

# BB REVIEW

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## Healthcare News

August 2008

### FRAUD & ABUSE

#### OIG Advisory Opinion No. 08-08

On July 25, 2008, the Office of the Inspector General ("OIG") issued Advisory Opinion Number 08-08 addressing whether a potential investment in an ambulatory surgery center ("ASC") by a group of surgeons and a healthcare entity would violate the Anti-Kickback Statute ("AKS").

The healthcare entity in question (the "Hospital Corporation") owns three hospitals and a physician group practice. The group of surgeons (the "Surgeon Investors") are members of a limited liability company ("the Surgeon Partnership"). The entity that would own the ambulatory surgery center (the "JV") would be owned 70 percent by the Surgeon Partnership and 30 percent by the Hospital Corporation.

In its opinion, OIG concluded that while the JV would not meet the hospital-physician ASC safeharbor, it would not impose a monetary penalty or any other sanctions under the AKS, because sufficient safeguards were in place to minimize the risk of fraud and abuse. OIG cited that although the Surgeon Investors would not own their interest in the JV directly, the Surgeon Investor's investment in the Surgeon Partnership would be proportional to their ownership of it, and therefore it would be as if the Surgeon Investors were investing directly in the JV.

Four of the Surgeons Investors ("Inpatient Surgeons") did not meet the requirement that at least one-third of a physician investor's medical practice income be derived from the performance of Medicare-payable procedures performed in the ASC. OIG reasoned, however, that the Inpatient Surgeons comprise only four of the eighteen Surgeon Investors, and they may practice at the ASC in the future.

The JV also did not qualify under the safeharbor because the Hospital Corporation represents a potential referral source to the ASC and the Surgeon Investors. The JV agreement, however,

contained certain commitments to limit the Hospital's referral capacity.

Finally, the opinion stated the proposed JV would not comply with the ASC safeharbor's requirement that services provided to the JV by the Hospital Corporation comply with the personal services and management contracts AKS safeharbor. All of the services, however, were set out in detail and the amount of payment was fixed.

### STARK

#### 2009 IPPS "Stand in the Shoes" Stark Provisions

The Centers for Medicare and Medicaid Services ("CMS") finalized the physician "stand-in-the-shoes" Stark law provision in the 2009 Inpatient Prospective Payment System ("IPPS"). Because of industry concerns, CMS delayed the effective date of the proposed 2008 'stand-in-the-shoes' provisions until December 4, 2008. Phase III regulations to the Stark law included a "stand-in-the-shoes" provision under which referring physicians were treated as standing in the shoes of their physician organizations for purposes of applying the rules that describe direct and indirect compensation arrangements under Stark.

The final rule adopted in the IPPS provides that a physician must "stand-in-the-shoes" of his physician organization and will have a direct compensation arrangement with an entity furnishing designated health services ("DHS") if: (1) the only intervening entity between the physician and the entity furnishing DHS is his physician organization; and (2) the physician has an ownership or investment interest in the physician organization. An ownership or investment interest is defined as an ability or right to receive the financial benefits of the ownership or investment, including, but not limited to, the distribution of profits, dividends, or proceeds of sale, or similar returns on investment.

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The final rule also provides that a physician may choose to “stand-in-the-shoes” of his physician organization and have a direct compensation arrangement with an entity furnishing DHS, if the only intervening entity between the physician and the entity furnishing DHS is his physician organization, and he does not have an ownership or investment interest in that organization. Thus, nominal owners of physician organizations may choose whether their relationships with DHS entities will be analyzed as a direct or indirect compensation arrangement.

In the IPPS, CMS did not finalize the DHS entity “stand-in-the-shoes” provision originally proposed in the 2008 Physician Fee Schedule. The Fee Schedule provision stated that where a DHS entity owned or controlled an entity to which a physician referred Medicare patients for DHS, the DHS entity would “stand-in-the-shoes” of the entity it controlled. The IPPS physician “stand-in-the-shoes” provision will become effective October 1, 2008.

**2009 IPPS Prohibits “Per Click” Arrangements**

On July 31, the Centers for Medicare & Medicaid Services (“CMS”) finalized several provisions related to physician self-referral in its fiscal year 2009 Inpatient Prospective Payment System (“IPPS”) final rule. Under the final rule, CMS has prohibited the use of “per click or per use” payments in certain rental agreements for office space and equipment and prohibited the use of percentage-based compensation in rental agreements for office space and equipment.

**1. Per Click or Per Use Payments**

In the 2008 IPPS proposed rule, CMS expressed its concern that “per click” and “per use” arrangements were inherently susceptible to abuse because a physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. CMS further proposed that such arrangements would not qualify for the Stark exceptions at § 411.357(a) and (b) for space and equipment leases. The final rule adopts the proposal contained in the 2008 IPPS and specifically applies to: (a) “per click” or “per use” payments to physician lessors for services rendered to patients who were referred by the physician lessor, or (2) “per click” or “per use” payments from physicians to DHS lessors where the physician leases the space or equipment and the DHS entity makes referrals. The final rule also revises the fair market value exception at § 411.357(l) and the exception for indirect compensation arrangements at § 411.357(p) to prevent parties from otherwise qualifying “per click” and “per use” arrangements for space and equipment

leases. It appears that CMS is directly concerned about the risks of over utilization and abuse resulting from physician referrals associated with diagnostic imaging equipment, laser treatments and urology ventures utilizing intensity-modulated radiation therapy (“IMRT”) technology. CMS is delaying the amendments until October 1, 2009, in order to afford parties adequate time to restructure existing arrangements.

**2. Percentage-Based Compensation Arrangements**

In the 2008 Proposed Physician Fee Schedule, CMS expressed its concern that physicians were using percentage-based compensation arrangements in ways that were not intended by CMS. Despite CMS’s stated intent that percentage-based compensation arrangements may only be used for compensating physicians for physician services they personally perform, it had come to CMS’s attention that arrangements involving percentage-based compensation formulae were being used for the rental of office space or for the provision of items and services, such as the rental of equipment. Accordingly, the final rule revises the Stark exceptions for space and equipment leases, fair market value and indirect compensation arrangements to prohibit the use of percentage-based compensation formulae in the determination of rental charges for the lease of office space or equipment. Notably, the final rule does not prohibit all percentage compensation arrangements in financial relationships between DHS entities and referring physicians. Percentage-based compensation arrangements currently remain acceptable for management and billing services under the final rule. CMS stated they will continue to monitor arrangements for non-professional services that are based on a percentage of revenue raised, earned, billed, collected or otherwise attributable to a physician’s (or physician organization’s) professional services. CMS is delaying the amendments until October 1, 2009, in order to afford parties adequate time to restructure existing arrangements.

**Under Arrangements Transactions:  
Stark Regulatory Definition of “Entity”**

In the 2008 Proposed Physician Fee Schedule, CMS proposed to revise the definition of “entity” at § 411.351 so that a person or entity would be considered furnishing DHS if (i) it is the person or entity that has performed the DHS or (ii) presented a claim or cause a claim to be presented for Medicare benefits for the DHS. In the final rule, CMS adopted its proposal and has amended the definition of “entity” at § 411.351 to clarify that a person or entity is considered to be furnishing DHS if it is the person or entity

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that has performed the DHS or presented a claim for Medicare benefits for the DHS. In the case where one entity bills for the service and a separate entity furnishes the service, both entities will be considered DHS entities. CMS is delaying the amendments until October 1, 2009, in order to afford parties adequate time to restructure existing arrangements.

The new "entity" definition has generally been supported by hospitals and hospitals view it as a victory and a regulatory shield against physicians seeking to share in technical fees for services that could previously have been provided under arrangements. Specialists, particularly urologists, oncologists, radiologists and cardiologists, generally opposed the rule and view it as a regulatory impediment to expanding patient access to cutting edge care.

**New Stark Exception Proposed by CMS for Gainsharing and Incentive Payment Programs**

On July 7, CMS issued its proposed 2009 Physician Fee Schedule along with other proposals, including the new Stark exception. The new proposed rule would add a regulatory exception to the Stark law to protect gainsharing and incentive payment programs between hospitals and physicians. The proposed Stark exception would cover incentive payment programs, also known as 'pay-for-performance' ("P4P") or 'value-based purchasing', and shared savings programs. Shared savings programs are commonly referred to as "gainsharing" arrangements.

The new exception represents a first effort by CMS to directly address the guidelines of acceptable P4P and gainsharing arrangements under the Stark law. Hospitals and physicians have previously relied on incorporating gainsharing elements into arrangements protected by other Stark exceptions, such as those for bona fide employment relationships, personal services arrangements, fair market value compensation, or indirect compensation arrangements.

Key elements of the exception include:

- Only hospitals may offer P4P or gainsharing programs.
- Only physicians or qualified physician organizations may participate in a program.
- Only cash or cash equivalent forms of payment are covered by the exception.

- Quality measures must be listed in the CMS Specification Manual for National Hospital Quality Measures.
- The term of the arrangement must be between one and three years.
- The arrangement must set baseline and target performance levels that are objective and verifiable. Baselines must include all previous P4P or gainsharing initiatives.
- Payments must be set in advance, not vary during the term of the agreement, not take into account the volume or value of referrals or other business generated by the parties, and may not be based on reductions in lengths of stay.

CMS will accept comments from the public on the proposed rule until August 29, 2008, and anticipates that the final rule will be issued by November 1, 2008.

**MEDICARE & MEDICAID**

**Bill Introduced; Requires Physicians Disclose Financial Ties to Imaging Services**

On July 28, Senator Chuck Grassley (R-Iowa) introduced the Medicare Imaging Disclosure Sunshine Act (S. 3343) (the "Act"), a bill that would require physicians to disclose any financial relationships with certain high-tech imaging equipment.

The independent Government Accountability Office ("GAO") reported last month that Medicare Part B spending for imaging services more than doubled between 2000 and 2006, to \$14.11 billion, and that the percentage of Medicare spending on imaging services provided in physician offices grew substantially.

The legislation would amend the in-office ancillary services exception to the Stark Law. The Stark Law generally disallows a physician from billing Medicare for services performed at entities in which the physician has a financial interest. The in-office ancillary services exception, however, allows physicians to bill Medicare for services performed in physician offices, including some imaging services.

The Act would require physicians to disclose to patients their ownership interests in diagnostic imaging equipment including magnetic resonance imaging equipment and computed tomography, and others. The bill also requires physicians to give patients a list of other

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suppliers where imaging services could be obtained.

**CMS Adds Fewer Items to List of Never Events than Expected**

In its fiscal year 2009 Inpatient Prospective Payment System (“IPPS”) final rule, CMS included only three new “never events”, although it proposed to add nine such categories in the proposed rule.

The three new never events are: (1) surgical site infections acquired following certain elective procedures, such as selected orthopedic surgeries and bariatric surgery for obesity; (2) certain manifestations of poor control of blood sugar levels; and (3) deep vein thrombosis or pulmonary embolism following total knee or hip replacement procedures.

In the 2008 IPPS final rule, CMS listed for the first time, eight categories of conditions that it considered preventable and for which it would not reimburse hospitals if acquired subsequent to admission. In the 2009 proposed IPPS rule, CMS proposed to more than double the categories of hospital-acquired conditions that it determined to be reasonably preventable by eliminating additional payments for nine new conditions. CMS pared the proposed list down to three categories in the final rule, as a response to strong objections received through the public commenting process.

CMS began listing never events in 2007 as directed by the Deficit Reduction Act of 2005 (“DRA”). The never event provisions of the DRA can be traced largely to the seminal 1999 Institute of Medicine (“IOM”) report entitled “To Err is Human: Building a Safer Health System.” The IOM report sparked a nationwide debate on the scope and costs of preventable medical errors that ultimately resulted in federal legislation.

**EMTALA**

**New EMTALA Regulations Address Community On-Call and Specialized Hospital Transfers**

In its Inpatient Prospective Payment Systems (“IPPS”) final rule, CMS revised two provisions of the Emergency Medical Treatment and Labor Act (“EMTALA”). First, the final rule permits hospitals to participate in formal community call arrangements whereby hospitals can divide their on-call responsibilities by time, place, and/or services. The call arrangements must clearly define call responsibilities and geographic area, and revise emergency services protocols.

Hospitals that are not designated as the on-call locations must still screen and stabilize patients who present to the emergency department.

The final rule also clarifies that when a patient is admitted as an inpatient to a hospital and the patient subsequently requires specialized emergency care, a specialized hospital (such as one containing a burn unit) is not required to accept the patient. CMS stated that if it required specialized units to accept patients, as it previously proposed, then inappropriate transfers may increase, and would further burden emergency rooms.

**TAX**

**IRS Releases Final Form 990 Package**

On August 19, the Internal Revenue Service (“IRS”) released the final redesigned Form 990 and instructions for the 2008 tax year that include changes to the Schedule H instructions for hospitals. The instructions clarify that Schedule H must be completed by organizations that operate at least one facility that is either licensed, registered, or recognized by a state as a hospital. This will be the first revision to the Form 990 since 1979.

Organizations must also list in Part VI the number and description of each type of other facility for which the organization reports information on Schedule H. The instructions clarify that generally applicable rules regarding subsidized health services apply to physician clinics and skilled nursing facilities.

The Form 990 is the key transparency tool that the public, state regulators, the media, researchers, and policymakers use to get information about the tax-exempt sector and individual organizations. The IRS has stated these instructions are the final step in its effort to bring the Form 990 up to date and to reflect the diversity and complexity of the tax exempt community.

The 2008 instructions include new features such as a sequencing list to help organizations determine the order in which to complete various portions of the form, revised general and specific instructions for the core form and schedules, a glossary of key terms, and a compensation table to help organizations determine where, when, and how to report most types of compensation paid to officers, directors, trustees, key employees, and highest compensated employees.

The IRS released a draft of the redesigned Form 990 on June 14, 2007. The final redesigned form

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was released on December 20, 2007 after the service considered approximately 120 public comments.

Links to the instructions are available at <http://www.irs.gov/charities/article/0,,id=185561,00.html>.

## COMMENTARY

### Obtaining Protected Health Information (“PHI”) in Litigation

The Health Insurance Portability and Accountability Act (“HIPAA”) Privacy Rules regulate the use and disclosure of Protected Health Information (“PHI”). PHI is defined as information regarding: (1) a person’s past, present, or future physical or mental health; (2) that identifies or could be used to identify the person who is the subject of the information; (3) created or received by a “Covered Entity”; and (4) which is transmitted or maintained in any form or medium, i.e., whether the information is communicated on paper, electronically, or orally. 45 C.F.R. § 164.501. PHI generally means health information that is identifiable with a patient and is in the possession of a covered entity.

The basic HIPAA Privacy Rule provides that, except in limited circumstances, a “covered entity” may not use or disclose an individual’s PHI without a written authorization containing certain prescribed elements. Permissive disclosures and exceptions to the general rule against disclosure are listed at 45 C.F.R. §§ 164.502 – 164.524. Exceptions include disclosures required by law, disclosures in judicial and administrative proceedings (if strict requirements are met), public health activities (abuse, neglect, domestic violence, etc.), law enforcement purposes (gun shots, burns, etc.), and a few other narrow exceptions.

#### **I. Obtaining Medical Records in Judicial and Administrative Proceedings**

• **Patient Authorization**—a covered entity may release PHI to a requesting party pursuant to a signed patient “Authorization.” 45 C.F.R. § 164.508. The traditional consent forms are no longer valid under HIPAA. A valid Authorization must contain numerous elements set out in 45 C.F.R. § 164.508, including:

1. Description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
2. Name or other specific identification of the persons or class of persons authorized to make the requested use or disclosure;

3. Name or other specific identification of the persons or class of persons to whom the covered entity may make the requested use or disclosure;
4. Description of each purpose of the requested use or disclosure;
5. Expiration date or expiration event for the authorization that relates to the individual or the purpose of the use or disclosure;
6. Signature of the individual;
7. Statement concerning the individual’s right to revoke the authorization in writing;
8. If the authorization is issued by a covered entity, a statement that the person or entity may not condition the individual’s treatment, payment or eligibility for health care services or other benefits on signing of the authorization; and
9. Statement regarding potential for the information disclosed pursuant to the authorization to be redisclosed by the recipient of the PHI and the information may no longer be protected by the Privacy Rules of HIPAA.

• **Court order**—a covered entity may produce PHI pursuant to court order authorizing the disclosure in the course of a judicial proceeding.

• **Subpoena; discovery requests**—in the absence of a court order, a requesting party must provide the covered entity with written satisfactory assurances (described in more detail below) that reasonable efforts have been made to (1) notify the individual who is the subject of the PHI or (2) secure a qualified protective order.

1. Notifying the patient—A covered entity may disclose PHI if it receives from the attorney a written statement and accompanying documentation demonstrating that: (a) the lawyer has made a good faith attempt to provide written notice of the request to the individual (if the individual’s location is unknown, to mail notice to the last known address); (b) the notice includes sufficient information about the litigation or proceeding in which the PHI is requested to permit the individual to raise an objection to the court or administrative tribunal; and (c) the time for the individual to raise an objection has lapsed and (i) no objections were filed or (ii) all objections

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filed were resolved by the court or tribunal and the disclosures sought are consistent with the resolution (NOTE: this can be accomplished through service of a notice of intent to serve a subpoena; the notice of intent is served on the individual's attorney; if there is no objection, the subpoena served on the covered entity should include the above assurances);

OR

2. **Qualified Protective Order**—A covered entity may disclose PHI if it receives satisfactory assurances that the parties have either agreed to a qualified protective order or the party seeking the PHI has requested a qualified protective order from the court or tribunal; a “qualified protective order” under HIPAA must:

- a. prohibit the parties from using or disclosing the PHI for any purpose other than the litigation; and
- b. require the return of the PHI to the covered entity (or the destruction of the PHI) at the end of the litigation or proceeding.

• **Deposition Notice**—if an attorney wishes to take the deposition of a covered entity (or its representative) and will ask the covered entity to disclose PHI without a court order, then the attorney must provide the covered entity with the written satisfactory assurances discussed above (i.e., gave individual notice of intent and right to object, but the individual did not object).

• **Other discovery requests**—any time that a request seeks the disclosure of PHI, the requesting party must provide the covered entity with the same written satisfactory assurances.

**II. Other Litigation Issues**

• Patient's right to restrict access to PHI (45 C.F.R. § 164.522)

1. Under HIPAA, a patient can request that his or her provider (covered entity) restrict how the provider uses or discloses PHI.
2. The covered entity does not have to agree to a restriction (doctors are told not to agree).
3. A covered entity that agrees to a restriction cannot use or disclose PHI in violation of the restriction, except in rare circumstances.

• Patient's right to access own PHI (45 C.F.R. § 164.524)

1. An individual has a right to access or obtain a copy of his own PHI in a designated record set (i.e., maintained to make a decision about a patient; doesn't include quality control documents).

2. Exceptions include that the patient does not have the right to access PHI compiled in reasonable anticipation of a civil proceeding (i.e., the work product doctrine).

• Patient's right to have a covered entity amend their medical records

1. A covered entity can deny a patient's request for medical records if the subject of the request:

- a. was not created by the covered entity;
- b. is not part of the designated record set; and
- c. is accurate and complete.

Since the HIPAA Privacy Rules have been in effect for more than five years, obtaining medical records and PHI in litigation has become somewhat routine, although it still involves going through a process which takes time, and all of the procedural requirements must be followed.