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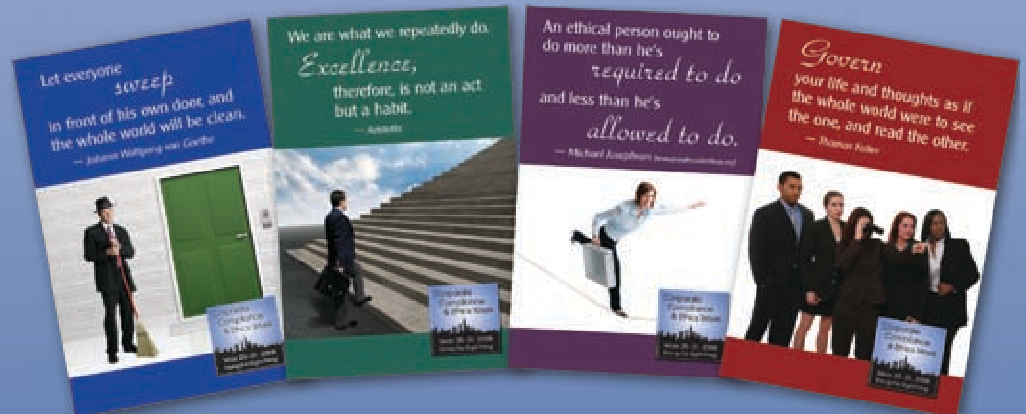

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New reimbursement rules for ambulatory surgery centers

By Jennifer N. Willcox, JD

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On January 1, 2008, a new Medicare reimbursement system for ambulatory surgical centers (ASCs) went into effect. The reimbursement changes will have a financial and operational impact on existing ASCs, and may drive changes in the structure and ownership of ASCs that open in the future. In addition, ASCs around the country are looking for innovative new ways to organize and operate. This article provides a brief summary of reimbursement and regulatory changes, and outlines some basic compliance issues, both in establishing ASCs and in operating them under the new rules.

ASC payment system changes

The burgeoning growth of ambulatory surgery centers, combined with a complicated new payment system, likely will mean increased government scrutiny (as evidenced by the new focus on ASCs in the Office of the Inspector General [OIG] 2008 Work Plan). One change that has received a lot of press is the increase in the number of procedures that can be performed in an ASC. Under the revised system, Medicare will pay an ASC facility fee for any surgical procedure performed there, except for those CMS has expressly excluded from coverage, because either performance of the procedure is not safe or an overnight stay is required. This change means that CMS added nearly 800 more procedures to the "ASC list." The new rates are based on the hospital Outpatient Prospective Payment System (OPPS), but involve a complicated equation that will result in ASCs being paid about 62% of the OPPS payment rates for the same surgical procedures. In practice, some types of procedures (e.g., orthopedics) will be reimbursed at a higher rate, but other procedures (e.g., gastrointestinal, pain management) will see decreased reimbursement.

Some of the procedures added to the ASC list will be paid at an even lower rate, because CMS is imposing a limit on procedures that are performed in a physician's office more than 50% of the time. To avoid what CMS sees as "gaming" the reimbursement system, the ASC payment will be limited to the lower of the ASC system rate or the amount CMS pays physicians for their practice expense when the procedure is performed in a physician's office. The ASC rate will also be a "package" rate, which will include certain ancillary items and services drugs, biologicals, contrast agents, and anesthesia. No separate payment will be made for implantable prosthetics and durable medical equipment (DME), except for those reimbursed as "pass through" items under OPPS, and for what CMS calls "device intensive" procedures.[1]

Establishing an ASC

Due to restrictions in the physician self-referral statute (commonly known as the Stark Laws) and the Anti-Kickback Statute, physicians who own an entity that performs designated health services (DHS) generally cannot refer patients to that entity. Because (in part) CMS wants to encourage usage of ASCs, some exceptions apply. Services reimbursed at a composite rate, like the ASC reimbursement system, are not DHS for purposes of Stark. Prior to January 1, 2008, procedures that were separately billed in an ASC (e.g., radiology procedures and certain drugs) still were subject to Stark. Under the new payment system, imaging procedures and certain drugs that are "ancillary" to the procedures performed at the ASC are no longer DHS.[2]

The Anti-Kickback Statute (AKS), includes "safe harbors" for certain forms of physician and hospital ownership of ASCs, when the ASC is an extension of the physician-investors practice. Compliance with a safe harbor is not mandatory, but satisfying a safe harbor is a guarantee that OIG will not subject an arrangement to civil penalties (and possible criminal prosecution). In each ASC safe harbor, the physician-investors in an ASC must be in a position to refer patients to the ASC. Physicians are considered to be in a position to refer patients if they derive at least one-third of their "medical practice income" from their own performance of procedures that require an ASC or hospital surgical setting according to Medicare rules (the "1/3 income rule"). For ASCs owned by physicians who serve multiple specialties (multi-specialty ASCs), the physician-investors also must meet the "1/3 procedures rule," where at least one-third of the physician's procedures that require an ASC or hospital setting must be performed at the ASC in which he or she is investing. When group practices are investing, all members of the group, rather than individual physicians, must meet the requirements.[3] Physicians meeting these requirements can collaborate with a hospital to jointly own an ASC, but the hospital cannot include any

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ASC costs on its cost report (unless required to do so), hospital space, equipment, and services cannot be used (other than for fair market value pursuant to other AKS safe harbors), and the hospital "may not be in a position to make or influence referrals directly or indirectly to any investor or the entity."[4]

Once you have qualified investors (physicians or physician groups, and/or a hospital), the ASC still must meet additional criteria:

- The terms on which investments are offered must not relate to the volume or value of referrals, or the amount of business "otherwise generated" for the ASC;
- Return on investment must be directly proportional to the capital investment;
- An entity or any investor must not loan funds to another investor, if the loan proceeds are used to purchase an investment interest;
- Patients receiving benefits under any federal health care program (including Medicaid) must be accepted and treated in a nondiscriminatory manner; and
- All ancillary services must be directly and integrally related to the primary procedures provided there, and none may be separately billed.

OIG has been very strict in reviewing ASCs, and in June of 2007, the OIG issued an advisory opinion that, in effect, prohibited a group of orthopedic surgeons from selling their interests in an ASC to a hospital at fair market value because, due to the increase in the value of the ASC, the surgeons would receive more than a proportional return on their investment.[5] But investors considering an ASC should recognize that compliance with each element of the safe harbor is not mandated. In many physician-hospital ASCs, strict compliance with every element of the ASC safe harbor will be impossible (as, for example, nearly all hospitals will be in a "position to refer"). In addition, the safe harbor requirement that all ancillary services must not be separately billed is contradicted by the changes to the ASC payment system, as discussed below. Generally, it is recommended that investors structure an ASC as closely as possible to the safe harbor elements, considering the business objectives of the parties, and adopt procedures to ensure that the ASC remains in compliance insofar as compliance is possible (e.g., regularly reviewing physician referral patterns and financial information to ensure the 1/3 income and 1/3 procedures rules are met, adopting policies that address when hospital-employed physicians may refer to the ASC, etc).

New trends in establishing an ASC

Some physician groups and hospitals are not necessarily interested in being joint venture partners, but they also are not ready to open an ASC on their own. Some hospitals and physicians are looking for arrangements where two Medicare-certified ASCs, owned by separate entities, are operated in the same space under a time-share or other arrangement. Others are trying to co-locate ASCs in space with existing hospital or other functions. The interpretive guidelines to the ASC Medicare regulations make clear that ASCs must be a "distinct entity" and that "the regulatory definition of an ASC does not allow the ASC and another entity to mix functions and operations in a common space during concurrent or overlapping hours of operation."[6] Still, ASCs are permitted to share common space with another entity (including another ASC), but only if the space is never used by both entities at the same time.[7] The basis for this "same time" prohibition is fear of double-dipping: the ASC facility fee was designed to reimburse ASCs appropriately for their overhead, and CMS is concerned that ASCs sharing common space are being overpaid.

As a result, "time share" arrangements are only permitted if the two ASCs (or an ASC and another entity) never operate at the same time (for instance, a "morning ASC" and an "afternoon ASC" in the same space likely would be permitted by CMS). But state licensure restrictions are an important consideration: one Medicare condition of participation for ASCs is compliance with state licensure law, and some states have concerns about infection control, privacy, and other matters when two licensed entities share the same space. Potential ASC investors looking to operate a "time share" ASC should work closely with their state's licensure agency to address any concerns.

Historically, CMS has carved out one exception to the rule requiring exclusive use. When imaging services were "integral to the performance of the surgical procedure," an ASC also could be enrolled with Medicare as an independent diagnostic testing facility (IDTF) and bill for radiology services directly related to, and furnished in conjunction with, a covered surgical procedure.[8] Under the new ASC payment system, CMS now will pay ASCs separately for certain "ancillary" imaging services and prescription drugs that are integral to the performance of the surgery when billed by the ASC on the same day as a surgical procedure, provided that a separate payment would be made for the service or drug under OPPS. Recognizing that the separate payments raise Stark issues (because covered ancillary services would otherwise be DHS), CMS also amended the Stark definitions[9] to make clear that such ancillary services could be billed by an ASC when performed or referred by physicians who have an ownership interest in that ASC (as noted above, no such changes were made to the AKS regulations). ASCs now need not be dually-enrolled as IDTFs in order to perform and bill for imaging procedures. CMS also changed the IDTF regulations, and fixed-based IDTFs are now prohibited from "sharing a practice location with any other

Medicare-enrolled individual or organization," so the change in radiology billing rules for ASCs is welcome.[10]

Ongoing compliance

Once an ASC is operational, it still should direct attention and resources to ongoing compliance. Although the OIG has not issued any compliance program guidance for ASCs, all compliance programs have the same general elements:

- A compliance officer and/or committee
- Baseline and ongoing audits to monitor compliance
- Written standards and procedures
- Investigations of allegations and incidents
- Open lines of communication (bulletin boards, anonymous tips, etc.)
- Enforcing disciplinary standards, and
- Training and education.

An ASC compliance program should focus on compliance issues that are endemic to all providers, and on risks that may be heightened in an ASC. Such areas include:

- Billing and coding (submitting claims for non-covered procedures, etc.);
- Beneficiary inducement (waiving co-pays or giving other items of value in order to influence a patient to use the ASC);
- Relationships with physicians that refer (above-market space or equipment leases, providing free services or staff to physicians, etc.); and
- Returns to physician-investors (based on referrals rather than capital contribution, etc.).

ASCs also should review the new payment system and other regulatory changes and update their compliance program accordingly:

- The new payment system likely will make certain types of procedures less profitable (e.g., gastrointestinal and pain management) and others more profitable (e.g., orthopedic procedures). If physicians are buying or selling their ownership interests in the ASC because of these changes, be aware of the OIG Advisory Opinion referenced above. Also, track whether all physician investors continue to meet the 1/3 income and, in cases of multi-specialty ASCs, 1/3 procedures rules.
- For ASCs that have billed as an IDTF for ancillary imaging services, evaluate whether IDTF enrollment is still necessary, and if not, adjust the compliance plan accordingly.

Conclusion

As ASCs proliferate, government scrutiny likely will increase. An effective compliance plan remains the best defense against allegations of fraudulent conduct or overbilling. Compliance plans need regular retooling, however, and changes to the payment system or new approaches to ASC operations such as "time shares" must be addressed in the plan. Consult with an experienced health care attorney in the area before starting down the ASC road or restructuring your existing ASC. Like patients, be sure your compliance plan gets regular "checkups." ■

This article is intended for educational and informational purposes only, and should not be relied upon for legal advice. Readers are advised to seek legal counsel before acting on any matters described in this article.

1 A CMS FAQ on these changes is available at www.cms.hhs.gov/center/asc.asp
2 But see Garcia v. Health Net of New Jersey (state "mini-Stark" law prohibits referring physicians from owning ASC).
3 ASCs also can have physician-investors who are not in a position to refer at all.
4 42 CFR §1001.952(r)(4)
5 OIG Advisory Opinion No. 07-05
6 State Operations Manual, App. L – Guidance to Surveyors: Ambulatory Surgical Services
7 See, e.g., letter from CMS Region 5 to Wisconsin Department of Health and Family Services dated Nov. 8, 1996
8 (6/17/03) S&C 03-22 Clarification of CMS Payment Policies Regarding ASCs/IDTFs Conducting Business From the Same Location
9 42 CFR §411.351
10 42 CFR §410.33(g)(15)

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