use or disclose a patient's protected health information for the covered entity's payment purposes, without a patient's consent (i.e. his or her signature). Therefore, federal law already permits the disclosure of medical records to CMS or its contractors, regardless of whether or not the beneficiary's signature has been obtained.

Signature Already on File

Almost every covered ambulance transport is to or from a facility, i.e. a hospital or a skilled nursing facility. In the case of emergency ambulance transports, the ultimate destination will always be a hospital. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. The term "related services", when used by hospitals and SNFs, can mean more than only entities owned by or part of the facility. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service", since the ambulance transports the patient to or from that facility for treatment or admission. Therefore, we believe a

valid signature will be on file with the facility. Additionally, for those transports provided to patients eligible for both Medicare and Medicaid, a valid signature is on file at the State Medicaid Office as a product of the beneficiary enrollment process.

Electronic Claims

It is also important to note that, as a result of section 3 of the Administrative Simplification Compliance Act and the implementing regulations at 42 C.F.R. §424.32, with very limited exceptions (e.g. providers or suppliers with less than 10 claims per month), ambulance suppliers must submit claims electronically. Thus, the beneficiary does not even sign a claim form. When submitting claims electronically, the choices for beneficiary signature are "Y" or "N". An "N" response could result in a denial, from some Carriers. That would require appeals to show that, while the signature has not been obtained, an alternative is accepted. As a result, many Carriers allow a "Y", even though the signature was not actually obtained, if one of the exceptions is met.

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

Program Integrity

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

Conclusion

Based on the above comments, it is respectfully requested that CMS:

- Amend 42 C.F.R. §424.36 and/or Pub. 100-02, Chapter 10, Section 20.1.1 and Pub. 100-04, Chapter 1, Section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambulance provider or supplier has documented that the beneficiary could not sign and no one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".
- Amend 42 C.F.R. §424.36 to add an exception stating that ambulance providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient

(Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.

- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

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

AMBULANCE SERVICES – AMBULANCE INFLATION FACTOR

NBFD has no objection to revising 42 C.F.R §414.620 to eliminate the requirement that annual updates to the Ambulance Inflation Factor be published in the Federal Register, and to thereafter provide for the release of the Ambulance Inflation Factor via CMS instruction and the CMS website.

Thank you for your consideration of these comments.

Sincerely,

Catherine Ord

Catherine Ord
EMS Manager

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Sutter Santa Cruz

A Sutter Health Affiliate

2025 Soquel Avenue
Santa Cruz, CA 95062

August 29, 2007

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

Re: Proposed Reconfiguration of CA Physician Payment Localities

Dear Mr. Kuhn:

I appreciate the opportunity to comment on the proposed physician rule and applaud you for taking this step to improve the credibility of the physician payment process as it relates to the current payment localities. You and I have met on several occasions to discuss this issue – I appreciate your concern and sincere desire to improve payment accuracy to providers who care for Medicare beneficiaries.

The General Accountability Office in its June 2007 report calls on CMS to reform the physician payment localities. It offers to CMS several options to improve payment accuracy. The current physician payment locality configuration has seen an erosion in payment accuracy since they were last reconfigured in 1996. Many providers and legislators have lost confidence in the ability of CMS to fulfill its obligation to make appropriate geographic adjustments to providers caring for Medicare beneficiaries under Part B of Medicare. Hospitals and other providers receive much more accurate payments from CMS for several reasons not the least of which is the fact that Metropolitan Statistical Areas (numbering approximately five times more than the current 89 physician payment localities) are used to base geographic adjusters to those providers.

The GAO is aware of this and acknowledging that CMS has been reluctant to increase the number of physician payment localities in order to assist CMS in preserving administrative simplicity calls for long-needed reforms to the 1996 localities. I have been a practicing physician in Santa Cruz County since 1984 and have invested considerable time in helping CMS, the California Medical Association, and numerous legislators in correcting this problem.

I support an amended Option 3 in your proposed rule. I am concerned about the inconsistencies in the GAFs that you publish for several CA counties especially as those inconsistencies significantly affect the configuration of CA counties into the locality groupings that you propose. I am also concerned that a fundamental mathematical error misapplied the text that you (and the GAO) proposed for this mechanism of grouping like-counties by similar costs. This is the 95% problem, which, I am sure that you are aware. It is outlined in the attached graph.

As you are aware, the Geographic Adjustment Factor (GAF) is used to compare global cost input differences between counties. It is not, however, used by CMS' intermediaries to pay providers. The actual GPCIs are used to do this. The GAF is a mathematical construct only. In order to properly calculate GAFs for individual counties or for an RVU-weighted assemblage of counties, you must use the actual GPCIs. This is the method that CMS has used since 1996. Bob Ulikowski, previous manager of the payment localities and GPCIs for CMS, has confirmed this to both me and other physicians in California who are well-versed with your methodology. It is essential that CMS share the actual county GPCIs and county RVUs as you have done in the past for each of the years: 1999 – 2006. The sudden lack of transparency by CMS is very concerning.

Two CA counties deserve special comment:

1. **Santa Clara County**. The 9.2% proposed drop in the GAF for this county when its 50th percentile HUD rent data apparently drops at the same proportional rate as adjoining San Mateo County (whose GAF drops at half the rate of Santa Clara) is disturbing. CMS should present, in its final rule, the mathematical formula used in the application of the 50th HUD rent data and its effect on the various practice expense GPCIs for California's counties.
2. **San Benito County**. This county is part of the Santa Clara/San Jose two county MSA. I cannot understand how this county, and this county only, had county specific, rather than MSA specific, rent data applied to it in the calculation of its GPCIs and GAF. The GAO applied the same consistent approach that CMS has used throughout the rest of California in the calculation of the GAF for this county. CMS should be consistent and should apply the same HUD rent data for Santa Clara and San Benito in the calculation of those counties' cost input factors. This is the methodology used by CMS elsewhere in this state. I support the GAO's approach which is consistent and fair. If CMS chooses to not follow the recommendation of the GAO as it applies to this county, I request that CMS describe in the final rule why it chooses to not do so.

Lastly, CMS should not longer provide special privilege to state medical associations in the initiation of proposed locality reform. State medical societies should have the opportunity to comment on proposed reconfigurations but should not have special standing. Congress has not supported this policy. Previous administrations have held such actions as unconstitutional. Despite this, I am aware that current CMA policy supports locality revision even if it causes a decrease in reimbursement to some CA counties.

My organization includes optometrists, physical therapists, audiologists, speech pathologists, occupational therapists, physician assistants, podiatrists, and nurse practitioners. All of these providers bill CMS for services provided to Medicare beneficiaries. However, none of these providers are represented by the state medical society. Therefore, CMS, as it acknowledged in the 2005 final rule, bears the responsibility to update the physician payment localities.

Sincerely,

Lawrence deGhetaldi, M.D.

C: Secretary Michael Leavitt, Department of HHS
Sam Farr, Member of Congress
Anna Eshoo, Member of Congress
Diane Feinstein, US Senate
Barbara Boxer, US Senate

Proposed CMS Option 3	est GAF	Corrected CMS Option 3 (Corrected Counties in Yellow)	Actual County GAF	CMS Threshold
Locality 01		Locality 01	GAF	
San Mateo San Francisco Marin	1.178	San Mateo San Francisco Marin Santa Clara	1.204 1.201 1.148	Floor for this Locality is 95% of San Mateo *95% of 1.204 =* *1.1438*
Locality 02		Locality 02		
Santa Clara Contra Costa Alameda Orange Ventura Los Angeles	1.116	Contra Costa Alameda Orange Ventura Los Angeles Santa Cruz Monterey	1.134 1.129 1.128 1.128 1.121 	Floor for this Locality is 95% of Contra Costa *95% of 1.134 =*
Locality 03		Locality 03		
Santa Cruz Monterey San Diego Sonoma Napa Sonoma Solano	1.061	Sonoma Napa Solano San Diego Santa Barbara Sacramento El Dorado San Bernardino	 1.053 1.053 1.047 1.033 1.023	Floor for this Locality is 95% of Sonoma *95% of 1.076 =* *1.0222*
Locality 04		Locality 04		
Sacramento El Dorado San Bernardino Placer Riverside San Luis Obispo San Joaquin	1.006	Placer Riverside San Luis Obispo San Joaquin Yolo Stanislaus Mono Nevada Kern	1.021 1.017 1.015 1.006 0.995 0.979 0.977 0.975 0.973	Floor for this Locality is 95% of Placer 95% of 1.021 0.96995
	0.950	Locality 05 Sierra Amador Rest of CA	 0.967 0.967 < 0.967	All remaining CA Counties move to Locality 05

Counties in yellow were wrongly assigned to the incorrect locality as proposed by CMS due to a mathematical error in the proposed rule.

The county in blue should be correctly assigned to the appropriate locality based on the application of the GAO's methodology in calculating its GAF.

Counties in green have different GAFs published by CMS in Options 1, 2 and 3 in the proposed rule. The GAF values in Option 1 were used in this chart.

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The Nebraska Board of Physical Therapy

301 Centennial Mall South
Lincoln, NE 68509-4986
Phone: 402/471-2299
Fax: 402/471-3577

August 27, 2007

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

Re: CMS-1385-P; Therapy Standards and Requirements

Dear Sir or Madam:

The Nebraska State Board of Physical Therapy Examiners submits the following comments on the proposed rules changing the definition of "physical therapist" in Section 484, Title 42 of the Code of Federal Regulations. The proposed rules are part of the 2008 Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008, found in Volume 72 of the Federal Register, published on July 12, 2007.

Under subsection (i)(B) and (ii)(B) of the proposed definition of "physical therapist" an applicant would need to have "[p]assed the National Examination approved by the American Physical Therapy Association." We strongly suggest that CMS rely on state licensure and that the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist" be deleted from the final rule. At the very least, the Centers for Medicare and Medicaid Services ("CMS") should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

We, along with all of the other state boards of physical therapy examiners, have already adopted a national qualifying exam for physical therapists, the National Physical Therapy Examination ("NPTE"). The Federation of State Boards of Physical Therapy ("FSBPT") develops and administers the NPTE in close collaboration with the state boards. Working together, we have developed a national passing score. The NPTE has been a valuable tool in screening physical therapist applicants. Through the NPTE, we have been able to successfully filter applicants. In turn, we, as a policing body, have been able to protect the public by ensuring that only qualified therapists are licensed to care for our citizens.

CMS should not usurp the states' function of licensing physical therapists and other professionals. CMS respects states' rights and state licensure for other health care professions, and it should continue to do so with respect to physical therapists. For example, CMS' regulations define a physician as a "doctor of medicine ... legally authorized to practice medicine and surgery by the State in which such function or action is performed." 42 C.F.R. § 484.4 (2006). Likewise, a registered nurse is defined as "[a] graduate of

an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing." 42 C.F.R. § 484.4. Establishing requirements that are different than what the states require for licensing PTs would be inconsistent with not only the rights of the states, but also CMS' own standards.

Moreover, the federal government should not impose an additional burden on the states, particularly since its stated desire for a national examination is already satisfied. The proposed mandate could result in the development of a second exam, which would create confusion and more work for the states, without benefit.

In the preamble to the proposed regulations, CMS says that it is seeking uniformity. Uniformity and consistency across the nation and across provider settings already exists. State licensing requirements apply to physical therapists without regard to where they practice. All states accept CAPTE accreditation. All states accept the NPTE and have adopted the same passing score. No federal regulation is required.

The Nebraska State Board of Physical Therapy Examiners strongly urges CMS to require only state licensure. Most importantly, CMS should remove the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist." At a minimum, CMS should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

We appreciate the opportunity to comment on the proposed rules regarding physical therapist and physical therapy assistant qualification requirements.

Respectfully yours,

The Nebraska State Board of Physical Therapy

Wayne Stuberg, PT, PhD

Chair, NE Board of Physical Therapy

Cc. NE Board of Physical Therapy

Theresa Cochran PT, President, NE Physical Therapy Association

NE Congressional Delegation

To: Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
US dept of Health and Human Services
Attention: CMS-1385-P
Box 8018
Baltimore, Md 21244-8018

Subject: Medicare Program: Proposed Revisions to Payment Policies under the Physician Fee Schedule, CY 2008, Proposed Rule

I am a private practice physical therapist, have been a practitioner for over 35 years with many years of post graduate specialty in the areas of women's health and orthopedic treatments. I am working in a Florida city where many specialty physicians are under one large limited practice group and have their own rehabilitation center that is physician owned. They have the majority orthopedic, neurological, cardiac, and other major referral resources for therapy practice making it very difficult for non affiliated therapy professionals to get patients from usual referral sources. Allowing more physicians in this small city to engage in for profit therapy practices would further limit access for patients to quality care. Physicians who receive direct financial benefit from these private arrangements are motivated to order therapy only for their own personal benefit, not to the referral source with the most expertise or best therapy practice outcomes. Patients are unaware they may have freedom of choice in where to go for therapy; they take the advice of their physician in most cases.

Please DO NOT ALLOW the continuation of this referral abuse. Free market access to therapy is critical to the appropriateness of expenditures by Medicare. Physical and Occupation Therapy are stand alone professions that should never be under the direct monetary influence from another medical owner. This is essentially like fee splitting or fee for referral. Physician supervision is never necessary with provision of appropriate rehab services when licensed therapists are present. This captive referral base leads to over utilization instead of appropriate treatment.

Thank you for consideration in this serious matter. Help us protect the integrity of therapy services and allow therapy to grow into the independent profession, free from other referral source abuse, that it is meant to be.

Sincerely, Elsa Nail, MSPT
Community Rehab and Wellness
3021 Lakeland Highlands Rd
Lakeland, Florida 33803

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DALE G. KIKER, M.D.

QUALIFIED MEDICAL EVALUATOR

Board Certified by the American Board of Anesthesiology in Pain Management

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August 29, 2007

Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Implantation of Spinal Neurostimulators

I am writing to express my concern over the proposed changes to CMS' OPPS and ASC reimbursement methodologies. In particular, my concern over the proposed rule which I believe will limit patient access to a beneficial technology.

CMS has proposed the elimination of a separate APC for rechargeable neurostimulators, which will directly impact hospital financial considerations, and the corresponding ASC reimbursement methodology. For the past two years, CMS has allowed reimbursement for this new technology, the rechargeable spinal cord stimulator. The additional reimbursement has been available either through a new technology pass-through in the hospital setting, or via the DMEPOS fee schedule in the ASC. The proposed rule to eliminate the pas-through, and group rechargeable stimulators and non-rechargeable neurostimulators into APC 0222, despite a documented significant cost differential, will change the decision process from a clinical decision to an economic decision process.

As a provider in a community in which a hospital has made a financial decision to eliminate this beneficial therapy, I am very concerned that the alternative site of service ASC will be forced to eliminate the therapy as well. The decision will be a direct result of CMS decision to only allow one APC for both rechargeable and non-rechargeable stimulators. Medicare and private payer patients will no longer have access to this valuable therapy.

We recommend that CMS create separate APC's for the rechargeable and non-rechargeable neurostimulators on the basis of the substantial cost differential. We believe that there is a substantial clinical improvement provided by rechargeable neurostimulators, and the therapy is worthy, clinically effective therapy.

Thank you for your consideration.

Cordially,

Dale Kiker, M.D.
DK/cm

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Gainesville Urology

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R. JUDD WILLIAMS, M.D.
DAVID S. WOO, M.D.
JAMES E. RENEHAN, M.D.
MARTIN C. LAXSON, PA-C

August 20, 2007

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

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Dear Ladies and Gentlemen:

I am a urologist practicing in Gainesville, Georgia at Gainesville Urology. I am aware of both the clinical and cost issues that are important to the Medicare beneficiary and CMS. I have been involved with providing my patient's lithotripsy and other new therapies for various urological disease processes. Without the involvement of joint ventures some of these therapies would likely not be available to our patients.

In July 2008, in the Professional Fee Schedule proposal, CMS attacks the substance of these joint ventures that have actually saved Medicare a significant amount of money.

Because of the expense of the technology, often times small hospitals would be unable to afford lithotriptors or other various lasers. Many of these lasers and lithotriptors are also portable and decrease the capital outlay that is necessary in order to bring that technology to these various communities.

Shockwave lithotripsy is also not a DHS. The driving force behind trying to prevent these physician arrangements is likely because of the over utilization of diagnostic imaging. It is difficult to over utilize a service such as lithotripsy because of it being a "cut and dry" indication most of the time.

Without the physician support in these joint ventures, many smaller communities will be unable to afford this treatment and this will cause the patients to undergo more invasive and probably more costly procedures with a less than adequate result.

If you were to agree to allow lithotripsy to be done in an outpatient surgical setting, this would also further reduce the costs. A similar proposal is presently being considered where reimbursement to outpatient surgery centers would increase, still being less than what is reimbursed to hospitals. This will likely move some hospital procedures into the more efficient and less expensive outpatient settings.

As I am aware there has not been any evidence that lithotripsy is being abused.

I request that you reconsider your stand on lithotripsy as a DHS.

Sincerely,

R. Judd Williams, MD

RJW:sm

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August 31, 2007

VIA ELECTRONIC MAIL AND OVERNIGHT COURIER

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

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

Dear Ms. Norwalk:

Reed Smith LLP is a global law firm representing virtually every type of entity operating in or related to the health care industry. This representation includes, among others: academic medical centers; device manufacturers; durable medical equipment suppliers; home health agencies; hospices; hospitals; pharmaceutical companies; physician groups; rehabilitation facilities; and skilled nursing facilities. On behalf of our clients, this letter provides comments and recommendations to the proposed changes to the Medicare Physician Fee Schedule for calendar year 2008 published in the Federal Register (72 Fed. Reg. 38,122) by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. We appreciate the opportunity to provide these comments and recommendations.

Our comments are focused on the "Physician Self-Referral Provisions" and limited to the proposal to change the definition of "entity" in the Stark law (42 C.F.R. § 411.351). Specifically, CMS proposes to make a significant change in the definition of "entity" which would severely proscribe so-called "under arrangements" that include referring physicians as owners. We are very concerned that the proposed rule will adversely impact the quality of certain services that are currently managed by entities having physician ownership. Similarly, the proposed rule will limit the ability of physicians to actively participate in the management and leadership of certain medical services offered by health care providers to their patients. The broadly worded definition of "entity" in the proposed rule will have unintended and far-reaching consequences, impacting entities and arrangements not previously subject to the Stark law.

Given these concerns, we urge CMS to: (1) withdraw the proposed change in the definition of "entity"; (2) reject the recommendation of the Medicare Payment Advisory Commission ("MedPAC") that the definition of physician ownership be expanded to include interests in "an entity that derives a substantial proportion of its revenue from a provider of designated health services"; and (3) study the prevalence and value of services furnished "under arrangements" with physician-owned entities. Alternatively, CMS should tailor its changes so as not to impose unnecessarily stringent requirements

upon existing relationships nor implicate entities and arrangements properly excluded from the Stark law. Ultimately, the current structure of the Stark law adequately addresses "under arrangements" and before CMS undertakes such a dramatic change in policy, the agency must fully understand the nature of these relationships, the value of physician participation in certain ancillary services offered by health care providers, and more thoroughly study the likely consequences of the proposed rule.

I. PHYSICIAN SELF-REFERRAL PROVISIONS

A. The "Under Arrangements" Proposal

1. Current Law

The Social Security Act and its Medicare provisions permit health care providers – such as hospitals, rural primary care hospitals, skilled nursing facilities, home health agencies, and hospices – to furnish services to beneficiaries "under arrangements" with third party vendors. The vendor has a contractual relationship with the provider for delivery of the services, and the provider (but not the vendor) bills for the services. According to CMS, the purpose of services provided "under arrangements" is to provide a means for hospitals and other providers "to obtain specialized healthcare services that it does not itself offer, and that are needed to supplement the range of services that the provider does offer its patients." 67 Fed. Reg. 50,091 (Aug. 1, 2002).

Taking the example of a hospital, while the vendor furnishes the services "under arrangements" with the hospital, the hospital remains fully responsible for patient care. Indeed, the Medicare Conditions of Participation require the hospital's governing body to be responsible for services furnished to its patients "under arrangements," including that (1) the governing body ensure that the services performed under a contract are provided in a safe and effective manner, and (2) the hospital maintain a list of all contracted services, including the scope and nature of the services provided. See 42 C.F.R. § 482.12(e)(1)-(2). Even when a physician-owned vendor provides services "under arrangements" to a hospital, the hospital must offer the minimum of administrative responsibility and control regardless of whether the services are provided "under arrangements."

Currently, the Stark regulations treat any transaction where a health care provider purchases services from a vendor "under arrangements" as a compensation arrangement, rather than an ownership interest. See id. § 411.354(a)(3)(iv), (c); 66 Fed. Reg. 856, 942 (Jan. 4, 2001). Moreover, the definition of "entity" only includes the person or entity billing for the designated health services ("DHS") service. See id. § 411.351. This approach permits a provider to enter into a service agreement where the provider purchases a discrete service from a vendor owned in whole or in part by physicians. Importantly, however, these arrangements must comply with a Stark compensation arrangement exception, such as the personal services exception, equipment rental exception, fair market value ("FMV") exception, or exception for indirect compensation arrangements. Each of these narrowly-tailored exceptions includes specific protections against abuse, such as overutilization.

2. The Proposed Rule

As noted above, since the effective date of the Phase I regulations on January 4, 2002, CMS has defined "entity" as including only the person or entity that bills Medicare for DHS, but not the person or entity that performs the DHS (if that person or entity is not also billing Medicare). See 42 C.F.R. § 411.351. CMS now proposes to extend the definition of "entity" to include the person or entity: (1) performing the DHS; and (2) presenting a claim or causing a claim to be presented to Medicare. In the proposed rule, CMS expresses its concern that hospital outpatient services furnished "under arrangements" with a vendor owned by referring physicians creates a risk of overutilization. See 72 Fed. Reg. at 38,186. Further, CMS cites "leasing, staffing, and similar entities having physician

ownership" as raising concern. See id. at 38,187. CMS also states that there may be no legitimate reason for such an arrangement other than allowing a physician to make money on referrals, particularly where the services furnished by the joint venture were previously directly furnished by the hospital. See id. at 38,186. Finally, CMS expresses concern that the "under arrangements" services might be furnished in a less medically-intensive setting, but billed at higher outpatient hospital prospective payment system rates. See id.

While CMS believes that its proposal to change how "entity" is defined sufficiently addresses the agency's concern, CMS also request comments on a related recommendation by MedPAC to expand the definition of physician ownership. In its March 2005 Report to Congress, MedPAC recommended changes to prohibit referrals by a physician who has an ownership in an entity "that derives a substantial proportion of its revenues from a [DHS] provider." As such, CMS now requests comments regarding whether to "implement the MedPAC approach, either in some combination with our proposed approach or instead of our proposed approach" and "what should constitute a 'substantial' proportion of revenue derived from providing DHS." Id. at 38,187.

B. Comments to "Under Arrangements" Proposal

1. Current Law Provides Protection Against Abuse

The Stark regulations currently treat "under arrangements" as compensation and not ownership relationships. Nonetheless, "under arrangements" must comply with stringent Stark exceptions for compensation arrangements. These exceptions are designed to prevent abuse and overutilization, and to ensure that medical decision-making is not corrupted. Indeed, in its proposed rule, CMS provides no explanation why the rigorous requirements of the compensation exceptions to the referral prohibition (discussed below) do not provide adequate protection against abuse.

For example, the personal services exception requires that: (1) the arrangement be set out in writing and specify the services covered; (2) the arrangement cover all of the services furnished by the physician to the entity; (3) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purpose of the arrangement; (4) the term of each arrangement must be for at least one year; (5) the compensation must be set in advance, not exceeding FMV, and may not take into account the volume or value of referrals or any other business generated between the parties; and (6) the services do not involve the counseling or promotion of a business arrangement. See 42 C.F.R. § 411.357(d)(1)(i)-(vi).

As another example, the indirect compensation exception requires that: (1) the compensation received by the physician (or immediate family member) must be FMV for items and services actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician for the DHS entity; (2) there is a signed, written agreement specifying the services covered; and (3) the arrangement must not violate the anti-kickback statute, or laws or regulations governing billing or claims submission. See id. § 411.357(p)(1)-(3).

2. The "Under Arrangements" Proposal Could Adversely Impact Properly Structured and Beneficial Management Arrangements

As noted above, the proposed rule would expand the definition of "entity" to include the person or entity (1) performing the DHS and (2) presenting or causing the submission of a Medicare claim. The revised, broadened definition of "entity," however, arguably could make properly structured and beneficial management arrangements "under arrangements" for purposes of the Stark law. Moreover, such management arrangements would be subject to unnecessarily stringent requirements for satisfaction of a Stark law exception.

For example, one type of service a hospital may obtain from an outside entity is management or consulting services. Companies specializing in management and consulting services, which are sometimes owned by physicians, contract with hospitals to manage the day-to-day operations of certain services offered by the hospital. Although the ultimate control and responsibility for the service (including billing for the service) is retained by the hospital, a physician-owned management company provides, among other things: (1) critical expertise in the discrete service area, (2) administrative efficiencies, and (3) involvement of physicians in the management and supervision of services.

Indeed, physician-owned management companies provide valuable services to hospitals beyond those provided by a hospital's medical staff. For example, physician-investors in management companies assist in controlling hospital costs by participating in supply utilization committee meetings. From a quality perspective, physician-investors assist in modifying and improving the hospital's clinical protocols by reviewing aberrant cases and communicating best practices to the medical staff. Similarly, physicians provide both new and existing staff members training in the latest treatments and clinical practices. Lastly, physician-investors are involved in decisions regarding the effectiveness and necessity of obtaining new technology. Under a management arrangement, physician-owned entities provide hospitals with unique knowledge and access to experienced clinicians.

As these management services do not include the actual performance of DHS, they are most appropriately viewed as not being "under arrangements." Even if they were deemed "under arrangements," under current law, the rigorous Stark compensation exceptions (e.g., indirect compensation exception) are still available to protect the arrangement. With the proposed rule, however, it is possible that the management company in such an arrangement could be viewed as an "entity" by either comprising part of the hospital's DHS or as having "caused a claim to be presented for Medicare benefits for the DHS." As such, the arrangement would need to comply with a more limited Stark ownership (rather than compensation) exception for protection.

It is unclear whether CMS intended the proposed rule to apply the unnecessary stringent Stark ownership exceptions to such arrangements when the compensation exceptions provide sufficient protection against abuse. Such an outcome could ultimately prohibit hospitals from obtaining beneficial management and consulting services from entities even partly-owned by physicians. The proposed rule could put these expert management services in jeopardy. As such, we urge CMS to: (1) withdraw the proposed change in the definition of entity; (2) specifically exclude entities not performing DHS from the definition of "entity;" or (3) otherwise tailor any changes to the Stark law so as not to impose unnecessarily stringent requirements upon these types of relationships.

3. The "Under Arrangements" Proposal Could Improperly Impact Entities and Arrangements Not Previously Subject to the Stark Law

Moreover, the expanded definition of "entity" in the proposed rule arguably could inappropriately impact entities and arrangements that never have been subject to the Stark law. Specifically, the expanded definition is so broad that entities not previously covered arguably could be subject to the Stark law merely because their goods or services comprise part of the DHS billed by the provider.

For example, orthopedic surgeons may have an ownership interest in a manufacturer of spinal implants. The manufacturer then sells its implants to the hospital where the surgeon performs his or her surgeries. Under the proposed rule, the manufacturer arguably could be considered an "entity" subject to the Stark law. Specifically, the proposed definition of "entity" would extend to an entity that "performs the DHS." As inpatient and outpatient hospital services are DHS, spinal implants could be viewed as being part of the DHS furnished to Medicare patients and billed by the hospital.

It is unclear whether CMS intended its proposed change to apply this broadly. Such an outcome could extend the Stark regulations to a large number of entities and arrangements not previously subject to law's prohibitions. As such, we urge CMS to: (1) withdraw the proposed change in the definition of "entity;" (2) specifically exclude entities not performing DHS from the definition of "entity;" or (3) otherwise tailor any changes to the Stark law so as not to implicate these relationships properly excluded from the Stark law.

4. MedPAC's "Substantial Proportion of Revenue" Test is Flawed

In addition to the recommendations above regarding the proposed rule, we note that MedPAC's "substantial proportion of revenue" test is similarly flawed. The MedPAC test is overbroad and would have unintended and far-reaching consequences. Specifically, the MedPAC proposal is not limited to entities performing, furnishing, or billing DHS. Instead, the MedPAC test would effectively prohibit physician ownership of entities providing any service to a provider of DHS, as long as the service resulted in revenue significant enough to trigger the test's application. Stated differently, any entity wholly or partially owned by physicians would be required to satisfy one of the stringent and limited Stark ownership exceptions for protection.

Such an expansive limitation fails to recognize the unique expertise physicians bring to a provider's clinical operations. Health care providers are complex organizations facing increasing competition in the numerous services they offer. Providers lacking innovative leadership in certain services must necessarily rely upon outside vendors, especially those having physician-owners. Accordingly, these vendors play an important role in bringing expertise, increasing quality of care, and improving cost-effectiveness. Indeed, physicians are uniquely able to merge clinical expertise with operational knowledge. As such, we urge CMS to reject MedPAC's "substantial portion of revenue" test.

5. CMS Has Provided No Data or Evidence to Substantiate its Concerns Regarding "Under Arrangements"

The proposed rule does not provide any substantiated reasons for treating "under arrangements" as ownership relationships. In the January 4, 2001 Phase I rule, the Health Care Financing Administration (now CMS) cited three specific reasons for treating "under arrangements" as compensation and not ownership relationships.

> First, given the sheer number of these arrangements, we think prohibiting these arrangements, would seriously disrupt patient care. Second, almost all these arrangements could be restructured to fit into a combination of the personal service arrangements and equipment lease exceptions (or fair market value exception), although this restructuring will in some cases be administratively burdensome. Third, we believe there is precedent in the statute for treating this situation solely as a compensation arrangement.

66 Fed. Reg. at 942.

We are aware of nothing occurring in the intervening years mitigating the stated reasons for treating "under arrangements" as compensation relationships. The number of these types of arrangements has not decreased and likely has increased. These arrangements have been and can be structured to satisfy applicable Stark compensation exceptions, thereby providing sufficient protection against abuse. Further, patient care would be disrupted by treating "under arrangements" relationships as ownership interests and requiring the reorganization of these relationships.

In the proposed rule, CMS offers no evidence to support its new concerns or even an indication of how the agency substantiated its concerns. Instead, CMS simply repeats general "concerns" and "beliefs:"

- "We continue to have concerns with services provided under arrangements."
- "We believe that the risk of overutilization...."
- "We have received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly."
- "There appears to be no legitimate reason for these arranged for services."
- "We are also concerned that the services furnished under arrangements to a hospital are furnished in a less medically-intensive setting."
- "It appears that the use of these arrangements may be little more than a method to share hospital revenues."
- "We believe that more and more procedures are being performed as arranged for hospital services."

Ultimately, CMS is proposing a significant change in the manner in which hospitals obtain certain vital services to their patients without substantiating its concerns, beliefs, or anecdotal reports. A substantial change in policy, such as the proposed rule, should be supported with reasoned analysis of available evidence. If additional research or data has been collected to substantiate its concerns, CMS has not made that evidence available for public comment. The agency's concerns, beliefs, and anecdotal reports are insufficient to overcome the reasons first articulated for treating "under arrangements" as solely compensation relationships.

II. CONCLUSION

We urge CMS to: (1) withdraw the proposed change in the definition of entity; (2) specifically exclude entities not performing DHS from the definition of "entity;" or (3) otherwise narrowly tailor any changes to the Stark law so as not to impose unnecessarily stringent requirements or implicate relationships properly excluded from the Stark law. The proposed rule is a dramatic change in policy and will result in a major change in how certain services are delivered to patients. Ultimately, physician involvement in the management and operations of health care providers is a long-standing tradition in our health care system, and the proposed rule as currently structured would severely and adversely impact that tradition.

We also urge CMS to reject the recommendation of MedPAC that the definition of physician ownership be expanded to include interests in "an entity that derives a substantial proportion of its revenue from a provider of designated health services." MedPAC's recommendation is even more expansive than the proposed rule. Finally, we urge CMS to not adopt the proposed rule without further study of the prevalence and value of services furnished "under arrangements" with physician-owned entities.

We appreciate the opportunity to submit these comments and recommendations. We are available and would be pleased to discuss these issues further with CMS.

Sincerely,

Reed Smith LLP

Reed Smith LLP

DAC:PWP

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August 30, 2007 www.cms.hhs.gov/erulemaking

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008; Proposed Rule

Dear Mr. Kuhn:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the proposed notice "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008" published in the Federal Register on July 12, 2007. We will address malpractice; budget neutrality; resource-based practice expense (PE) relative value units (RVUs); practice expense per hour; Relative Value Update Committee (RUC) recommendations; additional codes from the five year review; the independent diagnostic testing facility requirements; physician quality reporting initiative; and changes to reassignment and physician self-referral rules relating to diagnostic tests [Anti-Markup Provisions].

Malpractice

The ACR has suggested in the past that there is disproportionate allocation of the malpractice values between the professional component (PC) and the technical component (TC). The ACR's recommendation was to flip the malpractice values associated with each of the component parts so the technical component malpractice values are assigned to the professional component and the professional component malpractice values are assigned to the technical component. This is because physicians incur the higher costs for malpractice insurance.

In the past, the RUC also provided comments to Centers for Medicare and Medicaid Services (CMS) and they recommended that the CMS: 1) Flip the malpractice values associated with each of the component parts so the technical component malpractice values are assigned to the professional component and the professional component malpractice values are assigned to the technical component or 2) Make the malpractice values of the technical component equal to the malpractice values of the professional component. The ACR is aware that the AMA RUC comments being submitted in response to this proposed rule may reference a RUC Professional Liability Insurance (PLI) workgroup recommendation that the malpractice values in the technical component should be zero as there are no identifiable professional liability costs associated with providing the TC. CMS should be aware that this position has not been vetted and approved by the full RUC, and that the ACR disagrees with the conclusions of the PLI workgroup. Although

the ACR believes that the PC malpractice values should be higher, **the ACR does not believe that the malpractice values in the technical component should be zero.**

The ACR is aware that CMS is requiring independent diagnostic testing facilities to purchase a certain level of liability insurance. CMS is, therefore, acknowledging that some liability costs do exist in the TC and the ACR supports CMS'comments on this issue in past final rules. Also, other clinical staff such as radiology technologists and medical physicists purchase professional liability insurance and are represented in the TC. According to the American Association of Medical Physicists, "Medical physicists, due to their key role in the design and quality assurance of high-risk radiation therapy procedures, have a significant liability exposure, and so liability insurance is normally carried by the medical physicist's employer or by the medical physicist if self-employed. Typical policies are valued at $1Million Individual / $3Million Aggregate coverage."

Budget Neutrality

The ACR is again disappointed that the CMS decided to apply the budget neutrality adjustment by way of a physician work adjustment factor as a result of the increase in anesthesia physician work under the third five year review. The CMS decision is contrary to the views of almost the entire medical community that are expressed in numerous comments. The vast majority of professional societies whose members treat Medicare beneficiaries recommended that the budget neutrality adjustment be made to the conversion factor and not to the physician work values.

The ACR believes that being consistent with previous adjustments to the conversion factor is a more fair and equitable application of budget neutrality adjustments. In addition to its objection on a methodological basis, the ACR is opposed to the CMS decision because it places a disproportionate burden on hospital-based physicians whose compensation for medical services is derived only from the PC and is thus heavily dependent on the work RVU.

The ACR again strongly recommends that CMS reconsider applying the budget neutrality adjustment to the conversion factor and not to the physician work RVU.

Also, it appears that CMS has used the adjusted work RVUs as the allocator of indirect practice expense in its calculations for the proposed 2008 Medicare Physician Fee Schedule (MPFS). The work RVUs were adjusted solely to meet Medicare's statutory requirement to maintain budget neutrality. In fact, CMS does not even publish the adjusted work RVUs in the *Federal Register*. We believe the use of reduced work RVUs to calculate indirect practice expense costs results in incorrectly reduced PE RVUs and distorts the relativity of the fee schedule. **The ACR strongly recommends that CMS use unadjusted work relative values as the allocator of indirect practice expenses.**

Resource-based PE RVUs

Interest Rate

The ACR supports CMS' decision not to change the interest rate in the practice expense equipment cost calculation of 11 percent. Analysis of the 2007 Small Business Administration (SBA) data on loans and applicable interest rates seems appropriate.

Equipment Usage Percentage

The ACR supports the CMS decision not to change the equipment utilization rate of 50 percent until there is better data to show the correct percentage. Arbitrarily setting high utilization rates on higher priced equipment may not always be accurate. It should not simply be concluded that higher priced equipment is utilized at a higher rate. There are higher priced technologies such as proton beam radiation therapy or magnetoencephalography (MEG) that are highly beneficial to a select population but are not necessarily utilized at the same rate as other higher cost technologies. In addition, there is no standard definition of a work day among medical practices. Some medical practices are open 8 hours a day, but many others may be open longer or shorter hours. Those that are open longer hours may only be operating certain pieces of equipment on select days such as Mondays, Wednesdays and Fridays.

The ACR agrees that there is not sufficient evidence to justify an alternative proposal on this issue. We support the concept of data collection through extensive survey to accurately determine the utilization rate for **all** medical equipment, using a prospective evidence-based methodology. **The ACR disagrees with others who might propose that CMS arbitrarily choose a rate higher than 50 percent and then allow exceptions based on individual petition.** The ACR is willing and ready to work with CMS to ensure the appropriate equipment utilization rates are captured for the great variety of equipment used in our field.

Practice Expense Per Hour

The ACR appreciates CMS' and the Lewin Group's conclusion that weighing the ACR's supplemental survey data by practice size more appropriately accounts for the small, high-cost entities in the final PE/HR for radiology. The ACR has discussed extensively with the Lewin Group from the beginning of the survey process about how to weight the practice level survey data to be representative of all radiology practices, large and small, in the U.S., and is pleased that CMS agrees that ACR's approach more appropriately identifies the PE/HR for radiology.

RUC Recommendations for Direct PE Inputs and Other PE Input Issues

RUC Recommendations for DXA, CAD and Nuclear Medicine

The ACR appreciates CMS' decision with respect to the direct practice expense inputs for dual energy x-ray absorptiometry (DXA), computer-aided detection (CAD) and nuclear medicine services.

Table 5: Supply Items Needing Specialty Input for Pricing

The ACR supports the cost documentation being submitted by the Society of Interventional Radiology (SIR) for the vascular stent deployment system.

Table 6: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions

The ACR supports information being submitted by the SIR on the plasma pheresis machine with an ultraviolet light source.

Coding – Additional Codes From Five -Year Review

CMS proposes to bundle code 93325 (Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography) into codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, and 93350, apparently without adjusting the work values for these codes. The ACR opposes bundling when reporting of multiple codes is required to accurately describe the services performed. The ACR also believes that CMS should rely on the CPT® Editorial Panel and RUC processes to address issues relating to CPT code 93325 and should not rebundle any CPT codes independent of those processes. **The ACR requests that CMS withdraw its proposal to reject the RUC recommendation and to refer CPT code 93325 to the CPT Editorial Panel.**

Independent Diagnostic Testing Facility (IDTF) Issues

Revised Standard Number 6

CMS proposes to change standard 6 to read "Has a comprehensive liability insurance policy in the amount of at least $300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier and ensures that this insurance policy must remain in force at all times. The policy must be carried by a nonrelative-owned company. The IDTF must list the Medicare contractor as a Certificate Holder on the policy and promptly notify the Medicare contractor in writing of any policy changes or cancellations."

The ACR supports the requirement for an IDTF to have comprehensive liability insurance but is concerned that requiring a Medicare contractor to be listed as a Certificate Holder will create reluctance of insurance underwriters to issue such policies, since listing a Medicare carrier as a Certificate Holder could, theoretically, provide the government with contractual rights to indemnification or payment that it would not otherwise have.

New Performance Standard

CMS proposes to prohibit IDTFs from sharing space, equipment or staff with, or subleasing its operations to, another individual or organization. CMS would have prohibited IDTFs from entering into part-time leases, even if those complied with the anti-kickback and Stark exceptions. Many IDTFs lease space and technologists part-time to radiology groups. Alternatively, many radiology groups have limited liability corporations that own and operate IDTFs, employing the same technologists that work for the IDTF. As the government has recognized historically,

radiologists are not in a position to create abusive self-referral arrangements with IDTFs or other entities..[1].

The ACR, therefore, recommends that in its final rule, CMS amend the language of its proposal to read: "a new performance standard at § 410.33(g)(15), which states, 'Does not share space, equipment or staff or sublease its operations to another individual, organization, employee or contractor of such organization, that refers Medicare patients to the IDTF for designated health services (DHS)."

Supervision

The ACR agrees with the CMS proposal to delete the requirement that the supervising physician is responsible for the overall operation and administration of an IDTF. CMS proposes to clarify the standard that a physician providing general supervision can oversee a maximum of three IDTF sites by noting that the term "sites" includes fixed as well as mobile sites. The ACR is concerned that the supervising physician list for each IDTF site may not be kept updated. Failure to keep these records up to date may result in the appearance that a particular physician is supervising more than the allowed number of sites when, in fact, this is not the case. **At this time, the ACR requests that CMS delay the implementation of limiting a physician to supervise more than 3 IDTF sites.** The ACR would like to work with CMS to provide information on various practice patterns and to determine ones that are problematic.

TRHCA-SECTION 101(b): Physician Quality Reporting Initiative (PQRI)

Proposed Quality Measures for the 2008

In general, the ACR supports the PQRI as an important first step in moving towards a value-based reporting system for physicians. We also appreciate CMS' support for allowing measures to be developed through the AMA Physicians Consortium for Performance Improvement (PCPI) process, and the consensus development and endorsement roles played, respectively, by the Ambulatory Care Quality Alliance (AQA) and the National Quality Forum (NQF).

The ACR's membership has shown a good deal of interest in participating in the PQRI, based on feedback and questions received through our website. While the 2007 PQRI does contain measures which would allow diagnostic and interventional radiologists to report, as well as radiation oncologists, it is the ACR's goal to expand the number of measures applicable to a wider range of radiologists in 2008. This includes measures now under development by the AMA Consortium's Radiology workgroup relating to CT radiation dose reduction, mammography, exposure time reported for fluoroscopy, and expansion of reporting eligibility for two existing 2007 PQRI measures related to stroke/stroke rehabilitation imaging. While these proposed measures are not listed in Table 17 of the proposed rule as under AMA/PCPI development, it is the ACR's expectation that these measures will likely advance and achieve

[1]. OIG Advisory Opinions 29 May, 2003 (03-12) and (97-5) 15 Oct, 1997<http://www.oig.hhs.gov/fraud/advisoryopinions/opinions.html>

AQA approval prior to the final rule deadline of November 15, 2007 for inclusion in the 2008 PQRI.

The ACR supports CMS' proposal, Table 20, to include in the 2008 PQRI, those AQA starter set primary care prevention and screening clinical measures that were not included in the 2007 PQRI quality measures. The ACR also supports the two structural measures under Table 19, relating to adoption/use of e-prescribing and electronic health records, but would urge CMS to also consider expanding this list to include adoption/use of electronic Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS) which are vital ingredients of radiology patient safety and quality.

Addressing a Mechanism for Submission of Quality Measures via a Medical Registry or Electronic Health Record

The ACR supports the concept of allowing individual physician quality measures to be submitted directly through the vehicle of a medical registry, avoiding duplicate submission of the same data to CMS. We have reviewed the five options for registry-based reporting presented by CMS, and believe Option 3 to be the most feasible in terms of minimized burden on reporting physicians, and the fact that only aggregate individual physician reporting and performance rates must be reported out of the registry. Our major concern is the potential discoverability, under the Freedom of Information Act, of individual physician reporting and performance rates, and the counterproductive chilling effect this might have on physician registry participation. The ACR supports the pilot testing of registry-based reporting in 2008, but is unable to participate at this time as our registries are not collecting any PQRI data.

TRHCA—Section 101(d): PAQI

The following comments concern how CMS will use the $1.35 billion Physician Assistance and Quality Initiative (PAQI) Fund. Under the Tax Relief and Health Care Act of 2006 (TRHCA), CMS has the option of using all of this money for continuing PQRI bonuses in calendar 2008, or applying these funds to buy down the negative update to the Medicare Physician Fee Schedule for calendar year 2008. CMS has stated its preference to use the PAQI funds to support PQRI bonuses in 2008. ACR believes it is vital that the momentum built under the 2007 PQRI be maintained by assuring the program continues to pay bonuses in 2008. However, the payment of bonuses should be funded as a supplement to Medicare physician reimbursement, and not at the expense of lowering overall physician payments under the 2008 Medicare Physician Fee Schedule.

Speakers at a major pay for performance conference held in Boston in August frequently pointed to a performance bonus in the 5 to 10 percent range as the minimum necessary to effectively gain the attention of providers; a PQRI devoid of a bonus payment would all but end interest in this valuable Federal effort to raise the bar on quality for Medicare beneficiaries. As such, **the ACR recommends that PQRI bonus funding be independent, and not at the expense of, the 2008 Medicare Physician Fee Schedule update.**

Physician Self-Referral Provisions

General

CMS acknowledges that the medical landscape has evolved since Congress extended the Stark law in 1993 to reach radiology and radiation oncology services. There has been unanticipated and significant growth in the use of medical imaging services, particularly MRI, CT and PET. The ACR believes that much of the growth of medical imaging can be explained by the shift from the use of invasive surgical and diagnostic procedures to the use of non-invasive medical imaging studies; the maturation of technologies and the dissemination of their capabilities to practicing physicians; and the overall benefit to patients to establish a timely and accurate diagnosis for the clinical problems.

However, because medical imaging is safe, non-invasive and well tolerated by patients, there is a high potential for inappropriate utilization of these services. At the same time, because these high end procedures are necessary to the care of many patients with both medical and surgical disease, many non-radiologist physicians and physician groups have purchased high-end imaging equipment not only to provide these services for their patients but to also increase the ancillary income for their practices. As this trend has evolved, CMS' recognition that more imaging services occur today under the protective umbrella of the in-office exception that "are often not as closely connected to the physician practice" is truly an understatement of the problem.

In addition to outright purchase of high-end imaging equipment, self-referring physicians have entered into leasing arrangements, purchasing of diagnostic tests and reassignment arrangements that circumvent and subvert the original intent of the Stark legislation's ban on inappropriate self-referral. In its comments to CMS on the CY 2007 MPFS proposed rule, the ACR strongly supported the CMS proposals to restrict abuse through tightening the rules on purchased diagnostic tests and reassigned claims. **We are pleased that CMS, in its CY 2008 MPFS proposed rule, has decided to augment its 2007 proposed restrictions and extend those restrictions to include potentially abusive leasing arrangements, percentage-based compensation arrangements, services furnished "under arrangements," as well as to invite comments on amending the in-office ancillary services exception.**

In general, the ACR does not believe these proposals to be confusing or unfair, nor dos the ACR consider them to create uncertainty, ambiguity or create barriers to the delivery of care. **To the contrary, the ACR believes that barriers to the delivery of high quality care are inherent in the perverse effect on medical decision making that is engendered by the conflict of interest in self-referral of imaging.**

In-Office Ancillary Services Exception

The ACR strongly supports CMS revisiting and changing the in-office ancillary exception. As explained below, the ACR believes that, due to their complex specialized nature, "advanced imaging studies" that involve CT, MR and PET, as well as radiation therapy, should never be defined as "ancillary" services and, therefore, should not qualify for the in-office ancillary services exception. **Additionally, the ACR recommends that CMS require that physicians provide in-office ancillary services within one hour after a patient's scheduled office visit.**

We also recommend that CMS modify the definition of a "centralized building" to a location within five miles of the building where a physician or medical group furnishes designated health services. We would support CMS implementing this definition only if it adopts the ACR's recommendations to restrict the time and eliminate certain imaging services from those qualifying for the in-office medical exemption. **Finally, the ACR recommends that non-specialist physicians should not be able to use the in-office ancillary exemption to refer patients for specialized services involving the use of equipment owned, leased, or controlled through a joint venture by the referring physician unless the equipment provides the simple and truly "ancillary" services that Congress originally intended in this exception.**

The ACR believes that the in-office ancillary exception, as it is currently structured, has been counterproductive to what was originally proposed by Congress under the Stark laws. Congress intended to eliminate conflicts of interest for physicians in ordering imaging tests. Thus, while the laws preclude physicians from referring to an imaging center in which they have a financial interest under the in-office exemption, they do not preclude physicians from purchasing and owning the imaging equipment themselves. It was initially believed that the high cost of this equipment would deter most if not all physician practices from entering this market, but as the technology has matured and used imaging equipment became available, more and more self-referring physician practices have entered the market because they view imaging as a major ancillary revenue source. Unfortunately, these self-referring physicians now have significant financial incentives to order high-end imaging studies in order to get a return on their investment..[2]. CMS has long recognized an inherent conflict of interest when physicians are allowed to provide pharmacy services to their patients by prescribing medications and then selling the prescribed medication to their patients. We believe it is time to recognize that the same type of conflict arises when physicians are permitted to order medical imaging and then sell that imaging to their patients.

The ACR agrees with CMS that the original intent of the Congress in establishing the in-office ancillary services exemption was to allow patients to receive a test or procedure at the time of the office visit that was truly ancillary to the office visit and necessary to the diagnosis and treatment of the condition that brought the patient to the physician's office. Congress assumed that such testing would involve simple examinations such as laboratory tests and simple x-rays to visualize a fracture or a pneumonia. Congress simply could not have anticipated the expansion of this regulation beyond its original intended purpose and the subsequent abuse this expansion has permitted. Advanced imaging tests involving CT, MRI and PET clearly do not represent "ancillary" services. These tests are sophisticated imaging examinations, requiring the expertise of specialty physicians and technologists with advanced training in radiation safety, examination design and protocol and interpretation of complex image datasets sometimes involving thousands of images for a single patient. The argument that these tests are necessary to assist the physician at the time of the visit is spurious at best and deceitful at worst.

Likewise, radiation therapy services have no place in the referring physician's office and should never be considered as "ancillary" services. Radiation therapy represents a clearly distinguishable consultative medical service that is provided only after thorough evaluation of the patient's medical condition by many consultants. It is never provided as an ancillary service for

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[2]. Oran Technologies. Association of Otolaryngology Administrators. *An Introduction to In-Office CT.*

the "convenience" of the patient, and to allow self-referring physicians to provide it under the in-office ancillary services exemption is indefensible.

In-office imaging and radiation therapy may also deprive patients of the significant peer-review benefit of independent interpretation of the diagnostic studies and independent evaluation of the appropriate method of radiation treatment for cancer patients, which in turn may lead to unnecessary surgery or other treatment. When a physician with a clear financial interest is permitted to refer, perform, interpret and act on the findings of a diagnostic examination or make a financially-motivated decision on a course of radiation treatment, the patient is deprived of an objective outside review of the process under medical practice standards, peer-review and case-by-case oversight.

Despite claims that patients receive more convenient service from undergoing a study in an MR or CT scanner in their office suite, physicians have taken advantage of the in-office ancillary services exception, using financial incentives to more frequently order medically questionable studies and then fail to have a trained imaging specialist interpret them. In the physician office setting, studies such as CT, MRI and PET seldom, if ever, occur within the hour for patients for their patient's convenience. In fact, research shows that fewer than three percent of myocardial perfusion and PET nuclear medicine studies, along with MR and CT studies, even take place on the same day a patient visits a physician's office. Such sophisticated imaging studies require separate scheduling and patient preparation (e.g., fasting before study, pre-ingestion of drugs and/or contrast media).

These separately scheduled studies can be provided at a location where there is no financial interest to the referring physician, just as easily as they can be provided in the referring physician's office. Allowing these services to be performed in a "centralized building" is completely contradictory to the intent of Congress in creating this exception.

Congress and CMS have imposed laws and regulations that attempt to mitigate this problem by reducing the reimbursement for these high end examinations. Unfortunately, this only incentivizes those physicians who own or lease imaging equipment to order more studies in order to maintain the profitability of their equipment and inappropriately penalizes hospitals and independent imaging centers.

The ACR, historically, has opposed self-referral arrangements because they may improperly affect medical decision-making and may compromise quality patient care. There can be no question that self-referral in the United States, particularly in diagnostic imaging, has contributed to skyrocketing health care costs and frequently impeded quality of care. The BlueCross BlueShield Association in 2003 and the Medicare Payment Advisory Commission (MedPAC) in 2005 each reported that diagnostic imaging was the fastest growing type of medical expenditure in the United States, with an annual growth rate of nine percent that more than doubles general medical procedures..[3]. Technology developments in magnetic resonance imaging (MRI),

[3]. Miller, Mark E., Ph.D. MedPAC recommendations on imaging services. Testimony to Subcommittee on Health Committee on Ways and Means. March 2005.

computed tomography (CT) and ultrasound, coupled with a regulatory vacuum, have created incentives for entrepreneurs and clinicians to increase imaging volume..[4].

Such accelerated volume has certainly led to many unnecessary imaging procedures performed by self-referring physicians..[5]. As the MedPAC and BlueCross BlueShield data illustrate, more physicians are responding to financial and regulatory incentives to send their patients "where the money is.".[6]. Even more importantly, inappropriate and unnecessary medical imaging may compromise patient safety by exposing those patients to excess radiation. The ACR maintains that appropriate use of imaging services, competently performed and interpreted, will maintain quality of care and decrease health care costs.

Fundamentally, in-office medical imaging has proliferated because of the acquisition of high-tech imaging equipment by physicians who were not trained as radiologists, or even to supervise the operation of equipment or oversee these specialized procedures. Radiologists are trained for at least 4 years and usually as many as 5 or 6 years to perform and interpret imaging studies. In their practices, they do not have the opportunity to self-refer. All their patients are referred to them by other physicians, for no other reason than that they desire information about their patients. Conversely, nonradiologist physicians who operate their own imaging equipment (or, through various indirect arrangements own equipment to which they refer) are almost always in a position to self-refer or to refer within their group (which is essentially the same thing as self-referral).

Recent data illustrate how self-referral has spurred imaging utilization. The Department of Radiology at Thomas Jefferson University Hospital years ago formed the Center for Research on Utilization of Imaging Services (CRUISE). David Levin, M.D., and his colleagues have studied utilization trends and practice patterns in imaging, primarily using the CMS Physician/Supplier Procedure Summary Master Files. Their data have corroborated other studies and that have shown quite clearly that self-referring physicians are a major contributor to the rapid growth the Medicare program is experiencing in imaging.

Notably, a recently completed CRUISE study by Dr. Levin, et al. compared utilization trends in MRI, CT, and nuclear scans done on units owned by radiologists or nonradiologist physicians in their private offices. Between 2000 and 2005, the MRI utilization rate per 1000 Medicare beneficiaries increased by 83 percent in radiologist offices, compared with 254 percent in nonradiologist offices. The CT utilization rate increased by 109 percent in radiologist offices, compared with 253 percent in nonradiologist offices. The nuclear scan rate increased 40 percent in radiologist offices, compared with 192 percent in cardiologist offices (cardiologists are the only other specialty having major activity in nuclear scanning). These data substantiate the

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.[4]. BlueCross BlueShield Association. (2003). *Medical Technology as a Driver of Healthcare Costs: Diagnostic Imaging.*

.[5]. Moskowitz H, Sunshine J, Grossman D, Adams L, Gelinas L. "The effect of imaging guidelines on the number and quality of outpatient radiographic examinations." *American Journal of Radiology.* 2000 : 175:9-15.

.[6]. Hoangmai H. Pham, Kelly J. Devers, Jessica H. May, and Robert Berenson
"Financial Pressures Spur Physician Entrepreneurialism." *Health Affairs*, March/April 2004; 23(2): 70-81.

concerns that CMS has raised and further solidify the evidence against continuation of the in-office ancillary services exemption as it is currently structured.

The ACR understands that there are situations where the in-office ancillary services exception continues to be appropriate and include ultrasound in an obstetrician-gynecologist's office; echocardiography that cardiologists perform and interpret; and simple imaging examinations that need to take place for acute conditions and can be provided immediately (i.e., x-rays for possible fracture or pneumonia). In these situations, patients should be advised that their physicians own this equipment and are performing the studies to provide immediate patient care.

In response to the questions raised by CMS, the ACR firmly believes that changes to the in-office ancillary exemption are necessary.

The ACR recommends that certain medical services should not qualify for the in-office ancillary services exemption. Services that should not qualify, and should never be defined as "ancillary", are CT, CTA, MRI, MRA, PET, PET/CT and radiation therapy.

The ACR also recommends that restrictions should be placed on any service provided under the in-office ancillary services exemption to require that the exempted ancillary service must be provided within one hour of the time of the office visit.

In response to the questions of whether and how to change the definitions of "same building" and "centralized building" the ACR believes that, if convenience and timeliness of diagnosis are the rationale for the in-office ancillary services exception, CMS should require that a "centralized building" be within five miles of the building where the physician or medical group furnishes medical services. We would support this definition only if CMS adopted the ACR recommendations for time restriction and deletion of certain medical services from those qualifying for the in-office medical exemption.

The ACR recommends that non-specialist physicians should not be able to use the in-office ancillary services exemption to refer patients for specialized services involving the use of equipment owned, leased, or controlled through a joint venture by the referring physician unless the equipment provides the simple and truly "ancillary" services originally intended in this exception.

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests [Anti-Markup Provisions]

CMS again proposes to apply the "anti-markup" provision on the technical and professional component of diagnostic tests. This proposal would prevent imaging providers from marking up the TC or PC of studies, whether or not a billing physician or medical group outright purchases the professional component or the technical component, or whether the TC or PC provider reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity).

CMS also seeks comments on whether to impose the anti-markup rule to TCs that occur in a "centralized building." The ACR recognizes that CMS wants to close a perceived loophole in

which a part-time or leased group employee performs the technical component of imaging in a "centralized building," but the group neither gets a reassignment from the employee technician (one who cannot bill the TC or PC directly), nor buys the TC outright from the technician. **The ACR supports CMS applying the anti-markup provision to TCs that are performed in a "centralized building."**

The ACR continues to share CMS' concern "that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse.".[7]. For example, the ACR has learned of arrangements where the technical component (TC) for MRI procedures performed under a lease arrangement is billed to Medicare at a significant markup to the supplier's actual charge to the billing entity. The billing entity (usually the self-referring physician or medical group) thus is essentially in the role of a "broker" of imaging services. They neither provide the actual service nor interpret the images. Nevertheless, they garner the lion's share of the reimbursement for the simple process of "brokering" the transaction, in which their patient is captive and is not offered a choice of imaging provider.

Generally, the ACR agrees with the language proposed by CMS to amend § 424.50 and § 424.80 of its regulations. The ACR has advocated that Congress and CMS adopt quality standards to reverse this disturbing trend, ensure program integrity and safeguard against patient abuse. Consequently, we believe that the proposed purchased diagnostic test and reassignment changes could advance those critical objectives by influencing many physicians, medical groups and other entities to separately bill the technical and professional components of diagnostic studies.

The ACR supports CMS' proposal to exempt from the anti-markup provision diagnostic tests that independent laboratories have not ordered themselves. **The ACR urges CMS to extend this exemption to radiologists' offices.** However, we are concerned that the proposed anti-markup provisions include services performed by independent contractors and part-time employees of the billing physician or medical group. We believe that excluding only full-time employees of the billing physician or medical group from the anti-markup proposals could impair many legitimate, non-abusive arrangements where radiology practices engage exclusive contractors or employ exclusive part-time radiologists or in which radiologists independently contract with or are part-time employees of multiple radiology groups that do not engage in self-referral. The ACR offers the following alternative proposal. Since radiologists are not in a position to profit from abusive self-referral, CMS should extend the anti-markup exclusion to contractors and part-time employees of radiology physicians or radiology groups.

The ACR recommends that CMS change the language in the first column on page 38180 of the proposed rule to read "(unless the performing supplier is a full-time employee of the billing entity or the billing entity is a radiologist or radiology group)."

[7]. 2007 Medicare Physician Fee Schedule Proposed Rule. Federal Register. Vol. 71, No. 162. 22 August, 2006.

Unit-of-Service (Per-Click) Payments in Space and Equipment Leases

CMS proposes that the Stark regulatory exception for space and equipment leases may **not** include per click-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by the physician to the entity. The agency believes that such arrangements "are inherently susceptible to abuse" because the physician lessor would have a clear incentive to profit by referring more patients to the lessee. Imaging leases have boomed since CMS initially proposed the Stark space/equipment rental exception in 1998. Given the Congress' and state attorneys general interest in lease transactions, ACR welcomes CMS focusing on per-click leases in the Rule. We strongly support banning time-based and unit-of-service based leases, with a one-year grace period to allow physicians who have these leases to unwind them.

The ACR maintains that per-unit or "per click" leases fuel an incentive to order unnecessary examinations that is essentially as potent as if the ordering physician is a partner in a joint venture. Additionally, incentives to order unnecessary examinations are just as strong for non-Medicare patients..[8]. This further extends the waste of health care dollars.

Professor Jean Mitchell conducted a recent study, finding that almost half of all imaging done outside of the hospital setting was done in a self-referral situation by non-radiologists for CT, MR and PET. Among this group that billed for these procedures, 61 percent of MR, 64 percent of CT and 30 percent of PET billings were from groups that did not have equipment in their offices..[9]. For MR and PET, the data showed that the share of statewide volume billed by the physicians has grown dramatically since 2000. Many self-referring physicians have made the argument that there is a need to have CTs, MRs and PET machines in their office for patient convenience. Mitchell believes, and the ACR agrees, that the large amount of billings of these leases or "per click" arrangements located outside of their offices undermines the convenience argument.

The ACR encourages CMS to use its authority under section 1877(e)(1) of the Act to prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.

Perhaps the most abusive unit-of-service leasing arrangement is the scheme whereby a referring physician leases space on a unit-of-service or per diem basis from a MRI facility and then submits a claim to Medicare for the global fee..[10].;.[11]. Other provisions of this CY 2008 MPFS proposed rule

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.[8]. Mitchell, J., "The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging", Health Affairs, April 16, 2007.

.[9]. Mitchell, J., "The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging", Health Affairs, April 16, 2007.

.[10]. David Armstrong. WSJ May 2, 2005: "Own Image: MRI and CT Centers Offer Doctors Ways to Profit on Scans; Physicians Pay a Flat Fee For Procedures, Then Bill Insurers – at Higher Rate; Navigating Legal Landscape." .Wall Street Journal. 2 May, 2005.

would restrict any abusive profit to the lessee physician or medical group under such an arrangement. However, since the marketplace has repeatedly created an "advisory industry" (see attachment) to find loopholes, the ACR believes CMS could firmly close the door on such abuses by prohibiting all such arrangements.

The ACR believes that most leasing arrangements are economically driven, do not contribute to patient convenience or any other attributes that promote better patient care and generally drive up utilization. **The ACR supports a ban on all time-based and unit-of-service-based leasing arrangements.**

The ACR supports a one-year grace period to allow unwinding of such banned leasing arrangements.

"Set in Advance" or Percentage-Based Compensation Arrangements

In a further attempt to curtail certain abusive arrangements, CMS would clarify its original intent that percentage compensation arrangements could be used only for compensating physicians for the services they perform by disallowing arrangements that pay for services and items, e.g., medical equipment and office space, on a percentage of revenues the equipment or space realizes. CMS only would allow percentage-based compensation to pay for physician services that a physician personally performs; and that must be derived directly from service-related revenues.

In 2002, the ACR commented to CMS that it supported the ability of physicians to receive compensation for their professional services on a percentage-basis. The ACR agrees with CMS' decision to continue allowing such arrangements and proposed action to curtail potentially abusive percentage compensation arrangements to physicians for non-professional services.

Stand in the Shoes

The ACR shares the concern of CMS that inserting entities or contracts into a chain of financial relationships linking a DHS entity and a referring physician is a subterfuge that intends to circumvent Stark self-referral prohibitions. **Therefore, the ACR supports CMS' proposal to amend § 411.354(c) to require a DHS entity to stand in the shoes of another entity it owns, to which physicians refer Medicare patients for DHS.**

Under Arrangements

CMS also proposes to restrict certain services furnished 'under arrangements.' CMS is trying to determine the best approach to prohibit certain arrangements under which physicians supply items and services to DHS entities. For instance, a group of radiologists and cardiologists form a joint venture to purchase a 64-slice CT scanner to establish a cardiac imaging center on an academic medical center's campus. Instead of enrolling the venture as a supplier with Medicare and commercial payers, the venture enters into an "under arrangements" contract with the hospital. The venture would provide imaging services to registered hospital outpatients (some of whom the cardiologists would refer), while the hospital bills for the services rendered to

[11]. Bruce Jaspen. "Doctors' MRI Deals a "Sham", State Says." Chicago Tribune. 10 May, 2007.

Medicare beneficiaries under the HOPPS. In return, the hospital pays the venture a negotiated contract rate for each study it performs.
Current Stark rules do allow such referrals by the cardiologists to the joint venture for imaging because the cardiologists technically are not referring to the joint venture "entity," but rather to the hospital. Only hospitals submit claims to Medicare in the "under arrangements" context. CMS proposes to curb the risk of imaging overutilization by expanding its definition of "entity," so that a DHS entity includes both the person or entity that performs the DHS, and the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. CMS recognizes that independent diagnostic testing facilities (IDTFs), ambulatory surgical centers (ASCs) and other non-hospital settings have taken advantage of the "under arrangements" opportunity. Accordingly, CMS solicits comments on whether to adopt its approach; MedPAC's recommendation of broadening the Stark definition of "physician ownership;" or a combination of both approaches. If CMS adopts any of these approaches, the U.S. imaging environment would change dramatically. Referring physicians apparently would not be able to participate in joint ventures that provide services to hospitals and others "under arrangements."

The ACR historically opposes any financial arrangements that could harm patients, or give an economic incentive to perform unnecessary imaging. Therefore, we have supported federal legislative and regulatory action to prohibit self-referral or restrict its influence on patient care decisions.

CMS' fundamental concern that many referring physicians have prospered from joint venturing with hospitals for imaging services via "under arrangements" is shared by the ACR. These arrangements are essentially thinly veiled substitutes for the imaging centers that were the original target of the Stark laws. Many of these deals do not appear to have any clinical value yet they may well increase costs to Medicare beneficiaries and the Medicare program. **Thus, the ACR believes the CMS proposal to tighten "under arrangements" services could benefit patient care and reduce undue financial incentives.**

However, the ACR is concerned that the proposal to change the definition of entity at §416.351 to include both the person or entity that performs the DHS as well as the person or entity that submits claims or causes claims to be submitted to Medicare for DHS may not have its desired effect due to potential ambiguity in the interpretation of the meaning of "performs." **While the ACR supports this proposed change, we recommend that, in its Final Rule, CMS more specifically define the meaning of "performs" to avoid creation of future loopholes.**

The ACR is also concerned that the implementation of this "under arrangements' proposal, as well as the preceding "stand in the shoes" proposal, if instituted without a comprehensive implementation of all other CMS proposals in this rule, as well as recommendations from ACR on the in-office ancillary services exception, could lead to formation of multi-specialty groups of referring physicians for the sole purpose of providing high-cost imaging under the umbrella of the in-office ancillary services exception. This subterfuge would result in no relief from the current abusive practices and could result in a severe revenue loss for already-besieged hospitals.

The ACR, therefore, recommends that CMS not implement its proposed policies on self-referral on a piece-meal basis, but rather implement them in a comprehensive package that allows no escape for abusive practices.

In an environment where there is no shortage of legal advice to individuals who desire to benefit from regulatory loopholes, the ACR believes that CMS should tighten the noose on potentially abusive self-referral by using all the tools at its disposal. **Therefore, the ACR supports including the MedPAC recommendation to expand the definition of physician ownership in the current CMS proposal on services furnished "under arrangements."**

Additionally, we would recommend changing the language of the MedPAC recommendation to state "....an entity that derives a substantial proportion of its revenue from a provider of designated health services or from the business of providing designated health services." We would also recommend that, for this purpose, a "substantial" portion of revenue should constitute 50 percent or greater.

As CMS noted in an earlier Stark II final rule (Phase I; January 4, 2001), restricting "under arrangements" could disrupt patient care and cause administrative burden to physician practices and hospitals. We are aware that certain physician groups who are party to "under arrangements" have negotiated termination clauses if the arrangements no longer comply with federal law or rules.

However, should CMS adopt its proposal in the final MPFS rule effective January 1, 2008, we acknowledge that many physician-hospital ventures would need to be unwound. The ACR, therefore, recommends that CMS consider affording a one-year grace period to such ventures.

Conclusion

Thank you for the opportunity to comment on this proposed notice. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues on radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org..

Respectfully Submitted,

Harvey L. Neiman, MD

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Attachments to be sent under separate cover via U.S. mail.

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CMS

8-28-2007

As practicing urologist in Brazoria county, Texas, I have been providing my patients lithotripsy and other cutting edge therapies. I have an interest in a partnership with Healtronics that provides shock-wave lithotripsy and laser services. By accepting the risk of providing these costly services when hospitals refused to do so, urology joint ventures have greatly expanded patients access to effective treatments in Brazoria and Harris County.

The **burden of proof** required in this new proposal is detrimental to my practice. I already have to take care of the health problems of my Medicare beneficiary patients at a charitable price set by CMS and now I face a burden of proof. I would just like to focus on providing good quality health care for my patients and not have to worry about burden of proof.

Hospitals are generally unwilling to take risks and are often operating on razor-thin margins. They are averse to bearing the risk of low volume usage for new and innovative technologies and services. When physician joint ventures bring these beneficial technologies to hospitals, the hospital may require **per click arrangement** to protect themselves from the risk of low volume.

Percentage-based compensation enable new treatments and technologies to be offered for low or no volume procedures. An entity that brings the new technology should be compensated in proportion to the payments.

Stand in the Shoes
CMS reimbursement for ASCs are less than for hospitals. Many ASCs are owned or partially owned by hospitals with joint venture with physicians. If CMS views this as illegal then it would stifle future development of services that could be provided on a joint venture because lots of hospitals cannot afford to take all the financial risks involved.

For Services furnished under arrangements, I believed that, at least for the urological joint ventures, the primary purpose of physician investment is to improve patient care. We, physicians, want to have new technology available for our patients in order to provide the best patient care.

As the court in ALS vs Thompson noted, extracorporeal shock wave lithotripsy is not a DHS.

Finally, it appears to me that the reason CMS wants to ban services under arrangements where there is MD ownership is because it has heard of questionable diagnostic imaging arrangements. There is not identification in our case about abuse with lithotripsy or lasers.

Thanks for your time.

Sincerely,

Phil Blake MD

Phil Blake, MD, FACS, FICS
Member of Healthronics