Operating Notes: Proposed ASC Payment Rule; OIG Advisory Opinion

A “flurry” of health care developments impacting the outpatient surgical arena has occurred within the past month. We do not attempt here to describe them all in depth. We do, however, briefly describe those developments that we believe may be of particular interest to participants in outpatient ventures.

Proposed Changes to Ambulatory Surgical Center Payment System and 2009 Payment Rates

On July 18, 2008, the Centers for Medicare & Medicaid Services (“CMS”) published a proposed rule containing changes to payment rates and policies for ambulatory surgical centers (“ASCs”) for the 2009 calendar year. The payment rates are being updated for the second year of a four-year transition to align the ASC rates with those paid to hospital outpatient departments. Effective Jan. 1, 2008, the payment system for ASCs was revised to pay for more surgical services in an ASC in an amount based on a percentage of the payment rates for the same service under the hospital outpatient prospective payment system (“HOPPS”). For device-intensive procedures, ASCs receive the same payment for device costs as would be made under HOPPS. For ASC services that are performed primarily in physicians’ offices, the ASC payment is capped at the amount payable for the physician practice office expenses under the Medicare Physician Fee Schedule for the same service.

CMS is proposing to add six surgical procedures to the list of procedures payable by Medicare when performed in an ASC in 2009. CMS also proposes to add five procedures to the list of office-based procedures, and to update the list of device-intensive procedures and covered ancillary services and their rates.

Reimbursement amounts for 2,475 procedures would increase under the proposed rule, while reimbursement for only 92 procedures would decrease from 2008 rates. CMS projects that the total payments for services furnished to Medicare patients in ASCs in 2009 will be approximately $3.9 billion, compared with the projected payments of $3.5 billion for 2008.


CMS also issued a transmittal—available online at http://www.cms.hhs.gov/transmittals/downloads/R1572CP.pdf—on Aug. 8, 2008, requiring that, effective Jan. 1, 2009, the name and NPI of the ordering/referring physician must be reported on all claims for diagnostic services performed in an ASC. Prior to Jan. 1, 2008, ASCs were not able to bill for diagnostic radiology services since those services were not included on the list of ASC-covered...
procedures. Since implementation of the new payment system Jan. 1, 2008, ASCs have been able to bill for certain diagnostic services. The requirement to report the ordering/referring physician on claims for diagnostic services already exists for other Medicare Part B claims for diagnostic services.

**OIG Issues Advisory Opinion Regarding Joint Venture Between Physician Group and Hospital**

On **July 18, 2008**, the Office of the Inspector General of the Department of Health and Human Services (“OIG”) issued OIG Advisory Opinion No. 08-08. In the opinion, the OIG concluded that although the investment under review in an ASC by a group of surgeons and a hospital corporation did not meet any safe harbor under the federal anti-kickback statute, it would not impose sanctions. Although advisory opinions only apply to the specific facts and parties set forth within them, health care attorneys generally look to the OIG’s rationale and conclusions in advisory opinions for guidance in structuring similar arrangements.

OIG Advisory Opinion 08-08 provides insight into the OIG’s views on investments in ASCs by physicians who do not meet the requirements of a safe harbor, and also on joint ownership of ASCs by physicians and hospitals. The OIG’s analysis and conclusion in this advisory opinion raise the points described below, which should be considered by parties contemplating an ASC joint venture between physicians and a hospital.

**Factual Background**

The arrangement analyzed in this opinion was a joint venture, owned 30 percent by a health system and 70 percent by a large multi-site physician group. The hospital corporation owned three hospitals and a large physician group practice. The hospital’s physician group consisted of primary care physicians and specialty-care physicians.

The physician group investor consisted of 18 surgeons. The ASC safe harbor requires that the physician investor receive at least one-third of his or her medical practice income for the previous fiscal year or previous 12-month period from the performance of procedures payable under Medicare when performed in an ASC (“ASC Procedures”). Fourteen of the surgeon owners in the opinion met the “one-third income test” set forth in the ASC safe harbor under the anti-kickback statute. Although the remaining four surgeons did not meet the one-third income test, each of those four surgeons derived at least one-third of his or her medical practice income from procedures requiring a hospital operating room setting. Since these surgeons performed mainly hospital-based surgeries, they received little or no income from the performance of ASC Procedures.

**Investment by surgeons who do not satisfy the one-third income test**

Although four of the 18 surgeon owners did not meet the “one-third income test” set forth in the ASC safe harbor under the anti-kickback statute, the OIG distinguished this arrangement from “potentially riskier arrangements” based on the following factors:

**All active surgeons** – Because of their subspecialty of orthopedic surgery, these surgeons derived one-third of their medical practice income from procedures that require a hospital operating room setting, but they received little or no income from the performance of ASC Procedures.

**Small percentage of investors** – These “inpatient” surgeons comprised a small proportion of the surgeon investors. Fourteen of the 18 investors satisfied the one-third income test and used the ASC regularly as part of their medical practices.

**Rarely in position to refer** – The inpatient surgeons were rarely in a position to refer patients either to the ASC or to the other surgeon investors, except for occasional pain management procedures. The parties certified that they will not refer a procedure to the ASC unless the referring physician would personally perform the procedure.
**Investment by hospital corporation in a position to make or influence referrals to the ASC**

Even if all the surgeon investors had satisfied the safe harbor requirements, the joint venture would not have qualified for protection under the safe harbor applicable to ASCs owned jointly by physicians and hospitals because the hospital is in a position to make or influence referrals to the ASC. The OIG, however, considered the following safeguards that significantly constrained the ability of the hospital to direct or influence referrals:

**No actions to require or encourage referrals** – The hospital certified that it did not and would not require or encourage its physicians to refer patients to the ASC or to the surgeon group investor.

**Referrals not tracked** – The hospital certified that it did not and would not track any referrals to the ASC or to the surgeon investors by hospital-affiliated physicians.

**Fair market value compensation** – The hospital certified that any compensation paid to its physicians was and would be consistent with fair market value, and did not and would not take into account the volume or value of any referrals to the ASC, the surgeon group investor or the surgeons.

**Physicians informed annually** – The hospital agreed that it would inform hospital-affiliated physicians of these safeguards on an annual basis.

It is important to note that the OIG has included the factors listed above in at least three advisory opinions. Such safeguards should be instituted by any hospital investor in physician/hospital ASC joint venture.

**Services provided by hospital corporation pursuant to agreement that does not satisfy safe harbor**

Another requirement of the physician/hospital-owned ASC safe harbor is that any agreement for services provided by the hospital to the ASC must satisfy the personal services and management contracts’ safe harbor. The hospital-owned physician practice provided anesthesiology and part-time medical director services to the ASC pursuant to a written agreement. The anesthesia agreement did not meet the requirement of the personal services and management contracts’ safe harbor because it did not specify a schedule for the part-time services to be provided by the medical director. Although the anesthesia agreement did not meet a safe harbor, the OIG found that the nature of the services and the following circumstances do not raise the risk of fraud and abuse:

**Services specified** – The agreement set forth in detail all of the services to be provided by the hospital’s physician group.

**Services reasonable and necessary** – The parties certified that the services were reasonable and necessary for the ASC.

**Compensation is fixed, fair market value, and not tied to referrals** – The medical director stipend payable to the hospital’s practice was set forth in the agreement and was a fixed amount set in advance. The parties certified that the stipend amount was fair market value for the services and not determined in a manner that takes into account the volume or value of any referrals.

Any services arrangement between an ASC and a hospital investor should be carefully structured to satisfy the requirements of the personal services and management contracts’ safe harbor under the anti-kickback statute.

The OIG concluded that the safeguards put in place by ASC and its physician and hospital investors in the arrangement made the risk of the overall arrangement “sufficiently low” that the parties would not be subject to sanctions under the anti-kickback statute.

A copy of OIG Advisory Opinion No. 08-08 is posted on the OIG website at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/redacted_ao_08-08.pdf.
The issues described in this bulletin and other “hot topics” will be discussed in greater detail by Reed Smith attorneys at the **Fifth Annual Today’s Surgicenter Conference, September 18–20 in Las Vegas.** This year’s dual-track program will address issues of interest to both outpatient surgery centers and urgent care centers. The addition of the urgent care track is particularly timely. In August 2008, Fox News, *The Wall Street Journal* and *U.S. News and World Report* have all featured stories on urgent care centers. We hope that many of you will attend the conference next month. Visit [http://www.reedsmith.com/_db/_documents/3pg_Sept_final_LR.pdf](http://www.reedsmith.com/_db/_documents/3pg_Sept_final_LR.pdf) for more information. A brochure describing the program and agenda accompanies this update.

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