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IN THE NEWS

Monumental Changes to Stark Law and Medicare Rules Proposed

If finalized, will significantly impact physician ownership of ancillary (imaging) services, joint ventures and provision of ancillary services in their offices

On July 2, 2007, the Centers for Medicare and Medicaid Services (CMS) released a proposed set of regulations that would amend current Stark regulations and could potentially affect many physician/hospital relationships. The proposed changes clearly result from CMS's frustration with what it perceives as a growing number of arrangements that permit physicians to profit from their referrals of ancillary services, while side-stepping or working around existing Stark restrictions. The proposed changes could be effective as early as January 2008. Accordingly, now is the time to review arrangements to prepare for the anticipated changes.

End of Per-Click Arrangements. CMS is proposing to revise the exceptions to the leasing of equipment and office space Stark exceptions to do away with the use of per-click lease payments in those situations where a physician-owned entity leases space or equipment to another entity and the physician subsequently refers patients to that other entity for services. As an example, this means that a cardiology group or its members could not purchase a CT machine and lease it to a hospital or other entity on a per-click basis if the cardiologists refer patients to the hospital for CT scans.

End of Percentage Based Compensation. CMS is proposing to eliminate the use of any type of percentage-based fees for office and equipment leases. This means that a physician group could not receive payment based on a percentage of collections under an office lease, equipment lease, personnel lease, facility lease, billing service agreement, management services agreement or any agreement other than a professional services agreement with a physician practice that refers patients to the group.

Limits to "Under Arrangements". Perhaps the most dramatic change in the proposed rule is an amendment to the Stark regulations aimed at limiting the spread of "under arrangements" contracts. Historically, hospitals could purchase certain services that they did not currently provide, or did not wish to directly provide for their patients, by outsourcing such services "under arrangements" with a third party supplier. In such arrangements, which may involve inpatient or outpatient services, the third party actually provides the care and is paid by the hospital. The hospital remains responsible for the quality and overall scope of the service and bills the appropriate payer for the care under the hospital's provider number.

CMS notes that it is very concerned with the proliferation of these agreements, particularly between hospitals and joint ventures owned by physicians, as it gives the physicians an opportunity to profit from referring patients for the services. Assuming the CMS proposal becomes final and survives challenge, it will eliminate many, if not most, "under arrangement" relationships between hospitals and suppliers owned by referring physicians. Providers who are considering entering (or already have entered) into an under

arrangement services agreement should be aware that the adoption of these proposed regulations would necessitate the restructuring or even termination of such arrangements.

Diagnostic Test Anti-Markup Expansion. Currently, under the Medicare “purchased diagnostic test” rule, if a physician bills Medicare for the technical component of a diagnostic test performed by an outside supplier, the physician cannot mark up the charge submitted for the technical component. The rate must be the same paid to the outside supplier. Currently, this rule does not apply to the professional component. Now CMS is proposing to make it apply to the professional component too. This would eliminate the ability of a physician to profit from Medicare billings for professional component services that the physician purchases under contract or obtains via reassignment from an outside supplier.

Full Time Employee Proposed Requirement for Interpretations. Additionally, and perhaps more controversial, CMS is proposing that the anti-markup rule apply to part-time employees and part-time or full-time independent contractors. This means that the only technical or professional services a medical group could mark-up are those performed by the group’s full-time employees. This means that radiology groups, independent diagnostic testing facilities and group practices that have in-office imaging or diagnostic equipment may not be able to utilize a part time radiologist or as-needed radiologist to perform the interpretation since the office would be limited to billing Medicare no more than the amount actually paid to the radiologist (which would not take into consideration business costs of the operation, such as billing, rent and other overhead expenses).

New IDTF Performance Standards. Once again, CMS is proposing to revise the performance standards for independent diagnostic testing facilities. The proposed standards would require certain levels of insurance and insurance company reporting to CMS; that changes in ownership, location, general supervision and legal actions be reported within 30 days to CMS; maintenance of files of patient complaints and questions; and, most significantly, would prohibit the sharing of space, equipment or staff. Additionally, the proposal would eliminate the limitation on the number of IDTF sites a physician may supervise.

For questions about the Stark Law, [email us](#).

Medicare Rates to Physicians to Drop

Medicare payments to physicians will drop 9.9 percent unless Congress intervenes.

The Centers for Medicare and Medicaid Services issued a proposed rule July 2, setting the rate for the 2008 Physician Fee Schedule. The reduction is based on the controversial SGR or Sustainable Growth Rate formula. In recent years, Congress has stepped in to stop the SRG-based reduction. In 2007, it delayed a 5% reduction and froze payments at 2006 levels.

If your private-payor rates are linked to a percentage of Medicare rates, anticipate drops from your private payors too. Now may be a good time to renegotiate your private pay contracts if yours are currently linked to Medicare.

For questions about managed care contracting, [email us](#).

Be Careful in Selling and Buying Surgery Center Ownership Shares

New, Unfavorable OIG Advisory Opinion Issued

Surgeon owners of ambulatory surgery centers and hospitals interested in buying ASC shares need to pay close attention to a new advisory opinion issued by the Department of Health and Human Services’ Office

of Inspector General.

The OIG received an advisory opinion request regarding a proposal for physician investors in an established ambulatory surgery center to sell a portion of their ownership interests to a local hospital. The parties involved inquired whether the proposed business arrangement would constitute grounds for the imposition of sanctions under the Social Security Act, or violate the anti-kickback statute. The OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute, and administrative sanctions could potentially be imposed.

The freestanding, multi-specialty ambulatory surgery center (ASC) is owned and operated by three orthopedic surgeons, two gastroenterologists, and two anesthesiologists. The three orthopedic surgeons are the founding members of the group and collectively own shares representing 94 percent of company equity. The remaining doctors collectively own shares representing 6 percent. Under the proposed arrangement, the orthopedic surgeons would sell to the hospital the number of ownership units necessary for the hospital to have a 40 percent total share in the ASC. The amount paid by the hospital would be fair market value. However, **because the hospital would pay more per ownership unit than the orthopedic surgeons paid**, the orthopedic surgeons would receive a higher rate of return on their remaining shares than the Hospital would receive on its newly purchased shares.

The OIG found the arrangement problematic in that the hospital is in a position to make or influence referrals directly or indirectly to the ASC or its physician investors. Even though the hospital agreed to certain steps to limit its ability to make referrals (any physicians employed by the Hospital would be prohibited from referring to the ASC and the Hospital would take no actions to require or encourage its medical staff to refer patients to the ASC or to any physician investor and would not track such referrals) the OIG didn't like the arrangement.

There is a safe harbor for returns on investment in hospital/physician-owned ambulatory surgery centers. 42 C.F.R. § 1001.952(r)(4). Among the conditions of this safe harbor are that:

1. The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity,
2. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment of that investor,
3. The hospital must not be in a position to make or influence referrals directly or indirectly to the ASC or any of its investors, and
4. Investing physicians who are in a position to refer patients to the ASC must meet the requirements for surgeon-owned ASCs, single-specialty ASCs, or multi-specialty ASCs, as applicable. In the case of a multi-specialty ASC, each physician investor must receive at least one-third of his or her medical practice income from ASC procedures defined at 42 C.F.R. § 1001.952(r)(5), and must perform at least one-third of such procedures at the ASC in which he or she invests.

If all the conditions of the safe harbor are met, it protects "any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor" in the ASC.

The OIG concluded that the proposed arrangement did not qualify for safe harbor protection. For example, in reference to Section 2 above, the amount of payment made by the investor (hospital) would not be directly proportional to the amount of the capital investment of the investor.

The OIG then concluded that the proposed arrangement also posed a risk under the anti-kickback statute. The OIG listed the following concerns over the proposed arrangement:

- The hospital's proposed investment takes the form of a purchase of shares from the orthopedic

surgeons for cash, rather than an investment of capital in the Company itself. The investment is unrelated to the operation of the ASC. Instead, the proposed arrangement would permit the orthopedic surgeons to realize a gain on their original investment in the Company.

- Not all of the investing physicians are to sell a portion of their ownership units to the hospital at an appreciated price. This raises the possibility that one purpose of the hospital's investment is to reward or influence a subset of the investing physicians whose referrals of patients to the hospital or to the ASC itself may be particularly valuable.
- The return on the investment would not be directly proportional to the amount of the capital invested by each investor. The amounts payable to the investors would be proportional to their ownership interest in the Company; however, because the Hospital would pay more per ownership unit than the orthopedic surgeons paid, the orthopedic surgeons would receive a higher rate of return on their remaining shares than the hospital would receive on its newly-purchased shares.

The OIG admitted that none of these factors, whether standing alone or in combination, necessarily indicates fraud or abuse. However, given all the facts, the OIG could not conclude that the difference in cost of capital acquisition, which results in financial gain to a subset of the physician investors whose referrals may be particularly valuable, is not related, directly or indirectly, to the value or volume of referrals or other business generated between the parties, including referrals by the selling orthopedic surgeons to the Hospital or the ASC. Accordingly, it concluded that the proposed arrangement poses a heightened risk of fraud and abuse.

For questions about surgery center ownership and the federal law, [email us](#).

Florida Chiropractor Alleges Referral Kickbacks in Lawsuit

The Florida Times-Union reported on July 19, 2007 that Richard Kersey, a Jacksonville chiropractor, filed a lawsuit alleging that his former business associates are providing kickbacks for patient referrals and are wrongfully attaching his office to the scheme. Kersey alleges that doctors and physician assistants working in two Jacksonville hospitals are being paid by the chiropractor \$500 for each patient referral to the chiropractor. The hospitals were named as defendants in the lawsuit, which alleges violations of the state's deceptive and unfair trade practices act and the racketeering act. The hospitals and physicians denied the claims.

Physician Assistants Dispensing

Florida law now allows Physician Assistants to dispense drugs to patients if their supervising physician is registered as a dispensing practitioner and if the supervising physician delegates dispensing authority to the physician assistant. Next week a Board of Medicine committee will consider a form that will be used to memorialize the delegation of the dispensing authority.

Hospitals Required to Report Relationships with Physicians to CMS

In September 2007, 500 hospitals across the nation will be receiving mandatory disclosure forms from the Centers for Medicare and Medicaid Services. CMS will use the information on the "Disclosure of Financial Relationships" form to analyze the investment, ownership and compensation relationships between the hospitals and physicians. Hospitals have 45 days to respond or face penalties of up to \$10,000 for each day past deadline.

Medical Staff Bylaws Changes Likely

Hospitals may be asking their medical staffs to amend their medical staff bylaws in the near future, following the Joint Commission's approval of revised standards. The JCAHO website states that the intent

of the change is to support and reinforce a productive working relationship between the medical staff and governing body. According to a JCAHO web page, the revised standard now states that the medical staff bylaws must indicate what authority the medical staff has delegated to the medical staff executive committee, and how that authority is delegated and removed. Also, the revised standard now states that the medical staff has the ability to adopt medical staff bylaws, rules and regulations, and policies and propose them directly to the governing body, even if the subject matter had been delegated to the medical staff executive committee. The requirements in Elements of Performance (EPs) 9 through 33 must appear in the medical staff bylaws. However, the procedural details associated with the processes listed in EPs 26 through 33 must appear either in the medical staff bylaws, or in rules and regulations or policies. The organized medical staff may, if it desires, delegate to its medical staff executive committee approval of the procedural details associated with the processes listed in EPs 26 through 33, when these procedural details are placed in rules and regulations or policies.

For more information on the changes, go to:

http://www.jointcommission.org/AccreditationPrograms/Hospitals/revisions_std_ms120_approved.html

Medicare Releases Surgery Center Rates

Medicare recently published the much anticipated rates at which it will reimburse for services performed for Medicare beneficiaries at ambulatory surgery centers. The Centers for Medicare and Medicaid Services revamped its system for paying for surgeries, resulting in many more surgeries added to the list of ASC surgeries for which Medicare will pay. Often, private payors will follow Medicare's direction, so changes may be in store for the private-payor sector also. A list of rates by CPT code can be found at:

[http://www.cms.hhs.gov/ASCPayment/05_CMS-1392-P\(ASC\).asp](http://www.cms.hhs.gov/ASCPayment/05_CMS-1392-P(ASC).asp)

Proposed Changes to how Medicare pays for Clinical Trials

The Centers for Medicare and Medicaid Services issued on July 19th what it called a New Proposed Decision Memo on the Clinical Research Policy. In it, CMS proposes to expand the types of trials eligible for Medicare coverage beyond "qualifying clinical trials." If adopted, the memo would create a new definition of "clinical research" and of "usual patient care." The memo can be found at:

<https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210>

New Informed Consent Guidelines

Hospitals will be updating their informed consent guidelines following changes to the federal Medicare Conditions of Participation by the Centers for Medicare and Medicaid Services this spring. The new rules affect not only the informed consent process, but also documentation of informed consent. For example, hospitals must keep an informed consent on the chart for inpatients and outpatients, unless treatment is due to an emergency. The minimum elements for an informed consent include:

- Hospital name
- Name of specific procedure or treatment
- Name of the responsible practitioner who is performing the procedure or treatment
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or legal representatives
- Signature of the patient or legal representative
- Date and time the informed consent form is signed.

The guidelines removed the requirement that the witness be a professional witness.

No more Computer-Generated Faxed Prescriptions?

Reportedly to encourage physicians to adopt e-prescribing, the Centers for Medicare and Medicaid Services this month proposed a rule that would prohibit faxed prescriptions sent via computer.

As background, the Department of Health and Human Services adopted e-prescribing standards effective January 1, 2006. The standards included a SCRIPT standard for communications between physicians and pharmacies regarding prescription information. The rule provided that entities that transmit prescriptions via computer-generated faxes were exempt from using the SCRIPT standard. CMS says that it expected companies to start incorporating the SCRIPT standard in their software, but that did not happen. As a result, the pharmacy receives the paper fax and has to enter the prescription information electronically into their system. This causes delays and errors, CMS says. Accordingly, CMS is proposing to eliminate the computer-generated fax exemption for all prescriber/dispenser transaction. CMS says that doing so will encourage e-prescribers and dispensers to move as quickly as possible to using the SCRIPT standard.

Eleventh Circuit Decides Florida Kickback Case

On May 11, 2007, a federal appellate court vacated, in part, the criminal convictions and sentences of three defendants found guilty in Miami in 2005 in connection with an alleged \$10 million durable medical equipment and prescription drug Medicare billing scheme. This case is interesting in that the evidence of kickbacks itself was insufficient to taint all claims. This is a significant tightening of the breath of the federal anti-kickback statute.

In the appeal, defendants Pura Medina, Isabel Canepa, and Isabel Guerra appealed their convictions for conspiracy to defraud the United States, health care fraud and money laundering.

The defendants were allegedly taking part in a scheme that paid kickbacks to patient recruiters and to patients so they could obtain Medicare beneficiaries' names and identification numbers in order to bill Medicare for medical equipment and prescription drugs. The transactions were taking place between Ocean Medical Supply and United Pharmacy. Defendant Isabel Guerra had a 50% stake in both companies, Canepa was a secretary at Ocean Medical Supply and Medina was a secretary and technician at United.

Several witnesses testified about the scams the companies were conducting. Patient recruiters testified that that they would bring patients who needed to fill prescriptions into Ocean or United. The recruiters would then receive 50% of the profits after submitting the claims to Medicare. The recruiters would then turn around and give 50% of their profits back to the patients. Witnesses also testified that physicians were being paid to send patients to Ocean and United. There is testimony from Wendy Evans, a Special Agent with the FBI, that Guerra, in her capacity as part owner of both Ocean and United, signed documents to become a Medicare provider. Among other things, these documents certified that the Medicare provider would abide by the relevant Medicare regulations. The regulations provide that the supplier must "operate its business and furnish Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements." According to Agent Evans's testimony, Guerra signed these documents for Ocean on May 4, 2001, and for United on May 18, 2000.

In the ruling, the court said, among other things, that the paying of kickbacks alone was not sufficient to establish health care fraud.

In the appeal, the government argued that "the fact that patients received kickbacks for patronizing Ocean and United 'taints' any claims the defendants made to Medicare on those patients' behalf," according to the

opinion.

The government also argued that even if the prescriptions involved were medically necessary, and the patient received what was prescribed, the payment of a kickback is sufficient to establish the falsity required to defraud Medicare. The order stated “While we acknowledge that paying kickbacks like those at issue in this case is a violation of federal statutes, we cannot hold that this conduct alone is sufficient to establish health care fraud without someone making a knowing false or fraudulent misrepresentation to Medicare.”

The court did acknowledge the government's argument that persons must sign documents promising to abide by all Medicare rules and regulations when they registered to become a Medicare provider. However, the court said counts of substantive health care fraud that occurred before a defendant signed such an agreement “must fail.”

The government countered the court did not err, arguing that there was evidence that the “vast majority” of patients were paid illegal kickbacks and that any claim submitted on their behalf was fraudulent.

In the case, the trial court made no factual finding as to the amount of loss, the opinion said, and that lack of a specific factual finding constituted an error.

“Without further information from the district court, we cannot determine what factual basis was used to reach the conclusion that every claim submitted to Medicare constituted loss,” the opinion stated. “Indeed, upon our review of the record, there was not sufficient evidence that any of the prescriptions were not medically necessary, or were not delivered to the patients.”

On review, the court vacated the Guerra's convictions for the counts of health care fraud that occurred before she signed the Medicare documents, but affirmed her convictions for the other 12 counts of health care fraud as well as conspiracy to commit money laundering. Canepa's conviction for health care fraud was vacated, but her conspiracy conviction was affirmed. Medina's convictions on all counts in the indictment were vacated. The evidence was insufficient to support guilty verdicts, as to the last two defendants, on substantive health care fraud counts under 18 U.S.C.S. § 1347 because although paying kickbacks violated 42 U.S.C.S. § 1320a-7b(b)(2)(A), that conduct alone was insufficient to establish health care fraud without someone making a knowing false or fraudulent representation to Medicare. The pertinent statute, 18 U.S.C.S. § 1347, reads:

“Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to (1) defraud any health care benefit program, or (2) obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items or services shall be fined under this title or imprisoned not more than 10 years, or both...”

The court found that the jury could, however, infer that incidents occurring after the remaining defendant signed documents to become a Medicare provider that defendant committed health care fraud after she signed the application stating that she would follow Medicare rules and regulations. Further, no evidence was presented that the other two defendants knew that this defendant made these false representations to Medicare, and there was no evidence that either defendant defrauded or attempted to defraud any health care program.

Kickbacks and Diagnostic Imaging

In January of 2007, Illinois Attorney General Lisa Madigan intervened in support of the whistle-blower lawsuit filed by John Donaldson, the owner of several radiology centers in Illinois. Donaldson filed suit in 2006, claiming several MRI centers defrauded patients and insurers by overcharging them for imaging

services to allow the payment of illegal kickbacks to the referring physicians. This case is interesting for Florida Physicians and ancillary providers because Illinois health laws are similar to Florida's and because the case illustrates a continued crack down on physician relationships with imaging companies.

The complaint alleges that the kickbacks provide a financial incentive for physicians to order unnecessary or excessive scan services. The complaint also alleges that the schemes make it impossible for legitimate providers to remain in business. Donaldson claims he has experienced a substantial drop in physician referrals as more doctors choose to send their patients to the facilities that dole out the kickback payments.

To hide the scheme, the MRI centers and physicians use "lease agreements" to conceal what the attorney general characterizes as kickback payments. The so-called bogus leases provide for the rental of an imaging facility by the physician to perform the imaging services. However the physician performs no imaging services, and the MRI center employees perform all operations. The physicians simply refer patients and receive payment.

The complaint alleges the defendants are in violation of the Insurance Claims Fraud Prevention Act, the Illinois Consumer Fraud and Deceptive Business Practices Act. John Donaldson is seeking an injunction and \$50,000.00 in damages.

As background, the federal government has for a few years questioned contractual joint ventures. The Office of Inspector General issued a Bulletin in 2003 addressing contractual joint ventures, specifically questionable contract arrangements. The bulletin reiterates the dangers kickbacks can pose. The bulletin asserts that kickbacks lead to:

1. Distorting medical decision-making
2. Overutilization of services
3. Increased costs to federal health care programs
4. Unfair competition by freezing out competitors unwilling to pay kickbacks.

John Donaldson's complaint alleges 1, 2, and 4 above.

The OIG's Bulletin also lists several indicia of suspect contractual joint ventures which potentially indicate a prohibited arrangement. One of the examples seems to match the arrangement in the Donaldson case. The bulletin describes remuneration as a warning flag. The paragraph reads:

Remuneration. The practical effect of the arrangement, viewed in its entirety, is to provide the Owner the opportunity to bill insurers and patients for business otherwise provided by the Manager/Supplier. The remuneration from the venture to the Owner (i.e., the profits of the venture) takes into account the value and volume of business the Owner generates.

In the Donaldson case, the physicians (in the "owner" position) are billing for business provided solely by the MRI centers.

The Bulletin also explains that a "lack of business risk" may act as a red flag. The paragraph reads:

Little or No Bona Fide Business Risk. The Owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegating the entire operation to the Manager/Supplier, while retaining profits generated from its captive referral base. Residual business risks, such as nonpayment for services, are relatively ascertainable based on historical activity.

The physicians in the Donaldson complaint make only referrals, and then watch the money roll in, the complaint alleges. The entire operation is delegated to the MRI centers.

Another warning sign addressed by the bulletin is the scope of services provided by the “manager/supplier.” The list reads:

Scope of Services Provided by the Manager/Supplier. The Manager/Supplier provides all, or many, of the following key services:

- *day-to-day management;*
- *billing services;*
- *equipment;*
- *personnel and related services;*
- *office space;*
- *training;*
- *health care items, supplies, and services.*

The MRI centers listed in the Donaldson complaint provided all of these services. Physicians were paid for referrals only, it claimed.

*The content of this newsletter is not legal advice and should not be relied on as legal advice.
Consult your attorney for advice on these and other legal matters.*

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