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**White Paper**

# FRAUD AND ABUSE ISSUES IN BILLING 'SPLIT INTERPRETATIONS' OF CCT AND CTA (August 23, 2006)

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**For The American College of Radiology**

The advent of advanced cardiac computed tomography (CCT) and cardiac tomographic angiography (CTA) has expanded both the utility of these studies as diagnostic services and the specialties of the physicians rendering them. In 2006, both cardiologists and radiologists provide the interpretations of these services. The technologies involved in rendering these services are sufficiently different from prior modalities that the American College of Radiology and the American College of Cardiology have come together to develop new, more specific codes assigned to Category III code status because they do not meet the defined rigorous criteria necessary for Category I code status. *("Clinical Examples in Radiology Update Bulletin", Volume 1 Bulletin 2, 2005.* In terms of what the new technologies do,

> *While the technical parameters and field of view of a cardiac CT or MR examination will appropriately be tailored to help evaluate the cardiac anatomy and/or function in question, the images obtained will demonstrate adjacent anatomy, often including portions of the lungs, mediastinum, spine and upper abdomen. It has been documented that these studies often demonstrate clinically significant non-cardiac findings. (Weinreb et al, "ACR Clinical Statement on Non-invasive Cardiac Imaging" Journal of the American College of Radiology, Volume 2, #6 (June 2005) pp. 471 – 472.)*

As a result, the interpretation of these types of studies entails addressing the totality of the image which has been produced.

As cardiologists have moved more into the imaging arena as well, the American College of Cardiology Foundation/ American Heart Association have produced clinical competence statements pertaining to cardiac CT and Magnetic Resonance Imaging (MRI) to guide cardiologists in their rendering of these services. ("ACC/AHA Clinical Competence Statement

on Cardiac Imaging with Computed Tomography and Magnetic Resonance", Journal of the American College of Cardiology, Volume 46, #2 (2005) pp. 383 – 402) In a 2006 update for training in adult cardiovascular medicine dealing with the issues associated with imaging services, the American College of Cardiology has addressed the issue of incidental non-cardiac findings that may be produced by these technologies.

> *Regarding the cardiovascular medicine specialist performing a cardiac CT, the American College of Cardiology recognizes and endorses education and training of such individuals in the recognition of incidental scan findings in support of quality imaging care of patients with advanced cardiovascular disease. These cases require referral to a specialist or radiologist with expertise in chest imaging. (ACCF 2006 Updates for Training in Adult Cardiovascular Medicine (Focused Update of the 2002 COCATS 2 Training Statement, Task Force 12: Training in Advanced Cardiovascular Imaging (Computed Tomography), Journal of the American College of Cardiology, Volume 47, Number 4 (2006) pg. 917)*

Meeting the applicable clinical standards to provide the totality of the appropriate interpretation associated with these studies presents a number of significant legal challenges. The ACR has addressed some of these challenges. ("ACR White Paper on Split Interpretations", July 12, 2006)

Given the specific focus by cardiologists in their interpretations of these studies on the detection of cardiac disease which "does not encompass the entire lung field", contrasted with the broader imaging expertise of radiologists, mechanisms to be paid for the appropriate rendering of services in the current payment system can be problematic. Cardiologists seek the input of radiologists and in some instances radiologists have looked to cardiologists to provide their expertise in the interpretation of these studies. Three typical solutions have emerged to bring to bear for the patient the differing expertise of both specialties:

(1) The physicians use modifiers which purport to designate that neither the cardiologist nor the radiologist is performing the full service, but both are contributing to the interpretation;

(2) One of the clinicians performs the interpretation which is indicated on the claim form while the other specialist "over-reads" the images; and

(3) Radiologists join cardiology practices for this purpose only and reassign the right to payment to the cardiology group.

The legal implications in these various attempts to confront the limitations of the current billing system, particularly as it pertains to Medicare, can be significant. There are liabilities associated with basic Medicare reimbursement principles, potential false claims, Stark statute violations, antikickback violations, in addition to other concerns related to liability.

This White Paper elucidates the legal implications associated with Medicare billing for "split interpretations" where both a radiologist and a cardiologist are involved in delivering the

full service to the patient. This paper does not address issues pertaining to standards of competence for either specialty in providing the interpretations of these imaging services, nor does it address any of the issues associated with the technical components of such services.

Still further, this paper does not address the issue of the use of varying codes to describe the service. At this time, Medicare carriers around the country treat the new codes variably. For example, the Florida and Connecticut carriers recommend that clinicians using these codes provide patients with advance beneficiary notices (ABNs) that the services will not be paid for. Wisconsin recognizes two CTA codes, but none of the others. New York and New Jersey carriers recognize CTA codes but apply competence standards. Any clinician intending to use the new codes should consult their carrier's Local Coverage Determinations (LCDs).

Moreover, although there may be legal liabilities also associated with the submission of claims to commercial carriers using these methodologies, this White Paper addresses only the issues associated with the submission of claims to the Medicare program where any of the three solutions to the interpretive conundrum as noted above are employed.

The ACR White Paper (July 12, 2006) has taken the position that a single physician should have responsibility for the delivery of interpretation of cardiac CT and CTA. Yet that position does not confront the fact that radiologists and cardiologists are both involved in delivering these services in a variety of configurations throughout the country; nor does it analyze the legal pitfalls that lurk in these arrangements. This White Paper is not intended to either endorse or advocate on one hand, nor criticize on the other, any specific approach. Rather, this White Paper is intended to elucidate the liabilities to both cardiologists and radiologists as they contemplate how to organize their delivery of these services. Because of the complexities of the laws at issue, it is useful to review what they are and where they come from

## I. The Law

There are a range of statutes and regulations under the Social Security Act and elsewhere that may be applicable including the antikickback law, Stark and false claims issues.

### A. Anti-Kickback Statute

The Social Security Act, applicable to Medicare and Medicaid, provides that the receipt, solicitation or payment of any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, for referring an individual to a person for furnishing services to be reimbursed by Medicare or Medicaid or in return for purchasing, leasing, ordering or arranging for, or recommending the purchase, lease or ordering of any goods, facility, service or item for which reimbursement shall be made by Medicare or Medicaid is a felony punishable by up to $25,000 in fines, up to five years imprisonment or both (42 USC '1320a-7B). The liabilities extend to all parties to a prohibited transaction. In the Health Insurance Portability and Accountability Act of 1996, this provision was extended to all federal payors. In the Balanced Budget Act of 1997, violations became punishable by a $50,000 civil money penalty as well.

The general proposition that fraudulent acts under Medicare would be subject to penalty was enacted in 1972. The legislative history spoke of "penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the Medicare and Medicaid programs." (Sen. Fin. Comm. Rpt. to H.R. 1, Social Security Amendments of 1972 at 208). At that time it was stated that the criminal penalty provision would include such practices as the soliciting, offering, or accepting of kickbacks or bribes, including the rebating of a portion of a fee or charge for a patient referral involving individuals, providers of healthcare services, and business entities such as corporations, companies, associations, firms, partnerships, societies, and joint stock companies. There is no further elucidation on the prohibited practices in 1972. In 1972 the violations were to be treated as misdemeanors.

In 1977, the penalties were upgraded to felony status, and rewritten to clarify and restructure those provisions in existing law which defined the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid. (Sen. Fin. Comm. Rpt. to S.143, Sept. 26, 1977 at 10).

> *The bill would define the term "any remuneration" broadly to encompass kickbacks, bribes or rebates which may be made directly or indirectly, overtly or covertly, in cash or in kind. (Sen. Fin. Comm. Rpt. at 12)*

Under the "Medicare and Medicaid Patient and Program Protection Act of 1987" the Secretary of Health and Human Services ("HHS") was given additional authority requiring exclusion from Medicare and Medicaid of any individual or entity who has engaged in certain proscribed behaviors and permitting it in other situations. At the same time Congress required the publication of joint regulations from the Office of the Inspector General and the Department of Justice that would describe those transactions that might tend to induce referrals but would be protected nonetheless in "safe harbors." These authorities, along with considerably increased authority to assess civil monetary penalties in the amount of $50,000 for each violation, have now been extended in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

1. *Safe Harbors*

Safe harbor regulations were first published in 1991. For safety under any of the safe harbors, every element of the regulation must be met. Failure to conform with a safe harbor does not mean the transaction is per se violative. It does mean that the situation would be evaluated on a facts and circumstances basis subject to prosecutorial discretion.

In November, 1999, the OIG published final clarifications of earlier safe harbors with some new safe harbor protections. Clarifications and modifications address (1) the original investment safe harbors, (2) space and equipment leases, (3) personal services and management services, (4) sale of practice and (5) the discount safe harbor. New safe harbors were issued pertaining to (6) investments in providers in under-served areas, (7) ambulatory surgery centers, (7) investment in a group practice, (8) physician recruitment, (9) obstetrical malpractice

insurance subsidies, (10) referral agreements for specialty services, and (11) cooperative hospital service organizations. In general these are less restrictive than the earlier safe harbors.

2. *Advisory Opinions and Fraud Alerts*

As part of the provisions in HIPAA which have generally increased and expanded the government's enforcement authority, there was a provision enacted which requires the Secretary of Health and Human Services to issue advisory opinions regarding various forms of behavior posed to the Secretary by members of the public. This program is now in place and regulations implementing it set forth an extremely complex and detailed process to obtain an opinion. Without elaborating on all of those details, not only must highly specific and refined information be disclosed by and about the requester and the transactions, the Office of the Inspector General charges fees for preparing such an opinion. In addition, from time to time the OIG publishes fraud alerts on matters it considers worthy of attention in the industry.

B. Enforcement of the Anti-Kickback Statute -- Hanlester and LaHue

There is relatively little caselaw under the antikickback statute. Two cases, however, stake out significant aspects of the enforcement continuum. On April 6, 1995, the Ninth Circuit issued a decision reversing in part a decision by the Secretary of HHS, which had found that certain parties to a laboratory joint venture violated the Medicare and Medicaid anti-kickback statute. In this case, Hanlester v. Shalala, 1995 WL 148280 (9th Cir. 1995) ("Hanlester"), the Office of the Inspector General ("OIG") sought to exclude Hanlester, three physician-owned clinical laboratory limited partnerships that Hanlester established, Hanlester's corporate partner, and several of its individual officers and partners from the Medicaid program using the statutory authority given to the Secretary.

The OIG charged that these entities had paid illegal remuneration in the form of investment returns to physician investors in the labs to induce referrals to the labs, in violation of ' 1128B(b)(2) of the Social Security Act. The OIG also charged that these parties violated section 1128B(b)(1), which prohibits the solicitation or receipt of remuneration in return for referrals. This charge was based on the theory that the labs were merely a "shell" that allowed the parties to receive remuneration from SmithKline Bio-Science Laboratories, which managed the labs and performed most of the labs' tests.

The Ninth Circuit examined several issues regarding the construction of the anti-kickback statute's prohibitions. First, the court found that the statute's prohibition against remuneration "in return for" referrals did not require proof of a "quid pro quo" agreement to refer, as a prerequisite to a violation of the statute. Second, the court rejected the argument that the anti-kickback statute is unconstitutionally vague, noting that the statute regulates only economic conduct and not constitutional rights. Third, the court found that the statutory phrase "any remuneration" was intended to broaden the reach of the law beyond mere kickbacks, bribes, and rebates. Fourth, although recognizing that the term "induce" does not contemplate the mere encouragement of referrals, the court upheld the interpretation of that term to require "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business."

Among other issues, the court looked to see if there had been a violation of ' 1128B(b)(1), which prohibits the receipt of remuneration in return for referrals in the laboratory management contract with SmithKline. While recognizing that substantial economic benefits were received, the court did not find a violation because (1) similar contracts were common in the clinical laboratory field, (2) the parties believed their conduct was lawful and did not seek to hide payments, and (3) the test revenue flowed from the labs to SmithKline under the agreement, rather than flowing in the other direction.

Potentially, the most significant aspect of the opinion, however, was the court's position regarding intent. This court decided that a party can only violate the anti-kickback statute if it engages in prohibited conduct with the specific intent of disobeying the law. The Office of the Inspector General has taken the position that it believes the Hanlester opinion is only applicable in the Ninth Circuit, and that they will continue to aggressively enforce elsewhere.

In addition, in 1999 convictions and jail sentences were obtained by the government against two physicians and a hospital administrator for arrangements extending back to 1983 where the physicians were paid for services rendered to their nursing home patients when they were admitted to the hospital where the administrator was a manager. On appeal, the convictions were upheld demonstrating the continued vitality of the statute as far as the enforcers are concerned and the willingness of prosecutors to seek jail time for physicians and well-regarded hospital administrators. (US v. LaHue, 261 F.2d 993, (10th Cir. 2001))

C. Stark

In 1989, effective January 1, 1992, a law was enacted prohibiting physicians from referring Medicare patients for the provision of clinical laboratory services to entities with which they had a financial relationship, unless the relationship met one of a number of exceptions. That law became known as AStark I@, because there was a subsequent major extension of the types of restriction at issue for clinical laboratory services. The second iteration of Stark became known as AStark II@, and extended the services implicated by the anti-referral provisions to a range of other services including physical therapy, occupational therapy, outpatient drugs, radiation therapy, imaging services including MRI, CT and ultrasound, durable medical equipment, home health services and inpatient and outpatient hospital services.

Under the Stark II law (42 USC ' 1395nn, et seq.), effective January 1, 1995, it is prohibited for a physician (or an immediate family member) to refer a Medicare or Medicaid patient for designated health services to an entity with which the physician or family member has a financial relationship, unless the relationship meets one of seventeen statutory exceptions. Physicians are interpreted to include podiatrists, optometrists, chiropractors and dentists. It is prohibited to refer and the entity receiving the tainted referral is prohibited from submitting a claim. Violations are punishable by $15,000 civil money penalty for each improper claim submission and $100,000 for a circumvention scheme. Payments made pursuant to a tainted referral are overpayments. There is also potential liability for false claims which are punishable by triple the charges and up to $11,500 per improper claim.

Stark II defines financial relationships to include both direct and indirect compensation relationships. Stark II defines a compensation relationship as Aany arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity...The term >remuneration= includes any remuneration, directly, indirectly, overtly or covertly, in cash or in kind.@ (42 USC ' 1395nn(h)(1)(A) and (B)).

D. Relationship between Anti-Kickback Statute and Stark II

The anti-kickback statute applies to all Medicare, Medicaid and, as of January 1, 1997, federally financed programs, including CHAMPUS, Title V, etc. It applies to whomever is involved in a relevant transaction. Violations can be criminal or civil, and an exclusion may be imposed without a conviction or civil penalty. If you do not conform with a safe harbor, then the situation will be analyzed on a facts and circumstances basis.

Stark II, on the other hand, applies only to physician referrals and then only for the designated services and where there is a financial relationship between the referring physician and the referred to entity. There are two prohibitions under Stark: (1) the prohibition against the referral; and (2) the separate prohibition against a claim submitted pursuant to an improper referral. Stark does not offer safety zones. You either comply or you do not. For these reasons, transactions are usually analyzed first under Stark and then under the anti-kickback statute.

E. False Claims Liability

Another potential source of liability lies in the False Claims Acts which make false claims punishable as crimes, civil violations, and also provide a basis for civil money penalties as well as exclusion from federal program payment opportunities. Federal law makes it a felony to knowingly and willfully make or cause to be made a false claim or statement under any health benefit program which receives federal funding or a state health program including Medicaid. (42 U.S.C. ' 1320a-7b(a)). These healthcare specific statutes are in addition to the general federal False Claims Act which also makes it a crime to knowingly make or present false or fraudulent claims to the United States government. (18 U.S.C. ' 287). The federal False Claims Act permits the government to recover from a person who knowingly submits false claims a civil penalty of $5,500 – $11,000 per claim plus three times the amount of damages sustained by the federal government. (31 U.S.C. ' 3729(a)). It is this statute which provides the opportunity for whistleblower qui tam actions to enforce the Act.

Where the Stark statute requires no intent to find it has been violated, and the antikickback statute requires a knowing and willful violation, the liabilities for false claims fall somewhere between those, in terms of the requisite intent to find a violation. The statute requires a knowing and willful violation of its provisions, but such knowledge need not be only actual knowledge, but can be inferred where the person acts in deliberate ignorance of the truth or falsity of the claim or acts in reckless disregard of the truth or falsity of the information in the claim. (31 USC §3729(b)) No proof of specific intent is required and intent can be inferred from a pattern of behavior. There is even caselaw which has found that continuing to submit claims in the fact of carrier rejection can be the basis for a conviction. (US v. Lorenzo, 768 F. Supp. 1127 (E.D. Pa. 1991).

In addition to these basic provisions, false claims liability also traditionally has entailed charges of mail fraud, wire fraud, and even the application of Racketeer Influenced and Corrupt Organizations (RICO) statutes. (18 U.S.C. ' 1961). Administrative sanctions are also a threat to providers who submit false claims. The Office of the Inspector General can proceed administratively under the Medicare and Medicaid statutes to impose civil penalties of $11,000 per false claim plus three times the amount claimed. (42 U.S.C. ' 1320a-7a). There are also legal theories that connect kickbacks, false claims, and Stark.

F. Caselaw on Kickbacks, False Claims and Stark

A federal court case in Texas, US ex rel. Thompson v. Columbia HCA Healthcare Corporation (5th Cir., Oct. 31, 1997) found that a kickback might constitute a false claim B a case certain prosecutors have tried to make, previously unsuccessfully. The facts involved an ambulatory surgery center joint venture. Allegations regarding Stark II violations and whether cost reports based on services rendered in fulfillment of tainted referrals were false, were remanded to the district court. On remand, the District Court found that statements in a cost report which reflected referrals which generated kickbacks, could be considered false claims. (US ex rel. Thompson v. Columbia HCA Healthcare Corporation, (S.D. Tex, No. C-95-110, August 18, 1998) Still further the court found that a Stark violation does amount to an actionable false claim and that Aa pecuniary injury to the public fisc is no longer required for an actionable claim under the False Claims Act (FCA).@ The court was persuaded the FCA reaches all fraudulent attempts to cause the government to pay out money.

## II. Analysis

A. Use of Modifiers

Some clinicians have approached the issue of designating shared expertise with regard to CCT and CTA by documenting claims submitted to Medicare with the modifier "—52" which indicates reduced services. The primary legal issue in this instance is potential false claims liability.

Whether this is an appropriate manner in which to submit claims turns, in the first instance, on the definition of "an interpretation." Surprisingly, there is no single location in the Medicare manuals where the definition of a radiologic interpretation can be found. However, the Medicare Claims Processing Manual ("MCPM") 100-4 does address the implications of a full interpretation in the analysis of the appropriate approach to payment for x-rays and EKGs interpreted for patients treated in the emergency department.

For many years in emergency department care, Medicare paid for two interpretations—one done by the emergency physician in the moment of rendering care and another performed by a radiologist or cardiologist subsequently. In 2003, the policies pertaining to these dual interpretations were changed to specify that the interpretation that would be paid for would be the interpretation that was used contemporaneously in the care of the patient. In its review of what would qualify as an appropriate interpretation, the Manual distinguished between an "interpretation and report" of an x-ray or an EKG procedure and a "review" of the procedure.

*A professional component billing based on a review of the findings of these procedures, without a complete, written report similar to that which would be prepared by a specialist in the field does not meet the conditions for separate payment of the service…An "interpretation or report" should address the findings, relevant clinical issues and comparative data (when available). (MCPM, Ch.13 ' 100.1)*

The only instance in which the carrier is to pay for a second interpretation, identified through the use of modifier "—77," is unusual circumstances for which documentation is provided, such as the questionable findings for which the physician performing the initial interpretation believes another physician's expertise is needed or a changed diagnosis resulting from a second interpretation of the results of the procedure. Interestingly, in the application of the policies pertaining to which analysis of the imaging or the EKG qualifies for payment, consideration explicitly is not given to physician specialty as the primary factor in deciding which interpretation and report to pay, regardless of when the service is performed. By analogy then, an interpretation of cardiac CCT or CTA would necessarily address all of the findings in the image, relevant clinical issues and comparative data when available.

With the establishment of new cardiac CCT and CTA modalities the American College of Radiology, the American College of Cardiology, and the Blue Cross and Blue Shield Associations worked together collaboratively to establish new codes. Supporting their availability, the ACR stated the following

*It is important to note that the physician interpreting the study is responsible for the interpretation of all information on the axial source images of the pre-contrast, arterial phase sequence, and venous phase sequence, as well as the 2-D and 3-D reformatted images resulting from the study, cine review as noted in the CPT code proposal. ("Clinical Examples in Radiology Update Bulletin", Volume 1 Bulletin 2, 2005 pg. 3).*

Based on the Medicare statements regarding what qualifies as an interpretation, if the cardiologist were to submit a claim without performing all of the components of the interpretation himself, this could potentially be deemed a false claim since it is an intentional, inaccurate representation of the service provided. There are, however, analogies with respect to split billing, even between cardiologists and radiologists.

In the application of supervision and interpretation codes in interventional radiology, it is recognized that the cardiologist may perform the supervision aspect of the service while the radiologist performs the interpretation. For those studies, there is a recognition that the actual supervision of the service and the interpretation of it could take place on different days and by different physicians.

*In situations in which cardiologists, for example, bill for the supervisions (the "S") of the S&I code, and a radiologist bills for the interpretation (the "I") of the code, both physicians should use a "—52" modifier indicating a reduced service,*

*e.g., only one of supervision and/or interpretation. Payment for the fragmented S&I code is no more than if a single physician furnished both aspects of the procedure. (MCPM Ch. 13 ' 80.1)*

While the designation by both clinicians that they have rendered a reduced service would appear to obviate false claims liability because the statements made are accurate with regard to the nature of the service performed, with two separate claims submitted for the same patient for the same service, there is a possibility that one claim may be denied as not medically necessary. Further, as a practical matter, billing with the "—52" modifier creates processing problems because the carriers have no way to price the service. They are instructed that

*The fees for services represent that average work effort and practice expenses required to provide a service. For any given procedure code, there should typically be a range of work effort or practice expense required to provide the service. Thus, carriers may increase or decrease the payment for a service only under very unusual circumstance based upon review of medical records and other documentation. (MCPM Ch. 12 ' 20.4.6*)

Another example of both recognition of 'split services' as well as pricing for them is found in the surgical arena. The MCPM explicitly acknowledges the existence of 'co-surgeons' and 'team surgeons'. Co-surgery refers to surgical procedures involving two surgeons of different specialties performing the parts of the procedure simultaneously, i.e., heart transplant or bilateral knee surgery. These services are designated by both surgeons with a modifier "—62"; and each surgery is paid at 62.5% of the otherwise applicable surgical fee. By contrast, 'team surgeons' are two or more surgeons of different specialties engaged in the same procedure, and these surgeons both bill with the modifier "—66". The data must be sufficient to "allow pricing by report", which means the carrier decides how much to pay. (MCPM Ch. 12 § 40.8B)

Medicare has not recognized split interpretations for CCT and CTA by cardiologists and radiologists with explicit modifiers or pricing. As a matter of practical experience, it is entirely likely that even though the claim is submitted with the "—52" modifier it will be paid at the full amount thereby constituting an overpayment which will be recouped later. In any instance where a clinician is subjected to a post-payment audit, the carrier has the authority to evaluate any of the issues that arise in the practice and the likelihood of an analysis expanding beyond the simple problem of the overpayment where the modifier was used would not be unusual. As a result, although the use of the "—52" modifier may appear to be expedient, it likely does not solve the problem in a reasonable way, although it does not have significant legal exposure from a false claims perspective.

B. Over-Reads

Some physicians are approaching the split interpretation dilemma by billing for the entire interpretation and obtaining an over-read for the remaining portion from the other specialist. This is more common where cardiologists obtain over-reads from radiologists, but there are instances where radiologists are obtaining over-reads by cardiologists. The liabilities are the

same regardless of which specialty bills and which over-reads, but it is more common for radiologists to over-read for cardiologists.

Generally speaking the concept of an "over-read" is used to convey a quality control check of the validity of the interpretation provided by someone else. Often an over-read is not a complete interpretation and does not produce a full report, but is a process by which the over-reading physician engages in a quality control function, and usually after the patient has been treated based on the initial interpretation. Many radiologists, though, engage in activities that they characterize as "over-reads", which, in fact, are full interpretations. They provide this service on a discounted basis to other medical practices, providing their expertise to clinicians who are otherwise engaged in imaging services but seek the additional security of getting a board-certified radiologist's fail-safe analysis of the data. A true over-read would be something less than what the radiologist does when he bills Medicare for the same service. Unfortunately, there are no guidelines available as to how much less the radiologist has to do so as not to replicate the service for which he bills Medicare at a full rate. If the radiologist literally only looked at and reported the non-cardiac aspects of the images, then the service would not be equivalent to his own full CCT or CTA interpretation and would therefore be less problematic, but not without legal concerns.

The legal problems associated with over-reads include (1) false claims liability for the billing physician; (2) the discount safe harbor under the antikickback statute and potential reverse kickback liability for both; (3) the Secretary's exclusion authority for the discounting physician; (4) potential problems under the Medicare reassignment rules; (5) Stark statute compliance; and (6) antikickback issues in the cross-referral agreement among specialists.

1. *False Claims Liability*

The first legal dilemma with regard to this arrangement is who actually has rendered the service. When a physician submits a claim to the Medicare program, the CMS-1500 claim states not only that the services that were rendered were medically necessary, but the claim itself includes a certification and statement that the physician personally rendered the service. An "over-read", is not billable to the Medicare program and would have to be purchased by the billing physician from the reviewing physician if the reviewer is to be paid. (If the reviewer provides the service for free, where the cardiologists refer any other services to the radiologists, the free over-reads could be considered to induce the non over-read referral services which the radiologist can bill to Medicare and other payors.)

If the billing physician waits for the interpretation by the other clinician before submitting the claim to the Medicare program and then documents the full interpretation, the over-read service is not an over-read. Rather the cardiologist is obtaining from another physician a portion of the service which he is stating on the claim form he rendered himself.

Although there is no formal Medicare definition of nor policy statement regarding "over-reads", the first issue will be whether the service rendered by the billing clinician meets the definition of an interpretation as noted above. If either the radiologist or cardiologist includes the work of the other clinician in his claim to the Medicare program, and did not render the full

service himself, that would raise potential false claims liability. Having navigated that central problem, the next series of legal issues turn on the financial relationship between the billing physician and the over-reading physician.

*2. Discount Safe Harbor and Antikickback Issues*

The dilemma for the radiologists under these circumstances is that they are usually providing, at a significantly discounted rate, a service that they otherwise bill to the Medicare program at a higher rate. (If the over-read is not a full interpretation, it could be argued that there is no discount because the services are different.) If the radiologist bills the cardiologist the same amount that Medicare pays for the full interpretation, then the cardiologist gets no financial benefit from billing the interpretation with radiology input Where the radiologist is paid less than the full Medicare rate for the same service, both physicians need to take into account the discount safe harbor under the antikickback statute. This regulation was updated with the publication of the clarifications of regulations in 1999 and segregates by type of billing entity the obligations associated with discounting services.

Where physicians purchasing interpretations at a discount from others are implicated by this provision (42 C.F.R. ' 1001.952(h)(iii)), the selling physician is also implicated under the provision that states that the seller must inform the individual or entity submitting the claim or request for payment of the discount. The definition of a discount "means a reduction in the amount the buyer (who buys either directly or through a wholesaler or a Group Purchasing Organization) is charged for an item or service based on an arm's-length transaction." (42 C.F.R. ' 1001.952(h)(5)). An appropriate discount that is protected does not include supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, "unless the goods and services are reimbursed by the same federal healthcare program using the same methodology and the reduced charge is fully disclosed to the federal healthcare program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology." (42 C.F.R. ' 1001.952(h)(5)(ii)).

Where the cardiologist incorporates the radiologist's over-read into his service, and makes money as a result, because Medicare does not recognize a specified dollar value for the over-read, it could be seen that the radiologist's discounted service for this purpose is being provided in exchange for the continuing stream of referrals for other services from the cardiologists. This could be construed as a 'reverse kickback' giving the cardiologist an in-kind benefit -- the opportunity to make money on these services -- in return for the other work to be referred. The liabilities in a reverse kickback situation run to both parties.

3. *Exclusion from Medicare*

In addition, depending on the volume of business that the over-reading physician does at the discounted rate, there is a potential risk for exclusion from the federal healthcare programs under the provision in the statute which provides that a person or entity may be excluded from the Medicare program if he or she submits claims for a service substantially in excess of his "usual" charge. (42 U.S.C ' 1320a-7) Proposed regulations were published under this statutory provision in 2003 (See 68 Federal Register 53939, September 15, 2003) but they have never

been reduced to final form. In the proposed regulations, physician charges were excluded from the charges that would violate the statute; but the statute on its face does not require such an exclusion. In fact, the reference to 'usual charges' is a historical artifact reflecting the old Medicare physician reimbursement system which quantified the reasonable charge which would be paid as the lesser of the physician's usual and customary charge, or the reasonable charge calculated by Medicare based on its fee schedules which reflected artificial medical cost index limits. Now that there is no longer a Medicare recognized definition of the 'usual charge' since Medicare pays the lesser of the actual charge or the defined fee schedule price, in the absence of regulations it is possible that an enforcer could proceed under this provision if the over-reading physician was doing a substantial volume of discounted business.

4. *Reassignment Issues*

The right to be paid by the Medicare program for physician services belongs to the beneficiary who may assign the right to be paid to the physician. The physician has the right to accept or reject assignment of payment from the beneficiary. Physicians who accept assignment 100% of the time sign a 'participation agreement' which means they agree to accept assignment and Medicare's payment to them as payment in full, all the time, and as a result they are paid 5% more than a physician who does not participate but accepts assignment on an individual claim. Physicians who practice in any manner other than as a solo practitioner -- whether as employees of their own corporations or hospitals or under contracts with clinics or imaging centers, or any other configuration -- usually need to have the Medicare check for their services written in the name of the entity for which they work. To accomplish that goal they must 'reassign' the right to Medicare payment to the entity to which payment should be made.

Because of abuses in the early years of the Medicare program of providers selling their accounts receivable to commercial debt collectors ('factoring of the payment') and the resulting overly aggressive collection practices, beginning in 1972, Congress limited the circumstances in which reassignment would be effective and legitimate. Those rules have been modified over the years, most recently in the Medicare Modernization Act.

The reassignment rules implicate the ability of any physician to purchase the interpretation rendered by another physician. Cardiologists who may own or lease the technology to render CT and CTA services face another dilemma if the service rendered by the radiologist is deemed to be a purchased interpretation. Generally the rules require that the physician who rendered the service is the only person who can be paid the Medicare reimbursement unless there is a reassignment rule that permits the Medicare check to be written in the name of someone else. In the case where the cardiologist seeks to bill for the radiologist's interpretation, the arrangement will run afoul of the rules pertaining to who may purchase an interpretation.

A person or supplier (e.g., the cardiology group) which provides diagnostic tests may receive direct payment from Medicare for a purchased interpretation only if the tests "are initiated by a physician or medical group which is independent of the person or entity providing the tests." (MCPM, Ch. 1 § 30.2.9.1) Obviously where the cardiologist has determined that the CCT or CTA is medically appropriate and the group performs the technical component this

standard cannot be met. Although the penalty for a violation of the reassignment rules is direction from the carrier to cease the improper reassignment, there is potential liability for Medicare to revoke the right of the billing physician to receive any assigned and reassigned payments. (MCPM, Ch. 1 § 30.2.2B, 3)

*5. Stark Compliance*

The next issue associated with payment is the problem of the Stark statute which considers these imaging services to be "designated health services." Because the billing physician would have a financial relationship with the over-reading physician, the financial relationship would have to fall within one of the applicable exceptions. In this instance, the applicable exception would most likely be the personal services exception. The exception which is available establishes that the arrangement must documented in a writing signed by the parties, specifying the services covered, must cover all of the services to be furnished by the physician or family members, with a term of at least one year in the contract. The aggregate services contracted for may not exceed those that are reasonable and necessary for legitimate purpose and the compensation to be paid over the term of the agreement must be fair market value and not calculated in a manner that takes into account the volume or value of any referrals or other business generated between the parties. (42 C.F.R. ' 411.357(d)) This standard must be met even if the service the radiologist is providing is a true over-read and not a full interpretation.

6. *Safe Harbor for Interspecialty Referrals*

Finally, it is noteworthy that there is a safe harbor provision under the antikickback statute that recognizes referrals between specialties. That safe harbor protects arrangements under which an individual or entity agrees to refer patients to another individual or entity for specialty services in return for an agreement on the part of the party receiving the referral to refer the patient back at a certain time or under certain circumstances. (See 64 Federal Register 63547 November 19, 1999) The provision is specifically associated with obtaining specialty services of a limited nature. The standards associated with qualifying under the safe harbor include the fact that the service for which the referral is made must not be within the medical expertise of the referring party and must be within the expertise of the party receiving the referral. Second, the parties may receive no payment from each other for the referral, which would not be the case in most of these over-read arrangements. Finally, the only exchange of value permitted would be the monetary remuneration each party would receive directly from third party payors or the patient as compensation.

In discussing the applicability of this provision, the regulators addressed concerns of ophthalmologists with regard to services of optometrists, where the referral by the optometrist is conditioned on the agreement by the ophthalmologist to return the patient to the optometrist for the follow-up care included in the global case rate. In addressing these issues, the regulators explicitly stated that "the safe harbor does not protect referral arrangements where the parties bill Medicare using the 54/55 modifiers to indicate an 80%-20% split of the surgical fee for cataract surgery." (64 Federal Register 63548, November 19, 1999). Acknowledging that they did not mean to suggest that all specialty referral arrangements involving splitting of global fees were illegal, they resorted to their traditional view that anything not included explicitly in the safe

harbor is to be analyzed on a facts-and-circumstances basis subject to prosecutorial discretion. However, the preclusion on payment between the parties for these arrangements for safety calls into question the payment relationships obtained in the over-read transactions.

C. Bringing the Radiologist into the Cardiology Practice

In some instances physicians believe that one of the ways to avoid the dilemmas alluded to above in terms of split billing by physicians in separate practices is to have the radiologist reassign his right to payment to the cardiology group for the limited purposes of doing these interpretations so that he is then part of the cardiology group. The problems associated with this approach include (1) Stark statute compliance; (2) reassignment rule compliance and increased risk of audit; and (3) false claims liability.

*1. Stark Statute Compliance*

It has become possible for a cardiology practice to have a radiologist join their assignment account for a very limited purpose, and without becoming an employee, partner or shareholder based on the significant liberalization in the reassignment rules under Medicare allowing independent contractor physicians who render services on behalf of a group to reassign their right to payment to the group regardless of the location where the services are provided. Under those circumstances, any contractual arrangement is legitimate but the physician and the group to which he is reassigning must acknowledge that they share joint and several liability for any overpayments made and the physician must have access to the claims made on his behalf at any time. (MCPM, Ch. 1 ' 30.2.7)

While this provision is applicable for most Medicare services, it is further modified and restricted under the Stark statute. For 'designated health services' in Stark to be provided pursuant to the physician referral provisions which allow referrals by a physician (the cardiologist) to another physician "in the group" (the radiologist), an independently contracting physician is only a physician “in the group” when he is using the billing group’s premises (42 C.F.R. ' 411.351, 69 Federal Register 16130 March 26, 2004). This means that when the radiologist is performing these services as an independent contractor to the cardiology group he must provide the interpretation or over-read in the offices of the cardiologists. Neither telemedicine nor other approaches will work. The only exception would be if the radiologist became a part-time employee of the cardiology group; but under the Stark statute, he must be a 'bona fide' employee, pursuant to the requirements of the Social Security Act generally. For the radiologist to remain in his office, performing either over-reads or interpretations on his own time, interspersed with his other tasks of the day, hardly qualifies as a standard bona fide employee approach and could be construed as a circumvention scheme. In any event, for the cardiology group to bill for the radiologist’s services, he must join the cardiology group's assignment account under Stark because, as noted above, the cardiology group is prohibited from purchasing the professional component from another physician when the cardiology group instigated the order for the test.

*2. Reassignment and Increased Risk of Audit*

Another dilemma which arises by the inclusion of the radiologist in the cardiology group, even for this limited purpose, is the effect on the specialty designation on the cardiology group. Specialty code 70 must be recorded by the carrier claims records where an entity's physicians have more than one specialty. (MCPM, Ch. 1 ' 30.2.13C) This converts the cardiology practice into a multi-specialty group as far as the carrier is concerned. The effect of this change is that the utilization statistics against which the cardiology group will be profiled by the carrier for medical review and audit purposes will be decidedly different from those associated with a cardiology-specific practice. Multi-specialty groups include everything from two physicians of disparate specialties practicing together (e.g., a cardiologist and a gastroenterologist) all the way to very large groups of many physicians of disparate specialties. To the extent that the cardiology practice provides a much higher proportion of cardiology services to its patients than the peers in the multi-specialty group cohort -- which would be entirely expected -- the greater the likelihood of post-payment audit for aberrational billing patterns. This is not illegal, but merely problematic since an audit triggered for any single reason can go into any aspect of the practice under review.

Moreover, depending on the number of cardiology practices that are billing for CCT and CTA services in this manner, billing Medicare for a significant volume of these services, even by a cardiology practice which remains designated as such, still heightens the risk of scrutiny for medical review. Although carriers have discretion to allow multiple assignment accounts which pay the same tax identification number in complex, organized academic practices, and they have some discretion to permit this flexibility in a non-academic setting, there is absolutely no requirement that a carrier allow this differentiation in a radiology services as distinct from the cardiology services. The issue here is not the legality or illegality of the approach but rather the potential impact on the totality of the rest of the practice as a result of the redesignation of its specialty.

If these pitfalls could be effectively navigated and the risk of aberrational utilization patterns deemed acceptable to the cardiology group, there is still the problem of which physician's claim number to indicate as the physician rendering the service where the radiologist, even if now in the same practice, and the cardiologist are both contributing to the imaging.[*]

*4. False Claims Liability*

Medicare instructs the carriers that "each physician who performs services for a patient must be identified on form CMS-1500 in block 24k for the appropriate line item in accordance with instructions in the Medicare Program Integrity Manual." (MCPM, Ch.1 § 30.2.13B) In fact, the Program Integrity Manual says nothing about how to complete the CMS-1500, instead, the MCPM addresses the completion of 24k. Unfortunately, the instructions are not very helpful since they require that the form have on it "the PIN (the NPI will be used when implemented) of the performing provider of service/supplier if the provider is a member of a group practice."

[*] If the cardiology practice brought the radiologist in to do the total interpretation, this aspect of the problem disappears but the multi-specialty designation problem remains. This White Paper, however, is focused on 'split interpretations,' where both specialties contribute to one study.

(MCPM, Ch. 26 § 10.4) Even if the radiologist is part of the cardiology group, who would be indicated as "the" performing provider since both physicians would be contributing to the performance of the service?

Interestingly there are situations in which the Medicare manuals acknowledge that physicians in the same group may share the delivery of a service. Specifically, in the provision of anesthesia services, the MCPM states that

> *If anesthesiologists are in a group practice, one physician member may provide the pre-anesthesia examination and evaluation while the other fulfills the other criteria. Similarly, one physician member of the group may provide post-anesthesia care while another member of the group furnishes the other component parts of the anesthesia service. However, the medical record must indicate that the services were furnished by physicians and identify the physicians who furnished them. (MCPM Ch. 12 § 50C)*

In these situations, similar to the acknowledgment of the supervision and interpretation split billing, there is a programmatic recognition that more than one physician may be involved in providing a service designated by a single CPT code. However, in all of the circumstances where such Medicare recognition exists, there are specifically recognized boundaries to what each physician is contributing to the service. Despite the creation of the new Category III codes, there is no explicit Medicare acknowledgement of the possibility of the split interpretations and for one physician to assert that he has performed the entire procedure in the absence of any such formal recognition from Medicare in national policy could raise false claims liabilities as an intentional inaccurate statement regarding who performed the service.

## Conclusion

Until January 1, 2006, the technology for CCT and CTA had advanced beyond even what CPT codes recognized. The expertise of radiologists and cardiologists in providing the interpretations of these services can be complementary and enhance the quality of patient care. Cardiologists are increasingly purchasing or leasing the technologies that produce these services and are meeting the clinical competence standards promulgated by their specialty society. The Medicare billing system, however, has not caught up to the realities of medical practice[*]

There are examples of other services in which Medicare has explicitly recognized the shared contributions of multiple clinicians to one CPT code. In today's era of intense focus on collaboration, integration of care, and rejection of the traditional fragmentation of care delivery, it is time for Medicare to accommodate split interpretations with greater flexibility and formal designation of modifiers specifically capable of designating appropriately the relative contributions of the radiologists and cardiologists to share this service. The point is not to encourage or discourage a specific organizational approach to care delivery, but to acknowledge reality. In the absence of such recognition, radiologists and cardiologists alike face significant

[*] There is a developing payment model which would allow this collaborative approach with no necessity for any of the organizational and claims filing dilemmas noted here. See PROMETHEUS Payment at www.prometheuspayment.org.

legal liabilities in their efforts to be paid appropriately for these services. None of the three solutions identified so far is perfect. All have some risk associated with them, although the nature of the risk varies among the solutions. None is ideal.