SPECIAL ISSUE: Legal, Regulatory, Safe Harbor and Anti-Kickback Issues for ASCs

BECKER'S

ASC REVIEW

Practical Business, Legal and Clinical Guidance for Ambulatory Surgery Centers

Vol. 2009 No. 5

17 Key Legal Issues of 2009

By Scott Becker, JD, CPA

There are a number of legal and regulatory issues that are impacting ASCs. These range from antitrust cases to safe harbor issues to new Conditions for Coverage, which place specific additional burdens on surgery centers, as well as several other issues. This article provides a short summary of 17 key legal issues.

1. Patient disclosure. New Conditions for Coverage require that an ASC patient be notified of certain information related to physician ownership and related to advance directives. The disclosure must be in writing and prior to the date of the procedure. This requirement will make it critical that the physician become more engaged in the process of physician disclosure. The surgery center will have to take steps to en-

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ASC Lawyers Discuss Current Critical Legal Issues Facing Surgery Centers

By Lindsey Dunn

While ASCs face a variety of legal issues at their individual state levels, there are several national legal issues affecting the everyday affairs of a surgery center, according to ASC legal experts. The most critical are physician ownership, safe harbor requirements, out-of-network fees as well as recent updates to Red Flags laws and HIPAA.

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Mandatory Disclosure of Physician Ownership in ASCs Required by the Medicare Conditions for Coverage

By Scott Becker, JD, CPA, and Amber Walsh, JD

The final Medicare Conditions for Coverage were published Oct. 30, 2008 and went into effect May 18. One of the most significant changes in the

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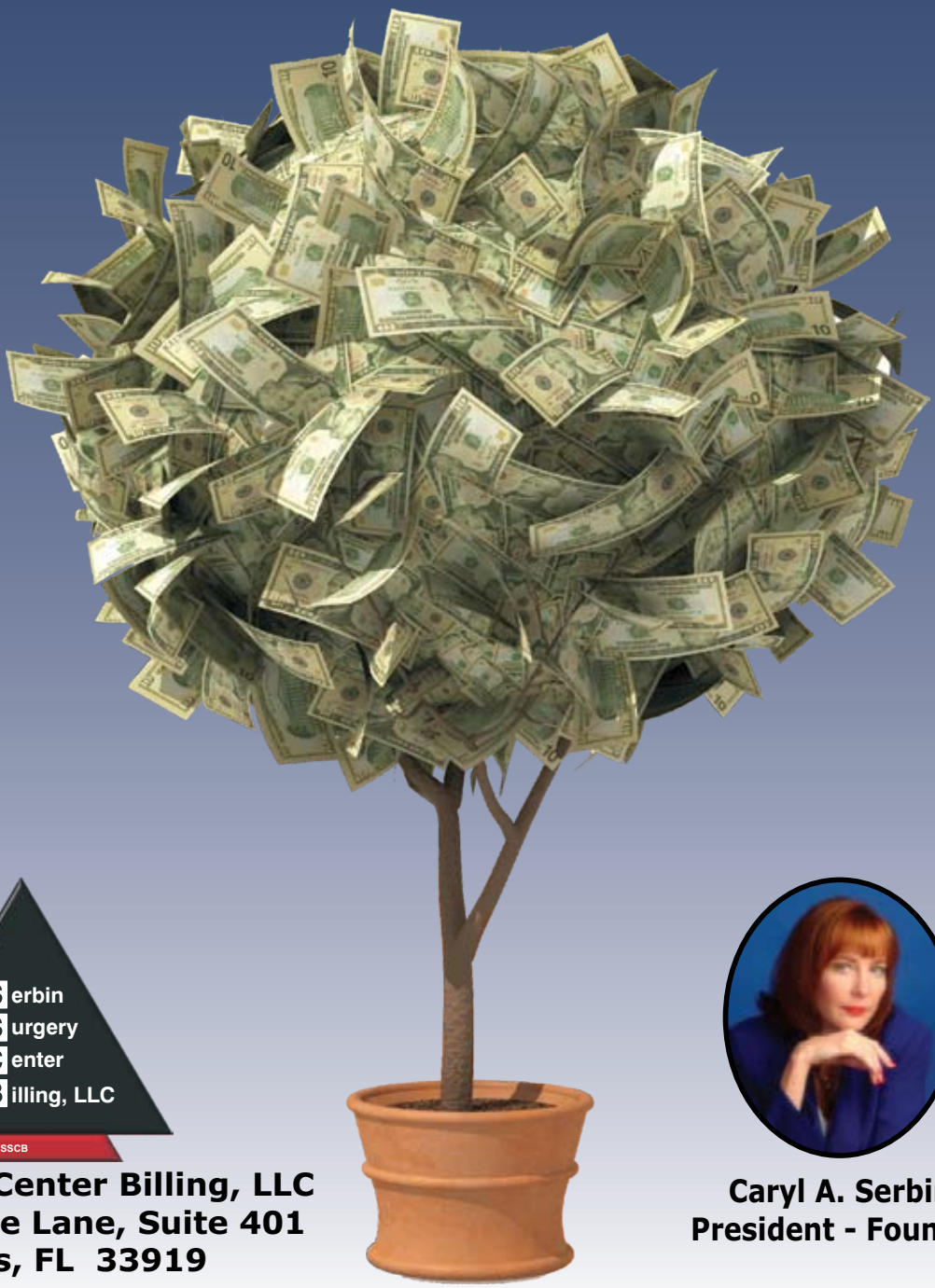

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FEATURES

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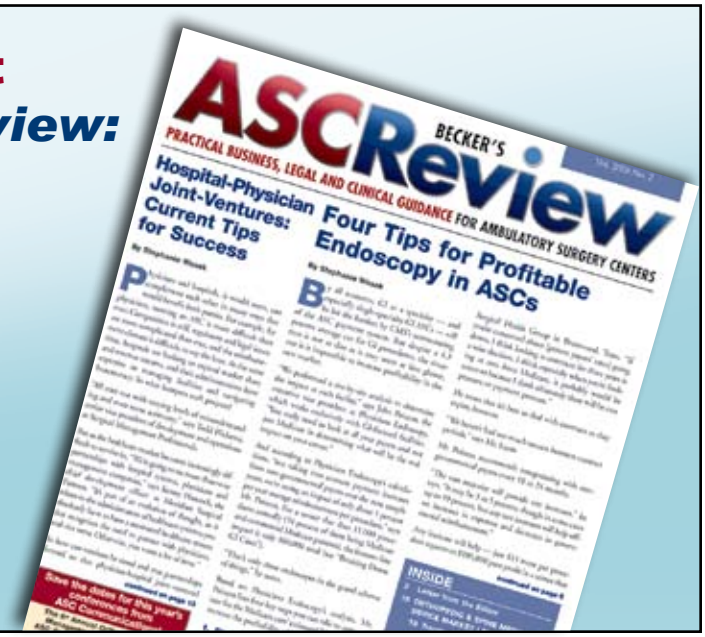

Publisher's Letter

New Medicare Conditions for Coverage for ASCs; Increased Scrutiny of Physician-Hospital Relationships; *Becker's ASC Review* E-Weekly; 16th Annual ASC Conference – Improving Profitability and Business and Legal Issues

By Scott Becker, JD, CPA

Healthcare providers, particular physicians and hospitals, are coming under increased scrutiny. There are both increased investigations of physician-hospital and provider relationships and increased burdens being placed on surgery centers. See, for example, BNA Health Care Report dated May 20 ("Physicians Under Increased Scrutiny in Health Fraud Cases"). This issue of the *Becker's ASC Review* focuses on legal and regulatory issues related to surgery centers.

1. Conditions for Coverage. A key problem with the new disclosure requirements under the Conditions for Coverage is their potential impact on "add-on"/same-day procedures. CMS, in an emergency measure driven by the efforts in part of the ASC Association, addressed this issue on May 18. There, the ASC Association reported:

"It is not acceptable for the ASC to provide the required notice for the first time to a patient on the day that the surgical procedure is scheduled to occur, unless:

the referral to the ASC for surgery is made on that same date; and the referring physician indicates, in writing, that it is medically necessary for the patient to have the surgery on the same day, and that surgery in an ASC setting is suitable for that patient.

In such situations the ASC must provide the required notice prior to obtaining the patient's informed consent. Cases of surgery occurring on the same day it is scheduled are expected to be rare, since ASCs typically perform elective procedures. Frequent occurrence of such cases may represent noncompliance with the advance notice requirement."

For more information, visit www.ascassociation.org/coverage.

2. Increased scrutiny of physician-hospital and physician-provider relationships. Each week we see a Fraud and Abuse or Stark Act settlement reached with respect to kickback type of relationships or Stark Act prohibited relationships. In the past, one could review every kickback case ever settled and reach the conclusion that in each case there was a party that was a very bad actor. One of the great concerns today is that the cases and settlements often involve conduct that is so common and so technical that it is much harder to come to the conclusion that the parties engaged in the issues leading to settlements were truly bad actors rather than victims of a random lottery approach to healthcare fraud.

This lottery situation to investigation makes it more critical than ever that each surgery center adopt and stick to a true compliance effort and plan.

This need not be an overly expensive effort but it does need to be a pervasive and ongoing focus of leadership of the center.

3. Becker's ASC Review E-Weekly. The Becker's ASC Review provides twice weekly information on surgery center business and legal issues. It also provides interesting information relating to the surgery center arena. Should you desire to be signed up for the ASC E-Weekly, either go to www.beckersasc.com or e-mail sbecker@mcguirewoods.com.

4. 16th Annual ASC Conference on Improving Profitability – Business and Legal Issues – ASC Communications/Ambulatory Surgery Foundation. Enclosed is an agenda for the ASC Communications/Ambulatory Surgery Foundation conference to be held Oct. 8-10. This is the 16th Annual Conference on Improving Profitability and Business and Legal Issues for Surgery Centers. The conference features more than 95 different speakers focusing very specifically on specialty-related issues, improving profitability issues, turnaround issues, joint venture issues, cost cutting issues, managed care issues and billing, coding and collecting issues. It should be an outstanding conference for both physician-owners, surgeons examining surgery center opportunities and for administrators and leaders of surgery centers. Should you desire more information about the conference, please e-mail sbecker@mcguirewoods.com or call (800) 417-2035. Finally, you can register by calling (703) 836-5904.

Should you have any questions about any of these items, please contact Robert Kurtz at rob@beckersasc.com or at (781) 219-4613; jessica Cole at jessica@beckersasc.com or at (312) 505-9387, or Scott Becker at sbecker@mcguirewoods.com or at (312) 750-6016.

Very truly yours,

Scott Becker

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17 Key Legal Issues of 2009
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sure that it is comfortable that disclosure is happening at the proper time. The language of the new Conditions for Coverage concerning this is as follows:

"The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of procedure."

The new rules create significant problems for last-minute procedures added onto the schedule, as it is virtually impossible to provide disclosure in advance of the date of the procedure if the physician is scheduling the procedure for the same day. In such situations, parties will take one of several approaches. First, some facilities will ask the physician to schedule the procedure for the next day rather than the same day, which is often not possible. Second, certain facilities will have the physician take the patient to a different facility because they simply cannot meet the disclosure requirement. Third, many facilities will schedule the procedure and make their best efforts to make sure the patient is properly informed, even if it is not possible to do so the day before the procedure. There will be efforts made to make the patient informed at the earliest possible time even if there is some risk that this will lead to problems with respect to certification or other types of problems or lawsuits arising from not meeting the disclosure rule exactly. See Letter from Editor for update on "add-on" procedures.

2. Healthcare reform. No one knows exactly what healthcare reform will look like. However, almost everybody expects that it will lead to an incremental increase in the amount governmental patients versus commercial patients. We can expect that a higher percentage of facilities patients will be paid at lower governmental rates than current commercial rates. For example, if a facility performs 4,000 cases and approximately 10 percent of those patients ultimately switch from commercial insurance to governmental insurance and the facility earns $900 per procedure versus the $1,500 per procedure that it currently earns, this would reflect a reduction of income of $400 times 600 patients, or $240,000. Where a facility earns $1 million, this may equate to a reduction of 24 percent of its profits. This is, of course, a very simple example, but it is probably the clearest path towards where healthcare reform will go. As to a more global view, it is very likely that reform will have many more implications.

There is some argument that the addition of governmental payment for many patients will also increase the total pool of patients available for ASCs. We expect that this will be of negligible benefit to surgery centers

3. Anti-kickback issues. We continue to see the evolution of different types of anti-kickback situations. These relate to issues where parties are trying to sell shares to physicians at prices that are below fair market value, situations where facilities are leasing equipment on a per-click basis from physicians (while not necessarily illegal, the lease fees must be fair market value and there must be very strong arguments to defend the practice as not intended to induce referrals under the Anti-Kickback Statute) and situations where parties want to sell different amounts of shares or pay different kinds of medical director fees to different physicians. We continue to see many types of issues that are in a gray area and other items that are black and white and should not be pursued. Over the new few years, as the government puts more money into anti-fraud initiatives, it will be important to keep an eye on what types of activities people are engaging in and what types of activities the government is particularly targeting.

4. Safe harbors — non-compliant physicians. Over the past few years, parties have become more aggressive in trying to redeem physicians who are not safe harbor compliant. We see less patience from existing physicians and more efforts to try and cause physicians that are not safe harbor compliant to be redeemed from surgery centers. In many situations, the parties may offer the physicians full value for the shares, even if they are not required to by the operating agreement, and give them a long period of notice to try to come into compliance with the safe harbor. In addition, it is important that safe harbor concepts not be applied in an indiscriminate manner. Rather, the safe harbor concepts should be applied to all parties if they are going to be used to redeem parties. Further, there is at least one significant case where the use of the safe harbors was challenged by a physician. While the case was dismissed on other grounds, it has provided additional comfort to parties who are looking to redeem physicians based on lack of safe harbor compliance. Again, it is critical that redemption be truly be based on compliance.

5. Safe harbors — indirect referrals. The government continues to pronounce great discomfort with indirect referral sources and non–safe harbor compliant physicians. They are increasingly very intelligent relating to cross-referral relationships as evidenced by the extreme caution they showed as the Office of Inspector General issued a positive advisory opinion for a joint venture between physicians and a hospital where only a small number of the orthopedic physicians were not safe harbor compliant (i.e., four out of 18 physicians were not safe harbor compliant). There, in fact, they prohibited the referral of cases from physicians to parties that would receive referrals and then use the surgery center for those cases. In reaching its conclusion, the OIG said:

"In the circumstances presented, notwithstanding that four Inpatient Surgeons will not regularly practice at the ASC, we conclude that the ASC is unlikely to be a vehicle for them to profit from referrals. The Requestors have certified that, as practitioners of sub-specialties of orthopedic surgery that require a hospital operating room setting, the Inpatient Surgeons rarely have occasion to refer patients for ASC-Qualified Procedures (other than pain management procedures, which are discussed below). Moreover, like the other Surgeon Investors, the Inpatient Surgeons are regularly engaged in a genuine surgical practice, deriving at least one-third of their medical practice income from procedures requiring a hospital operating room setting. The Inpatient Surgeons are qualified to perform surgeries at the ASC and may choose to do so (and earn the professional fees) in medically appropriate cases. Also, the Inpatient Surgeons comprise a small proportion of the Surgeon Investors, a majority of whom will use the ASC on a regular basis as part of their medical practice. This Arrangement is readily distinguishable from potentially riskier arrangements in which few investing physicians actually use the ASC on a regular basis or in which investing physicians are significant potential referral sources for other investors or the ASC, as when primary care physicians invest in a surgical ASC or cardiologists invest in a cardiac surgery ASC.[1]

In this case, although the arrangement did not meet every requirement of the safe harbor in question, certain other factors led the OIG to conclude that although the arrangement posed some risk, the safeguards put in place by the parties sufficiently reduced the risk of illegal kickbacks to warrant granting the positive advisory opinion.

6. Buy-in pricing for junior physicians and new physicians. Parties continue to look for ways to reduce buy-in amounts for junior physicians. There are increasing arguments for lower valuations based on the impact of the changing economy on surgery centers and the uncertainty of profits going forward. It is also possible for juniors to buy a lesser number of shares, to obtain loans from companies that are in the business of providing financing for physician buy-ins (such buy-ins are not guaranteed or supported by any other investor) and to engage in opportunities like recapitalizations to further reduce the cost and value of the center. Again, a key issue is to ensure that one is not selling shares to junior physicians at below fair market value to induce the referral of cases or the retention for cases.

7. HIPAA. The Health Insurance Portability and Accountability Act continues to be updated in a manner that adds additional burdens. One of the biggest burdens in the most recent amendments with respect to the HIPAA laws requires that a patient be notified of any sort of inadvertent breach of disclosure of confidential information. Previously, centers and healthcare providers could decide on a case-by-case basis whether or not to notify the patient of an inadvertent breach. Now, all breaches must be noti-

fied to the patient. Further, under the newly revised HIPAA, the patient has the right to receive medical records with little cost even if the surgery center must incur costs to provide the medical records.

8. Red Flags Rules. The Red Flags Rules that were intended to help credit and finance companies track identify theft and other types of related issues are being read to apply to almost all industries where financing is extended. They also add additional cost to all kinds of industries, including the healthcare industry. They continue to be delayed by the government in terms of actual implementation.

9. Can I kill a partner physician? One question that ties closely into the safe harbor concepts is, "Can I kill a physician who does not perform cases at the center?" The answer, briefly stated, is you cannot kill such physician. However, there are possibilities to work with the safe harbors and compliance guidelines to see if the party is someone that should be redeemed pursuant to not complying with the safe harbors.

10. Sale of additional shares to highly productive physicians. We often see a situation where a physician who produces proportionately more than he owns wants to buy additional shares in the surgery center. In general, it is very hard for a management company or the center to facilitate this. It is possible for that physician to try and buy additional shares from other partners. Here, the other partners cannot sell the shares to him or her simply to help keep his or her cases at the center. If they do want to sell shares, for reasons unrelated to retaining volume, it is not illegal for them to sell shares to him or her. The sale of shares should be at fair market value.

11. Profiting from anesthesia and pathology. Increasingly, we see situations where centers are looking for ways to profit from ancillary services such as anesthesia, pathology or other areas. Again, there are certain ways in which an ASC can profit from anesthesia in a legal manner, and then there are certain ways in which there are more significant concerns with respect to the legality of profiting from anesthesia. This area has recently come under scrutiny from the American Society of Anesthesiology.

The laws with respect to profiting from pathology are somewhat murkier. There is an ability often for gastroenterology practices related to surgery centers to perform pathology services in their own office and profit from these. However, there is a whole range of analysis that has to be performed to ensure that such efforts comply with the Fraud and Abuse laws, the Stark Act and the Anti-Markup Provisions.

12. Antitrust issues. There are two key types of antitrust issues that are most prevalent in the ASC industry. First, there is a question as to whether a hospital and physicians can jointly contract together to try and obtain better rates from managed care payors. Here, the key issue is trying to ensure that two entities can be considered one entity for purposes of the antitrust laws. This makes them legally incapable of conspiring with each other. Generally, there is a great deal of law on this across the country. For example, if a hospital owns 80 percent or more of the surgery center and has substantial control of the surgery center, there are very strong arguments that conspiring together is not possible from an antitrust law perspective. When the ownership is between 50 percent and 80 percent, the determination differs by district court, which is to say by region of the country. Further, the amount of control the hospital has over the surgery center is a critical component of the ultimate determination. Where a hospital owns less than 50 percent of the surgery center, it is still possible to be considered one entity, but the hospital must have substantially all control of the surgery center.

The other common issue that arises from an antitrust perspective is a situation where a surgery center is excluded from being able to serve payors due to aggressive hospital competition. Here, the challenge for the surgery center is showing that the hospital provides more than simple competition but rather a conspiracy to harm the physician-owned surgery center or an effort to monopolize the market.

13. Medical staff bylaws. Medical staff bylaws issues constantly arise in the surgery center context. These are in several distinct contexts. First is determining whether or not to waive a provision to the medical staff bylaws in order to allow a physician to remain on or join the medical staff even though he does not technically meet a specific qualification. There are pros and cons to periodic waivers of provisions as to specific physicians. Second is the issue as to how to remove a physician from medical staff due to some sort of medical conduct issue or other issue. Here, to obtain the protections of the Healthcare Quality Improvements Act, it is critical that a surgery center follow its medical staff bylaws exactly and also follow the rules of HCQIA.

A third issue related to medical staff bylaws is how the redemption from the medical staff bylaws impacts being redeemed from the surgery center as an owner. Here, there is commonly a requirement in the operating agreement that a member must be on the medical staff to be owner in the surgery center. It is critical that the two efforts be somewhat divided from each other. In essence, this means that the effort must be made first to make sure that the decision under the medical staff bylaws be handled separately and not tied to ownership. Then, once it is completed, the operating agreement redemption issues are burdensome.

14. Hospital outpatient department transactions and "under arrangements" deals. Over the last few years, a type of transaction where parties put together an infrastructure company and then provided all of their surgery center services to a hospital "under arrangements" became very popular. This was because it allowed the hospital to continue to charge hospital outpatient department rates and allowed the physicians, in part, to own the infrastructure by staying aligned with the hospital. In addition, physicians were getting paid as well as they would typically do in a surgery center. In essence, this type of structure abrogated the benefit to CMS of the lower payment rate for ASC services. The Department of Health and Human Services, as part of the most recent Inpatient Prospective Payment System, changed a number of related Stark Act provisions. In that regard, they specifically outlawed this type of arrangement:

"In the CY 2008 PFS proposed rule, we noted our continuing concern about the risk of overutilization with respect to services provided "under arrangements" to hospitals and other providers because the risk of overutilization that we identified in the 1998 proposed rule has continued, particularly with respect to hospital outpatient services for which Medicare pays on a per-service basis (72 FR 38186). We proposed to revise our definition of entity at §411.351 to include both the person or entity that performs the DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS . . .

In this final rule, we are adopting our proposal with modification and amending 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 that has performed the DHS, (notwithstanding that another person

or entity actually billed the services as DHS) or presented a claim for Medicare benefits for the DHS. Note that where one entity performs a service that is billed by another entity, both entities are DHS entities with CMS-1390-F 1110 respect to that service. We are delaying the effective date of the amendment to the definition of "entity" at §411.351 until October 1, 2009 in order to afford parties an adequate time to restructure arrangements."[2]

15. "Per-click" relationships. As a corollary to the under arrangement structures, there have been several types of transactions and deals set up as "per-click" arrangements. These include such items as gamma knives, lithotripters, lasers, CT and MRI scanners and other types of equipment. Generally, the government has now outlawed (at least in the Stark context) per-click relationships. Although the changes to the Stark Act and the accompanying regulations do not necessarily apply to surgery centers, their analysis and concerns would be applicable under the Anti-Kickback Statute to surgery centers. Thus, it would be unlawful for the provider of designated health services (such as imaging services) to rent equipment or real estate from a referring physician on a per-click basis that he or she would rent to the surgery center or hospital. CMS offered an explanation of its position in the commentary to the new rules:

"At this time we are adopting our proposal to prohibit per-click payments to physician lessors for services rendered to patients who were referred by the physician lessor. We continue to have concerns that such arrangements are susceptible to abuse, and we also rely on our authority under sections 1877(e)(1)(A)(vi) and 1877(e)(l)(B)(vi) of the Act to disallow them.

We are also taking this opportunity to remind parties to per-use leasing arrangements that the existing exceptions include the requirements that the leasing agreement be at fair market value (§411.357(a)(4) and §411.357(b)(4)) and that it be commercially reasonable even if no referrals were made between the parties (§411.357(a)(6) and §411.357(b)(5)). For example, we do not consider an agreement to be at fair market value if the lessee is paying a physician substantially more for a lithotripter or other equipment and a technologist than it would have to pay a non physician-owned company for the same or similar equipment and service. As a further example, we would also have a serious question as to whether an agreement is commercially reasonable if the lessee is performing a sufficiently high volume of procedures, such that it would be economically feasible to purchase the equipment rather than continuing to lease it from a physician or physician entity that refers patients to the lessee for DHS. Such agreements raise the questions of whether the lessee is paying the lessor more than what it would have to pay another lessor, or is leasing equipment rather than purchasing it, because the lessee wishes to reward the lessor for referrals and/or because it is concerned that, absent such a leasing arrangement, referrals from the lessor would cease. In some cases, depending on the circumstances, such arrangements may also implicate the anti-kickback statute."[3]

16. New Jersey self-referral law. Over the last two years, New Jersey had a series of cases that provided great concern to physician-owned surgery centers. Briefly stated, a statute called the Codey Law was read to prohibit physician ownership of surgery centers if they were not truly and completely office-based. This ruling caused great concerns for surgery centers because traditionally the view has been that physician ownership in a surgery center was generally permitted under the Codey Law, although people acknowledged there was some risk. This law was amended to clarify that physician ownership for existing centers it places very severe restrictions on the further development of physician-owned surgery centers. This is now the first state in the country that has a prohibition on physician ownership of surgery centers.

17. Out-of-network reimbursement. The ability to profit substantially from out-of-network patients continues to decrease. While many parties profit from out-of-network payments, payors are increasingly aggressive regarding recoupment, regarding assuring that parties collect appropriate co-payments from patients and regarding increasing co-payment and deductible responsibilities significantly. Thus, the ability to make outsized profits or have serious negotiation leverage through the use of out of network continues to be hampered. ■

This is intended as a brief summary of 17 key legal issues facing surgery centers today. Should you have additional questions, please contact Scott Becker at sbecker@mcguirewoods.com.

Notes:
1. OIG Advisory Opinion No. 08-08.
2. CMS-1390-F 1107 et seq.
3. CMS-1390-F 1077 et seq.

ASC Lawyers Discuss Current Critical Legal Issues Facing Surgery Centers
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Physician ownership

Robert Mosher, JD, partner at Nossaman, and a leading expert in healthcare law, mergers and acquisitions and partnerships, says that the most frequent legal issue he deals with involves physician ownership, and, more specifically, the buying and selling of ASC units.

"One of the legal issues that seem to be problematic for surgery centers is the buying out of retiring owners and the bringing in of new owners," he says. "Many ASCs struggle with interpreting their current agreements regarding buying and with the legal requirement of selling for fair market value."

When an ASC needs to sell units due to a financial struggle, finding buyers who are willing to pay fair market value can be an uncertain process for the current partners. "ASC owners must be proactive about bringing in new partners," says Mr. Mosher. "They cannot wait until there is a crisis or profitability problem. Instead, they should be constantly evaluating new partners that can improve the profitability of the center."

Brian Kalver, JD, counsel with Wilentz, Goldman & Spitzer, agrees that the selling of new shares is a very relevant issue and one that he deals with on a daily basis. "The owners want to be able to present investment terms that they feel are fair and will be attractive to new physicians," he says. "Owners often believe that a fair price is an investment equal to the investment they made."

When ASCs look to buy and sell units, determining the fair market value of a facility can be problematic.

"What the owners think of as 'fair' and what is 'fair market value' can be quite different," says Mr. Kalver. "Although we recommend that clients use fair market value to determine the cost of buy-in, there is not a lot of regulatory guidance on how exactly to determine this value."

ASCs tend to use valuation firms or choose from among several different mathematical formulas to establish their fair market value.

Mr. Mosher recommends that ASCs use valuation firms to determine their value. "Valuation firms look at recent major changes — such as expanded service offerings or new physician recruitment — in addition to the historical performance of the center," he says. "Valuation firms can take into account certain aspects of a business that a mathematical formula cannot." Mr. Mosher suggests that large firms consider signing a regular contract with a valuation firm for these services to ensure the most accurate fair market value is offered to prospective buyers.

Mr. Kalver agrees. "A fair market value determination must generally take into account future earning potential," he says. "If an ASC determines its fair market value by using a formula that calculates a multiple of last year's earnings, but half of the physician-owners left the center, taking half of the center's patient volume with them, the new owners buying into the center would have done so at too high of a rate using a formula that relies heavily on the last year's earnings."

Mr. Mosher recommends that centers be cautious when selecting a formula to include in the agreement regarding the buyout of any retiring physicians. "Owners should be conservative when determining these formulas," he says. "Centers should work to find a formula that works for both the older physicians that are nearing retirement as well as the younger ones who will be required to buy them out."

Mr. Mosher suggests that owners revisit this provision in their agreements, if they have not recently, to determine "if it makes sense and will work going forward." Mr. Mosher adds, "Revisiting the issue at a time when a buyout is not approaching will allow all partners to approach the issue with a clear head."

Another legal issue involving physician ownership is the updated CMS Conditions of Coverage requirements for the advance notice of physician financial interest.

According to Amber McGraw Walsh, an associate with McGuireWoods in the firm's healthcare department, the new Conditions of Coverage for ASCs, which were published Oct. 30, 2008 and became effective May 18, require several advance notifications to patients, including notice of physician financial interest in the ASC, patients' rights and advance directives.

These Conditions of Coverage require that ASCs notify patients of physician financial interest in a facility in writing in advance of the day of the patient's procedure.

"'In advance' is generally considered to mean at least one day prior to the planned procedure," says Ms. Walsh. "ASCs should very clearly list every physician-owner in the ASC and make sure that the document that is distributed to patients or patients' representatives is written in a manner that is easily understood.

"ASCs would ideally post the disclosure document in the facility in addition to giving a copy directly to the patient," says Ms. Walsh.

If the patient is not scheduled for an initial appointment at the ASC before the date of surgery, the ASC may be able to meet the advance requirement by providing verbal notice over the telephone and mailing or e-mailing the written materials to the patient or instructing the patient to download the materials from the ASC Web site.

Safe harbor requirements

Another area where ASCs can find themselves in legal entanglements that may result in litigation is their adherence to safe-harbor requirements. If a center wants to comply with the requirements of safe harbor laws and avoid facing potential violations of the anti-kickback statue, it must ensure that all physician-owners are adhering to the one-third threshold. That is, at least one-third of each physician-investor's medical practice income for the year must come from the physician's performance of outpatient surgical procedures and at least one-third of those procedures must be performed at the specified ASC. This ensures that a physician's investment in an ASC actually represents an extension of the physician's office.

If a center decides to exempt physicians from this threshold, and therefore forgo its safe harbor status, it must be consistent in who it will exempt.

"It is easy to state the tests a center will use to determine safe-harbor compliance, but it is difficult to implement them in a real-life setting without being discriminatory," says Mr. Mosher. "Centers need to establish the specific circumstances in which they will exempt physician-owners and be consistent in applying that policy. For example, a physician taking military leave may be exempt while a physician claiming they just can't meet the criteria probably should not be."

Michael Schaff, JD, LLM, MBA, chair of the corporate and healthcare departments and shareholder of Wilentz, Goldman & Spitzer, agrees that, at times, adherence to safe harbor requirements can be problematic for ASCs.

"Unproductive owners are a concern for surgery centers," he says. "Physician-owners may want to eliminate an owner that is failing to bring a certain volume of patients to the center, but centers have to be extremely careful here. The physicians that own the center may not be aware that it is improper to base ownership on the volume or value of referrals."

ASCs that want to ensure all owners are productive can include safe harbor provisions in their agreements, Mr. Schaff says. However, he warns that centers that include this provision must enforce it for all physicians and not selectively.

Mr. Schaff cautions that ASCs that decide to forgo safe harbor provisions must be very careful in dealing with underperforming physicians.

"You must be careful not to force them out due to their lack of cases brought to the center," he says. "Even if you have a no cause termination provision in your center's documentation, the ousted physician can seek recourse for being terminated based on lack of referrals. In no circumstance should the basis of terminating a physician's ownership be based on her lack of referrals unless the center has a provision whereby failure to meet the appropriate safe harbor has been triggered, and she and all others that do not meet the criteria for ownership are treated similarly."

Mr. Schaff says that some of the ASCs he has worked with have had success using peer pressure to negotiate a buyout. However, Mr. Schaff again warns that any conversations surrounding the physician to be bought-out should not refer to the physician's underperformance.

Out-of-network fee waivers

The waiver of out-of-network patient fees is another legal issue that is very relevant to surgery centers. Many ASCs across the country have a significant portion of their business coming from procedures for out-of-network patients. Insurers pay more for these procedures due the absence of a contracted rate, making them attractive, but the patient's financial obligation is higher as well.

Andrew Wachler, managing partner at Wachler & Associates, a healthcare attorney for more than 25 years, says that out-of-network billing is one of

the key legal issues for ASCs. "From my experience, this is one of the biggest issues where ASC leaders are looking for guidance," he says.

Some ASCs choose not to collect the full amount of an out-of-network patient's financial responsibility, such as a co-payment or co-insurance fee, because procedures on these patients are profitable even without these fees. However, the legality of waiving these fees is an issue that is currently under debate. ASCs are required by CMS to collect these fees for Medicare patients, but restrictions on this practice when dealing with private insurers varies by state.

Healthcare legal experts agree that what is allowed and what is restricted in regard to out-of-network fee waivers is a state-by-state issue. As a result, ASCs must be aware of the laws and guidance that affect their state.

"I suggest that ASCs have someone outline for them what exactly is allowed or restricted in their specific state," says Mr. Wachler. "This is a very difficult task to do without legal counsel."

Mr. Wachler recommends that ASCs analyze state law — including false claims, anti-inducement, anti-kickback and unfair competition law — as well as the opinion of the state attorney general and state case law to determine the legality of waiving the fees within their state.

Waiving out-of-network fees without an appropriate analysis of state law could put ASCs at risk. For example, if a bill for a procedure for an out-of-network patient is $100 and the ASC bills the insurer for 80 percent of that fee but does not collect the co-insurance from the patient, the actual bill for the procedure is only $80. By reporting that the service was worth $100 to the payor, providers could be at risk for violating the false claims act in some states. As a result, ASCs need to be sure their policies for waiving these fees fits within their state law.

Mr. Kalver suggests that ASCs ask themselves, "Is there an obligation to collect money from the patient? Am I violating a state law or misrepresenting a charge by waiving the fee?"

Mr. Wachler recommends that ASCs who want to continue waiving out-of-network fees provide notice to all private payors of these policies. He warns, however, that providing the notice in itself can be problematic because it makes the payor aware of your actions.

Mr. Wachler also suggests that ASCs talk with billing vendors, many of which he says are quite astute at dealing with out-of-network billing issues, to develop business processes that align with the legal requirements of each state.

Red Flags requirements

In addition to advance ownership disclosure requirements, another legal issue that is likely to affect the day-to-day business practices of ASCs is the Red Flags Rule, part of the Federal Trade Commission's Fair and Accurate Credit Transactions Act. The Act, which was issued last fall and goes into effect Aug. 1, will require many businesses, including healthcare providers, to develop, implement and administer an identity theft prevention program designed to detect signs, referred to as "red flags," of identity theft, as well as to prevent and mitigate it.

"Healthcare providers are deemed creditors by the FTC because they typically do not collect for services in-full upfront," says Ms. Walsh "As a result, ASCs must ensure that their facility implements an identity fraud detection policy that meets the requirements of the Red Flags Rule."

Ms. Walsh suggest that providers should think about which red flags will apply to their facility and work to implement a policy that looks for and responds to those red flags. "In determining what red flags they should be aware of, I recommend that healthcare providers and their legal counsel spend time looking at the examples provided by the FTC and enact policies that appropriately address these red flags," says Ms. Walsh. "Once the policy is enacted, every worker should be aware of what to look for and what response to take if a red flag appears."

HIPAA requirements

Recent changes to HIPAA requirements as part of the Health Information Technology for Economic and Clinical Health Act, which was passed in February by Congress, are also expected to change the current business practices of ASCs, specifically in regard to the ways in which they report breaches of protected health information security and privacy.

"The HITECH Act expands the obligations of covered entities," says Ms. Walsh. "For example, the Act changed the requirements for reporting breaches of protected health information. In the past, your responsibility in the case of unauthorized disclosure as a healthcare provider was to mitigate the harm, which meant you sometimes reported the breach to the patient. Now, the patient must be notified."

Ms. Walsh says that additional changes to HIPAA as a result of the Act expand patient rights and the roles of business associates as well as a number of other changes.

Proper counsel is essential

All the legal issues discussed will continue to affect the business practices of ASCs for some time to come. In order for ASCs to ensure that these practices meet these and forthcoming legal requirements and restrictions, legal experts suggest that surgery centers seek sound counsel to advise them.

"Surround yourself with experienced and knowledgeable advisors," says Mr. Schaff. "Physicians tend to do what they feel is right, and what might feel right or makes sense from a business or logical perspective could actually land them or other ASC leadership in jail. I recommend that each surgery center find both an attorney and accountant that are experienced in healthcare law to guide them as they work to bring their business practices in line with the ever-changing legal environment surrounding ASCs." ■

Contact Lindsey Dunn at lindsey@beckersasc.com.

Mandatory Disclosure of Physician Ownership in ASCs Required by the Medicare Conditions for Coverage
(continued from page 1)

Conditions for Coverage is the requirement for ASCs to provide patients with certain verbal and written notification of rights and of ownership in advance of the date of the service. The notice must be provided in a language in any manner that the patient or the patient's representative understands. ASCs specifically must:

1. Post the written notice of patient rights set forth in the Conditions for Coverage in a place or places within the ASC likely to be noticed by patients (or their representative, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address and telephone number of a representative in the state agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

2. Disclose physician financial interests in the ASC. Disclosure of information must be in writing and furnished to the patient. This disclosure — which had previously been a safe harbor requirement — is now a requirement for all centers. Further, disclosure must be provided in advance of the procedure — i.e., generally made prior to the date the patient has the procedure.

3. Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable state health and safety laws and, if requested, official state advance directive forms. The ASC must also inform the patient or patient's representative of the patient's right to make informed decisions regarding the patient's care and must also document in a prominent part of the patient's current medical record whether or not the individual has executed an advance directive.

4. Establish a grievance procedure for documenting the existence, submission, investigation and disposition of a patient's written or verbal grievance to the ASC and notify the patient of the same.

The requirement that such notice be provided "in advance" is generally considered to be at least the day before the procedure is scheduled for all of the above notifications. See "Publisher's Letter" for an update as to "add-on" procedures. If the patient is not scheduled for an initial appointment at the ASC before the date of surgery, the ASC may be able to meet the advance requirement by (a) providing verbal notice over the telephone and (b) mailing the written materials to the patient (or instructing the patient to download the materials from the ASC Web site) and, on the date of the procedure, having the patient bring the notice materials with a signed acknowledgement that they were provided in advance of that day. There is no requirement that all of the above notices be included in the same documentation, but it will be critical for the ASC to ensure that the above verbal and written notices are provided and properly documented in patient records. ■

A copy of the Conditions for Coverage can be found at www.cms.hhs.gov/CFCsAndCoPs/16_ASC.asp

If you have any questions about the patient notice requirements or other aspects of the new Conditions for Coverage, please contact Scott Becker (sbecker@mcguirewoods.com) at (312) 750-6016 or Amber Walsh (awalsh@mcguirewoods.com) at (312) 750-3596.

Checklist for the Changes in the ASC Medicare Conditions for Coverage

By ASC Association of Illinois

The following checklist was prepared by the ASC Association of Illinois for the changes in the ASC Medicare Conditions for Coverage (effective May 18).

Governing Body — Policies & Procedures (written):

✓ Specify all details of quality assessment and performance improvement program (QAPI) and allocate sufficient resources and evaluate for effectiveness

✓ Approve disaster preparedness plan and review reports

✓ Designate grievance officer

✓ Designate qualified infection control officer

Management & Operations — Policies & Procedures (written):

✓ Policy and process for prompt return of any money incorrectly collected

✓ Written transfer agreement with a nearby hospital (update if necessary)

✓ Develop a disaster preparedness plan *and* plan must be coordinated with state and local authorities

✓ Expand policy and procedures on patient rights

✓ Must inform patients with verbal and written notice on patient rights — find way to do in advance of DOS

✓ Post expanded notice on patient rights in lobby/reception

✓ Disclose to patients physicians' financial interest in ASC — find way to do in advance of DOS

✓ Establish a formal grievance procedure (process, deadlines and reporting)

✓ Inform patient of policies on advanced directives — find way to do in advance of DOS

✓ Improve privacy and security of clinical records

Clinical — Policies & Procedures (written):

✓ Patient has a responsible adult to whom patient will be discharged *or* (written) waiver from surgeon

✓ Develop self-assessment and feed data into QAPI with measurable improvements

✓ Develop proactive QAPI program and document improvements

✓ Conduct performance improvement activities (projects) each year

✓ Formal Medicare-approved radiology service

✓ Maintain an infection control program and plan of action

✓ H&P + physician assessment > 30 days before DOS

✓ H&P on chart prior to starting surgical procedure

✓ Document pre-surgical assessment prior to procedure and note any changes in patient's condition since H&P

✓ Document pre-surgical anesthesia risk assessment

✓ Document post-surgical patient assessment

✓ Provide written discharge instructions

✓ Provide patient with overnight supplies

✓ Make follow-up appointment with surgeon as appropriate

✓ Discharge order signed by surgeon *or* other procedure

✓ Discharge patient to a responsible adult *except* if exempted by the attending physician

✓ Never event reporting

This checklist is intended as a summary and guide regarding several key changes in the Medicare Conditions for Coverage for ASCs. These changes become effective as of May 18, 2009.

The checklist is not intended as a substitute for actual Medicare standards, conditions, rules or interpretive guidelines. This checklist was prepared by the ASC Association of Illinois, Mark Mayo, Executive Director. For further information, please contact Mr. Mayo at mayconsultant@msn.com. ■

Conditions for Coverage Crosswalk

View a crosswalk grid illustrating the changes between the previous and new ASC Conditions for Coverage created by Dawn Q. McLane RN, MSA, CASC, CNOR, chief development officer for ASC development, management and consulting firm Nikitis Resource Group, at www.beckersasc.com/pdfs/cfc2009.pdf.

The ASC Association: The Last 10 Years

By Scott Becker, JD, CPA

The ASC Association, over the last 10 years, has done a better job of advancing and appropriately protecting the interests of its members than any other trade association that I am aware of.

There is no set of physician-owned facilities that has better respect and that has a better public relations perspective than the ASC industry. This is largely due to the incredible organizational and leadership efforts of the ASC Association over the last 10 years.

The ASC Association, in addition to doing a tremendous job of advocating for its members in Washington, D.C., has done an incredible job of retaining the vibrancy of the organization. There are few trade associations that can boast of its financial health of the ability to draw more than 2,500 people to its annual meeting. The ASC Association has done a remarkable job of providing education to its members and staying a completely vibrant organization.

We applaud the board of the ASC Association and the leadership of Kathy Bryant who has been a tireless and incredibly intelligent advocate for the industry. She has accomplished more in the last several years with the ASC Association than most parties have accomplished in a lifetime. We encourage each surgery center to join the ASC Association and to contribute to the ASC PAC.

Learn more about the ASC Association at www.ascassociation.org. ■

15 Medicare/Medicaid Anti-Kickback and Fraud and Abuse Statute Cases Making Headlines in 2009

This is a short summary of 15 anti-kickback and fraud cases and investigations that have made headlines in 2009. The situations involve a range of participants including hospitals, device companies, physicians, payors and other suppliers.

1. Medtronic whistle-blower suit. A lawsuit filed by two former Medtronic employees of the company's Memphis-based spine business accused 120 leading spine surgeons across the country and 18 medical device distributors of promoting "off-label" use of the Medtronic product Infuse, which is used in spine surgery to promote bone growth between vertebrae. The product is approved by the FDA for use in the lower back but was allegedly being used in neck surgeries by a number of spine surgeons. Although off-label use of the product is not illegal, the plaintiffs claimed that the defendants took a total of $8 million in consulting fees for promoting the product in 2006. A Massachusetts federal judge dropped the suit in March, ruling that the case did not constitute a whistle-blower suit and blocked an amended complaint by the defendant. However, a civil suit is still active in federal court.

2. Orthopedic device maker antitrust/anti-kickback suit. A lawsuit against Zimmer, Stryker and three other orthopedic device manufacturers accused the device makers of driving the McCulloughs, a family of commissioned salespeople for a competitor of the defendants, out of business. The McCulloughs claimed the defendants provided kickbacks to orthopedic surgeons for using their products over competitors. A federal judge dismissed the antitrust case against the Zimmer and Stryker in March, stating that the plaintiffs lacked standing to bring an antitrust action and lacked insufficient evidence for racketeering charges, which the suit also alleged. The three other device manufactures named in the suit, DePuy, Smith & Nephew and Biomet, previously settled with the McCulloughs.

3. Federal oversight of orthopedic device makers ends. The U.S. Attorney's office ended 18 months of federal oversight of orthopedic device manufacturers Zimmer, Depuy, Biomet, Stryker and Smith & Nephew in March. The federal oversight resulted from charges by the U.S. Attorney's office in 2007 that the device makers violated anti-kickback statutes by paying tens of thousands of dollars to surgeons as incentives to use their products. The companies avoided prosecution by agreeing to new corporate compliance procedures and federal monitoring. Zimmer, DePuy, Biomet and Smith & Nephew remain subject to the terms of separate agreements entered into with the OIG until 2012.

4. NueroMetrix kickback allegations. In February, medical device maker NeuroMetrix agreed to pay $3.7 million as part of a deferred prosecution agreement for federal allegations from the U.S. Attorney's office that it gave kickbacks to physicians. The allegations accused NeuroMetrix of paying physicians in the form of free boxes of disposable biosensors for use with the company's NC-stat System to encourage the physicians to recommend the device to colleagues. NeuroMetrix also allegedly asked physicians to seek reimbursement using a higher valued CPT code under certain circumstances when physicians performed a nerve conduction study using the NC-stat System. Of the $3.7 million, NeuroMetrix agreed to pay $1.2 million as a criminal penalty after admitting that it provided the free biosensors; the remaining $2.5 million in civil damages will settle the kickback and fraudulent up-coding allegations. Under the deferred prosecution agreement, NeuroMetrix will not be prosecuted in connection with the illegal kickbacks if the company complies with the obligations of the agreement for a term of 36 months.

5. Illinois radiology centers kickback suit. Fourteen radiology centers in Illinois that allegedly paid illegal kickbacks to doctors in exchange for referrals agreed to pay a total of $1.2 million to settle a lawsuit filed by the Illinois Attorney General in January. The case, which was filed in 2007, alleged that the radiology centers entered into sham "lease" agreements with doctors under which the doctors paid a reduced rate for MRI and CT scans, charged the patient's insurance carriers a higher rate and then pocketed the difference. The lawsuit asserted that the defendants' actions violated the Consumer Fraud and Deceptive Business Practices Act, as well as Illinois' anti-kickback law, the Insurance Claims Fraud Prevention Act.

6. UnitedHealth Group class action suit. UnitedHealth Group, the nation's second largest health insurer, agreed to pay $350 million to resolve a class action lawsuit with the American Medical Association and the Medical Society, the State of New York and the Missouri State Medical Association in January. The suit alleged that UnitedHealth's wholly-owned subsidiary, Ingenix, rigged the databases that health insurers rely upon to set the "reasonable and customary" rates they charge for out-of-network physician fees so that providers and health plan member were underpaid for these services. The company also settled a separate investigation into these practices by the New York Attorney General for $50 million in January. UnitedHealth admitted no wrongdoing in conjunction with either investigation.

7. Medicaid fraud suits against New York hospitals. Seven hospitals in New York were accused in January of fraudulently billing Medicaid for more than $50 million for alcohol and substance abuse treatment even though the hospitals lacked a state license to provide this treatment. The lawsuits, brought by the New York State Attorney General and U.S. Attorney Benton Campbell, also claim that four hospitals — Columbia Memorial Physicians Hospital Organization in Hudson; Long Beach Medical Center; New York Downtown Hospital; and St. Joseph's Medical Center in Yonkers — allegedly paid kickbacks to Missouri-based SpecialCare Hospital Management Corp. to get more patients into drug treatment programs. The suit also accused Queens' Parkway Hospital, which closed in 2008, of trying to bribe homeless patients to participate in a detox program. The other defendants are the former Our Lady of Mercy in the Bronx and Benedictine Hospital in Kingston. The state settled for $4.5 million with Our Lady of Mercy, now run by Montefiore Medical Center, which denied all wrongdoing.

8. Florida HIV clinic Medicare fraud scheme. The owners and operators of two Miami medical clinics named Medcore Group and M&P Group of South Florida, and a phlebotomist at one of the clinics, were charged and plead guilty in January of conspiring with others to submit approximately $5.3 million in fraudulent claims to Medicare. The defendants admitted that they entered into kickback arrangements with Medicare beneficiaries whereby the beneficiaries were paid every week in exchange for their Medicare billing information, thus allowing the clinics, which claimed to specialize in the treatment of HIV-positive patients, to submit fraudulent bills. The defendants also admitted that none of the Medicare beneficiaries needed the injection and infusion treatments administered and billed to Medicare by the clinics. Four additional co-defendants in the case did not plead guilty and stood trial in March. All four co-defendants, which included two physicians, were found guilty.

9. Texas medical supply companies' Medicare fraud scheme. Rhonda Fleming, who owned several Houston-based medical supply companies and a Medicare billing firm, and her two business associates were convicted by a federal jury in April of healthcare fraud, conspiracy to defraud Medicare and wire fraud. The three were found to have participated in a $36 million Medicare fraud scheme and face sentences of up to 20 years in prison for each count.

10. Biomet spinal product sales investigated. The U.S. attorney's offices in Massachusetts and West Virginia began investigating Biomet, a leading orthopedic device manufacturer, for improper sales, promotion and billing by its spinal device unit, EBI, in January. The company allegedly promoted the off-label use of its spine stimulation devices, which resulted in fraudulent Medicare and Medicaid billing. The federal probe in West Virginia stemmed from a whistle-blower lawsuit alleging that a West Virginia surgeon implanted the devices in clinical research without asking for the consent of the patients. The complaint also alleges that on 15 occasions, a representative of the EBI unit was in the operating room while the spinal products were used for off-label proposes. The Massachusetts investigation may have stemmed from another whistle-blower suit from March 2005 which claimed Biomet was improperly billing bone-growth stimulators as devices that must be purchased rather than rented. Biomet denies both allegations.

11. Yale-New Haven Hospital settles Medicare fraud allegations. Yale-New Haven (Conn.) Hospital agreed to pay $3.77 million in March to settle an investigation by the U.S. Attorney's Office, District of Connecticut, in response to allegations by CMS that it billed Medicare for inflated charges related to infusion therapy, chemotherapy and blood transfusion services. Authorities claimed that the organization billed Medicare for multiple units of these services when the program only allows payments for a single unit of infusion therapy and chemotherapy administration per patient, and one unit of blood transfusion per day. The hospital also disclosed, under the OIG's Provider Self-Disclosure Protocol, that it had inadequately documented claims pertaining to services provided in its oncology infusion services in patients' medical records, including dispensing medication and conducting laboratory studies without written orders signed by a physician; the protocol encourages such voluntary disclosure. Under the settlement, Yale-New Haven Hospital did not admit liability.

12. Illinois physician pleads guilty to fraud. James Durham, MD, of Benton, Ill., pleaded guilty in April to charges that he overcharged Medicare and Medicaid for services while president of Franklin (Ill.) Rural Health Care Clinic. Dr. Durham was accused of instructing employees to bill Medicare and Medicaid for services not covered by the payors. In total, Dr. Durham improperly charged Medicare for $42,503 and Medicaid for $145,388 between Jan. 1, 2003, and May 31, 2006. Dr. Durham faces possible prison time and a $100,000 fine and will be sentenced in July.

13. WellCare settles Medicaid fraud allegations. WellCare, a Tampa, Fla.-based health insurer, agreed to pay $80 million in May to settle allegations that it defrauded Florida's Medicaid program. The U.S. Attorney's Office in Tampa accused WellCare of submitting fraudulent charges to Medicaid and Florida Healthy Kids Corp., which cost the programs around $40 million. Under the agreement, WellCare agreed to a civil forfeiture of $40 million and an additional $40 million in restitution to Medicaid and Healthy Kids. In addition, WellCare agreed to implement new reporting policies, institute corporate financing governance programs and retain and pay an independent monitor to ensure compliance.

14. Houston's Methodist Hospital settles Medicare fraud charges. The Methodist Hospital in Houston agreed to pay $9.9 million in March to settle allegations that it improperly increased charges to Medicare patients. The allegations brought by the Dept. of Justice against the hospital claimed that Methodist inflated charges for inpatient and outpatient care to receive outlier payments — supplemental reimbursement to hospitals to pay for care when it is unusually high — that it should not have received. The hospital denied the allegations.

15. Synthes settles kickback inquiry. Synthes, maker of the ProDisc artificial spinal disk, settled an inquiry in May by the New Jersey Attorney General, which accused the device maker of failing to disclose financial conflicts of interest for doctors researching its products. The Attorney General accused Synthes of compensating physicians who were testing the ProDisc for recommending its use to patients with company stock. Synthes agreed to disclose any future payments or investments held by doctors involved in researching its products through its Web site and will pay $236,000 to reimburse the Attorney General's office for its investigation. ■

A Practical Compliance Plan Approach for ASCs

By Scott Becker, JD, CPA, Melissa Szabad, JD, and Amber Walsh, JD

This article provides an overview list of the steps to be taken to implement a compliance plan for an ASC.

Initial steps to implementing a compliance plan

A summary of the steps to be taken to implement a compliance plan ("Plan") and to commence the ASC's compliance efforts are as follows:

1. Provide a draft of a compliance plan;
2. Review the entire Plan in detail;
3. Discuss the Plan and safe harbors with the board of managers of the ASC;
4. Edit and revise the Plan;
5. Adopt the Plan at the board level;
6. Appoint a chief compliance officer;
7. Host an initial all-staff meeting to acknowledge the Plan and obtain employees' acknowledgments of their receipt and review of the Plan; and
8. Present the Plan to owners and distribute a copy of the Plan.

Key annual and periodic efforts

As a center adopts the Plan and takes the first steps toward implementing the Plan, there are a handful of specific focal points that can be used as guideposts for your compliance efforts. The intent of these guideposts is to provide a method to ensure significantly enhanced compliance efforts on a reasonably practical basis. The guideposts include:

1. All staff and physician compliance meetings. The ASC should periodically (at least annually) host a one- to two-hour conference or discussion whereby healthcare regulatory concerns and issues are explained to all staff and all physicians. These should include a discussion of the impact of the Stark Act, the Medicare/Medicaid Fraud and Abuse Statute, reimbursement, fee-splitting, HIPAA and other issues of concern to the organization, its employees and physicians. These meetings may be handled in person and may be supplemented by periodic teleconferences.

2. Owner and board of managers meetings. A discussion of compliance initiatives should be included on the agenda for all regular meetings of owners and the board of managers.

3. Billing and coding review and audit. At least annually, an outside firm should be utilized to perform a sample review of the ASC's billing and coding efforts to ensure compliance with billing and coding rules. Internally, this effort should be supplemented a number of times per year. Billing and coding remains a key focus of investigative efforts. Thus, a disproportionate amount of attention should be spent on reviewing and improving billing and coding efforts.

4. Employee complaints. The ASC should establish methods whereby employees can report misconduct or healthcare regulatory concerns. Here, any reporting employee should be assured that his or her reporting will have no negative impact upon the employee's career with the ASC. In fact, such actions should be encouraged and applauded.

5. Seminars. Key leaders of the ASC, both on an overall basis and as to the various departments, should be encouraged to attend one to two compliance-related seminars every year. This is intended to inform and to educate such persons as to compliance issues. The chief compliance officer should make it a key point of his or her efforts to ensure that such persons continue to gain additional knowledge on compliance related issues.

6. Compliance plan. At least annually, the Plan should be reviewed as a whole by counsel and by key executives to ensure that the Plan is appropriate for the organization and to update the Plan to take into account changes in the regulatory environment.

7. Compliance manual and periodic updates. Periodically (ideally annually), specific literature in the form of articles or summaries should be provided to employees throughout the organization to continue to raise the level of consciousness as to compliance issues.

8. Wall certificates. Posted notices to employees should be placed in appropriate places informing the employees of the ASC about the Plan and the need to report compliance issues to the ASC.

9. HIPAA privacy standards. The HIPAA privacy standards require the ASC to appoint a privacy official and to adopt a separate HIPAA compliance plan.

10. Background checks on employees and contractors. The ASC should ensure that all employees have not previously been excluded from Medicare or Medicaid. ■

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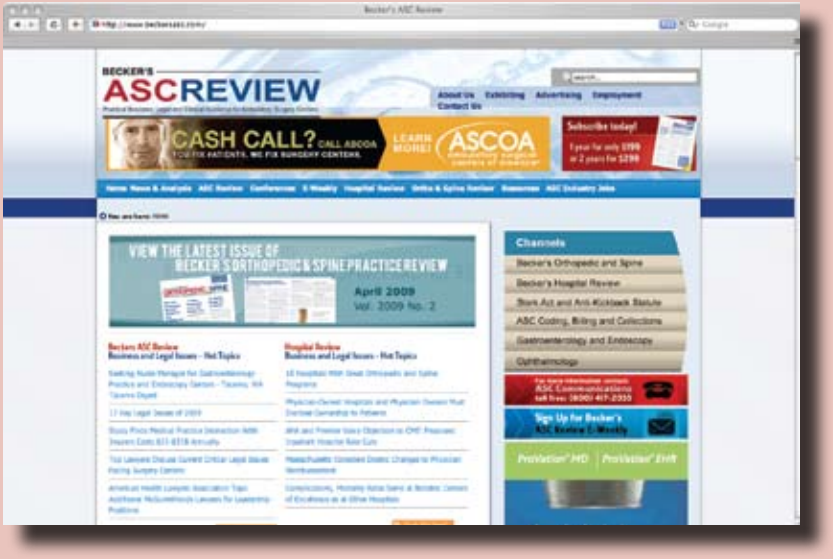

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HHS' Inspector General Issues Advisory Opinion on Physician On-Call Coverage

The Department of Health and Human Services Office of the Inspector General issued an advisory opinion on hospital emergency room on-call coverage that determined a flat-fee payment schedule presented a low fraud and abuse risk.

The 12-page opinion was issued to the unnamed 400-bed hospital, the sole provider of inpatient acute care services in its unidentified county. The hospital currently has no arrangement to compensate on-call physicians for treating uninsured patients presenting with emergencies, some of whom present medical malpractice liabilities. Increasingly the hospital is finding shortages of specialists for on-call duty.

According to the letter, the hospital set up a proposed compensation arrangement that would allow physicians treating financially eligible uninsured patients to submit claims to the hospital's patient financial services department and would compensate physicians based upon a flat-fee payment plan.

The OIG determined in its legal analysis that the proposed compensation arrangement presents "a low risk of fraud and abuse."

The advisory opinion, which only applies to the proposed arrangement by this hospital, is viewed as guidance for others in the industry wrestling with the same issues.

On-call coverage continues to be a hot-button issue between physicians and hospitals as specialists increasingly are refusing to provide coverage in an era of growing numbers of uninsured patients. At the same time, hospitals are obligated by the federal EMTALA law to provide those services.

To read the OIG's advisory opinion on physician on-call coverage, visit www.oig.hhs.gov/fraud/docs/advisoryopinions/2009/AdvOpn09-05.pdf. ■

Bart Walker of McGuireWoods Discusses 6 Issues Affecting Loan Closing Costs

By Renée Tomcanin

The current economic situation and other factors have limited the access ASCs and physician groups have had to loans. The process has also become longer and more costly. Here, Bart Walker, JD, of McGuireWoods in Charlotte, N.C., discusses six legal issues that are affecting loan closing costs.

1. A longer process

In an ideal market, Mr. Walker says the physicians or the group involved in the surgery center start-up or acquisition — the borrowers — would contact several banks — the lenders — early in the process. After evaluating the proposals from the lenders, the borrowers select which lender they would like to work with and are then sent a term sheet or commitment letter from the lender.

Once signed, the borrowers then enter into draft negotiations with the lender. Finally, when an agreement is made, the borrowers sign the final loan documents.

This process, which used to take anywhere from a few weeks to several months, is now taking considerably longer for ASCs in the current market due to a variety of reasons.

"Lately, lenders have been scrutinizing everything more carefully," Mr. Walker says. As a result, each step of the loan process requires more time than it had in the past.

2. Increased scrutiny for a "specialty subsector"

The increased scrutiny of lenders means that it is taking longer to get term sheets and commitment letters approved by their credit committees. Although industries across the board are experiencing this similar phenomenon, "ASCs feel it more acutely because it's such a specialty subsector," Mr. Walker says.

For example, many unique business relationships occur in ASCs. "If you are dealing with lenders who don't fully understand the business, they may feel less comfortable with certain more traditional loan terms," Mr. Walker says.

The changing nature of physician ownership in ASCs is one of these terms. Many loans prohibit individual physicians or guarantors from selling their ownership in the borrower entity, so that if one leaves or is no longer a borrower, the borrower entity is in breach of the agreement, according to Mr. Walker. However, due to the nature of the surgery center setting, physicians who were original guarantors may retire or move to other regions. At the same time, other physicians come into the practice to take the place of those original guarantors who left.

"This doesn't affect the overall operation of the center," Mr. Walker says. "A general commercial lender doesn't usually come across a situation like this." He suggests that it is important to educate lenders about these types of situations early on in loan negotiations. This way, lenders can have a better understanding of what type of

business an ASC is, thereby cutting down on negotiations, misunderstandings and reducing the time it takes to get to closing.

3. Legal opinion letters

More lenders are requiring legal opinion letters from the borrowers' attorneys, according to Mr. Walker. "This is a letter from the borrowers' attorney that says, among other things, that the loan documents are legally binding and enforceable against the borrower parties," he says.

Historically, he says, these kinds of letters were not seen for most loans under around $10 million. Now, due to the current market, banks are asking for more assurances when they lend money, and they are frequently asking for opinion letters.

"They act as an extra assurance policy or 'stamp of approval' for the bank," Mr. Walker says.

Drafting these letters takes additional time for the borrowers' attorneys, therefore adding not only time but additional legal fees. "It can get really expensive really quick," Mr. Walker says.

However, this added cost depends on what the banks are asking of the attorneys. "Any law firm of any size usually has a form opinion letter and a committee to review it," he says. "Expenses can add up because it takes time to go back and forth between the attorney's office and the bank."

The good news is that usually only a single attorney represents the group acquiring the loan for the ASCs. "We represent all of the physicians or owners of the ASC collectively," Mr. Walker says. "Sometimes, physicians can have competing interests, and they may want to separately engage outside counsel, which is fine too."

4. A higher cost for ASCs

As a result of the extended loan process, legal fees and loans have become more costly for ASCs that are looking to take out a loan. Mr. Walker estimates that closing costs have increased 25-50 percent in some cases over what they had been in the past. However, lenders are still willing to make loans to very credit-worthy borrowers, he says.

Also contributing to higher costs is the additional time and money the borrowers have to spend on other professionals aside from attorneys. According to Mr. Walker, this includes administrators, accountants and financial advisers.

5. More guarantors required

The increased scrutiny of loan agreements by lenders has resulted in many lenders requiring more responsibility by and information on the guarantors of the loan.

"Higher levels of personal guarantees have been required recently," Mr. Walker says.

In the past, physicians entered into pro rata agreements on loans, meaning that they were responsible only for the percentage of the ASC that they owned. In the present market, some lenders are requiring all of the physician partners or personal guarantors involved in a transaction to be responsible for the entire debt, according to Mr. Walker.

Sometimes this arrangement requires physicians and other guarantors to disclose a good deal of their financial information, including personal information, to the lender.

6. More documentation required

In what Mr. Walker calls one of the "most onerous" stages of the loan process, more banks are requiring the signature of every guarantor on the loan. "In other words, lenders today are less willing to close without 100 percent of the signatures," he says. In the case of ASCs, this means every physician-owner must sign some or all of the final loan documents.

"Banks are less willing to fund ASCs without having everything documented. They are less willing to waive certain conditions to closing, such as missing signatures," he says.

The future of loan closing costs

Although many people are still willing to jump through these hurdles to acquire loans, Mr. Walker notes that the additional hassle has led many ASC groups to decide to look into other means of financing their center.

"If an ASC is on the fence whether or not to get a loan to finance new equipment, for example, or to fund it on its own, more have decided to use distributions to get the equipment," he says. "The added time has many saying, 'Forget it. We'll fund it with cash.'"

Mr. Walker sees the market beginning to bottom as the economic situation begins to stabilize. However, he notes that restrictions and regulations will be tight for the foreseeable future.

"Ultimately, the market will normalize," he says. "People will realize which lenders are more stringent when it comes to loans, and it will be to the lender's advantage to ease up some."

In the long run, Mr. Walker says that it is still possible for ASCs to access loans in the current market. He says ASC must remember that the process will take much longer than it had in the past and that there are few more obstacles in the path than there were before. "It's not unbearable or impossible, unless you aren't prepared for it," he says. ■

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Protecting Your Facility and Physicians From Medicare Fraud Investigations: Q & A With Tom Pliura

By Lindsey Dunn

Tom Pliura, MD, JD, an independent attorney specializing in healthcare issues for surgery centers and physician practices and founder of zCHART and the zCHART EMR, discusses the increase in physician fraud investigations and offers suggestions as to how physicians and administrators can protect themselves from these investigations.

Q: There seems to be an increase in the number of physicians being investigated for Medicare and Medicaid fraud. Why do you think we are seeing these increases?

Tom Pliura: In my opinion, we are seeing these increases due to the federal government's decision to make healthcare fraud a target area. We have seen an increased emphasis by the government cracking down on allegations of fraud for the last couple of years due to HHS including these investigations in its "scope of work." The federal government can potentially save a lot of money by cracking down on Medicare fraud. The same goes for states and Medicaid fraud. As a result, I'm not surprised that we are seeing more physicians and healthcare providers being investigated for this than in the past.

Specifically, HHS is paying careful attention to the services that cost the government a lot of money. The costs of certain services have risen dramatically over the past few years. Take rehabilitation for example. In the past 10 years, there has been a dramatic increase in these types of services. The government investigates and asks questions like "Are these services medically necessary?" or "Are these increases in services being provided not because they are medically necessary but instead merely to generate income?"

Q: What are the most common types of suspected fraud that you are seeing physicians investigated for?

TP: Billing for services not medically necessary and billing for services not rendered, intentionally or unintentionally, are some of the more common types of fraud being investigated. One big issue is the place of service. If a biller says a procedure was performed in the office when in fact it actually occurred in a hospital, this could be interpreted as fraud, even if the place of service code mistake was unintentional. The government uses a carrot-and-stick approach to encourage physicians to perform procedures in their offices because this saves Medicare on facility fees. As a result, Medicare provides a higher fee to the physician for some procedures performed in-office.

Where a physician can get into trouble is if he or she does not properly document where the procedure is being done in the patient chart. When the biller receives the chart, she or he may just pick a place of service to avoid hassling the physician with questions. If the biller guesses wrong, you could be at risk for an investigation

Another issue where fraud occurs is with unbundling certain services. Again, this may be intentional or unintentional. For example, a biller might unwittingly unbundle a particular service that should have been bundled together under one single CPT code.

For example, let's say a patient goes in for a colonoscopy and during the colonoscopy the physician decides to perform a hemorrhoid service. Because colonoscopies are bundled by

Medicare, the facility should not bill separately for the hemorrhoid treatment. If for some reason this is unbundled, it could be viewed as healthcare fraud because it profits the facility.

Finally, billing for follow-up office visits is also an area where we are seeing facilities getting into trouble. Many Medicare fees for medical incidents include a follow-up visit. If these are billed for separately, or an additional follow-up is requested by the physician, the government might look into these practices. For example, let's say I go in for a wound infection after surgery and my doctor requests a follow-up in one week. The question becomes "is that additional follow-up appointment medically necessary?" The problem is it's often a judgment call on the part of the physician in many ways. As a result, it's important physicians document why each follow-up they request is medically necessary.

Q: What can physicians do to ensure that they are not inadvertently involved in fraud?

TP: You have to educate your staff about the importance of being accurate. Often, the physician or physician-owners don't even see the billing process once the chart leaves the committing physician's hands, but those physicians are ultimately responsible if improper billing occurs. Doctors have to take an active role in the billing procedures of their facility or they could inadvertently be involved in fraud. Physicians are great at keeping up-to-date in their clinical specialties but they are not so good at keeping up-to-date on billing and reimbursement rules, which are often very complex.

One problem is that physician education deals only with clinical issues, yet many physicians own their own practices, surgery centers or other facilities. Most were never formally educated about how to bill or how to run a business office. Physicians need to involve employees who are familiar with the rules and who keep abreast of these regulations. Physicians need to understand this and work to ensure that their facilities are following up-to-date and proper procedures.

They also need to document why each medical decision they make is medically necessary. If a physician can support their judgment calls, they are at much less risk for being found to have acted fraudulently, if an investigation occurs.

I don't think that the government wants to split hairs here. The government is focusing on issues and areas that have historically been at risk for fraudulent activity, and rightfully so. The government is comparing data on facilities and physicians and looking for outliers. If they find a facility or physician that has considerably more follow-ups, for example, than others, then they will start to take a careful look at the facility's or physician's records.

The main thing is that physicians and centers need to get guidelines into place and follow them. I recommend that all facilities have a random audit system in place. You don't have to audit every chart; 5 percent of cases would be fine. But, the audit has to be performed by someone outside your billing department. You don't need to spend a lot of money on this, but simply showing that you have a procedure in place can protect you if an allegation of fraud is ever made against you or your facility.

If you have these guidelines, and follow them and use common sense, any inconsistencies that investigators find can be easily supported. Your decisions, or your physicians' decisions, are easily defensible because you have clearly documented medical reasons for those decisions. ■

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11 Key Concepts From the Stark Law

By Scott Becker, JD, CPA, Ji Hye Kim, JD, and Jessica Smith, JD

The Stark law prohibits physicians from ordering designated health services for Medicare patients from entities with which the physician, or a family member, has a financial relationship unless an exception applies. This article reviews 11 key concepts under the Stark Law, in the context of changes to the Stark law made by CMS.

1. Agreements between providers and referral sources must be in writing

CMS has set forth numerous exceptions to the Stark law. These exceptions permit certain financial relationships between providers of DHS and physician referral sources, so long as certain conditions are met. These exceptions almost uniformly require that the agreement between a provider of DHS and the physician referral source be in writing. For example, the following exceptions to the Stark law require a written, signed agreement: office space and equipment rental, personal service arrangements, physician recruitment arrangements, group practice arrangements and fair market value compensation arrangements. 42 C.F.R. 411.357.

CMS has indicated that the purpose of requiring a written agreement is "so that [the agreement] can be objectively verified, and meets the terms and conditions of [the exception.]" 66 F.R. 949 (Jan. 4, 2001). The inadvertent error of not placing an excepted financial relationship in writing generally means that the arrangement will not meet an exception, even if all other requirements of the given exception were satisfied.

The key excepted financial relationship that need not be in writing is for bona fide employment relationships. 42 C.F.R. 411.357(c).

2. Per-click leasing arrangements

As of Oct. 1, physician referral sources and providers of DHS will no longer be permitted to have per-click relationships for office space and equipment leases. Four exceptions currently permit these types of arrangements: the office space exception, the equipment lease exception, the fair market value exception and the indirect compensation arrangement exception. 411 C.F.R. 411.357(a), (b), (l), and (p).

The 2009 Hospital Inpatient Prospective Payment System final rule modified these exceptions to explicitly exclude per click arrangements for lease of equipment or real estate. 73 F.R. 48343 (Aug. 19, 2008). CMS limited per-click leasing arrangements in large part due to its concern that "such lease arrangements create the incentive for overutilization, because the more referrals the physician lessor makes, the more revenue he or she earns." 73 F.R. 48715 (Aug. 19, 2008).

These changes that prohibit per-click office space and equipment leasing arrangements will go into effect on Oct. 1, 2009. Any existing per-click office space or equipment lease arrangement that relies on one of these exceptions will need to be restructured prior to the Oct. 1, 2009, compliance deadline.

3. Percentage-based arrangements

The revisions to Stark law made by the IPPS do not extend to percentage-based compensation formulae outside of the office space and equipment lease context. Thus, "if a compensation formula for physician compensation for items or services — other than the rental of office space or equipment — was permissible prior to Oct. 1, 2009…

that formula would not be made impermissible by this final rule." 73 F.R. 48712 (Aug. 19, 2008).

For example, percentage-based management and billing service relationships are still permissible so long as they satisfy certain criteria set forth in the Stark law and anti-kickback statute.

CMS has indicated, however, that the prohibition on percentage-based compensation arrangements may be extended outside of the office space and equipment lease context: "although we are not extending, at this time, the prohibition on the use of percentage-based compensation formulae to arrangements for any non-professional service (such as management or billing services), we reiterate our intention to continue to monitor arrangements for nonprofessional 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." 73 F.R. 48710 (Aug. 19, 2008).

4. Lithotripsy arrangements

As mentioned, the Stark law prohibits physicians from ordering DHS for Medicare patients from entities with which the physician has a financial relationship. Lithotripsy services are not considered DHS. *Am. Lithotripsy Soc. v. Thompson,* 215 F. Supp. 2d 23 (D.D.C. 2002). The IPPS commentary confirms this analysis, suggesting that lithotripsy services are not DHS regardless of whether the services are billed by the provider or a hospital. 73 F.R. 48730 (Aug. 19, 2008). As a result, the upcoming prohibition on per-click leasing arrangements will not apply to lithotripsy lease arrangements or under-arrangement agreements. CMS draws a very significant distinction between leases of equipment which can generally no longer be per-click and services agreements which include some equipment therein, and can be per-click or per-service. In the case of lithotripsy, the distinction is critical to whether urologists can make other DHS referrals to the hospital.

A urologist who leases a lithotripter to a hospital through a leasing agreement on a per-click basis cannot make other referrals to that hospital (i.e., other referrals outside of lithotripsy). Per-click leasing agreements, in short, will not meet an exception and thus the urologist cannot make other referrals. A per-click lithotripsy agreement, in contrast, that provides overall lithotripsy services (not just equipment) may be structured to fit into the fair market value exception. Thus, the urologist would be able to arguably make other referrals to the hospital.

In the case of a local urologist providing lithotripsy services to a hospital at which he or she generally practices, the key question will come down is the agreement a lease of equipment or a service agreement.

Two key comments from CMS as to this issue are as follows:

> Currently, lithotripsy is not considered a designated health service for purpose of the physician self-referral law. Therefore, if the physician owners of the lithotripsy partnership make referrals to the hospital for lithotripsy services ONLY, the physician self-referral law would not be implicated, and a per-unit or percentage based compensation formula for the compensation arrangement between the lithotripsy partnership and the hospital would be prohibited, even if the compensation arrangement is considered to be a lease of equipment (and other items or personnel).
>
> If the physician owners of the lithotripsy partnership refer Medicare patients to the contracting hospital for any designated health services (DHS), the compensation arrangement between the lithotripsy partnership and the hospital must comply with an applicable exception to the physician self referral law. Where a compensation arrangement between the hospital and the physician-owned lithotripsy partnership is considered to be a lease of equipment, a per-unit or percentage-based compensation formula would fail to satisfy the requirements of any of the potentially applicable excep-

tions for the lease of equipment found in §411.357(b), §411.357(l) or §411.357(p).

5. Professional courtesy

CMS recognized the longstanding tradition of extending professional courtesy to physicians and their family members in 2004 by promulgating an exception to the Stark law for professional courtesy arrangements. 69 F.R. 16116 (March 26, 2004). The professional courtesy exception covers free or discount services provided to a physician or his or her immediate family members, so long as certain conditions are satisfied. 42 C.F.R. 411.351.

Specifically, the arrangement must be: (i) extended to all physicians on the medical staff or in the community; (ii) for items and services routinely provided by the entity; (iii) set forth in writing and approved by the provider's governing body; (iv) unavailable to any physician or family member who is a federal health care program beneficiary; and (v) does not violate the anti-kickback statute or any billing or claims submission laws. 42 C.F.R. 411.357(s).

6. Retention payments

A hospital, federally qualified health center or rural health clinic may make retention payments to physicians in order to induce them to stay in its geographic service area. Retention payments may be made when a physician has a bona fide offer or presents a written certification that he or she has a recruitment opportunity that would require the physician to relocate at least 25 miles outside of the entity's geographic service area. 42 C.F.R. 411.357(t).

The Stark law recently added more flexibility to the retention payments exception by widening the "geographic service area." 72 F.R. 51065 (Sept. 5, 2007). The entity's "geographic service area" not only encompasses a Health Professional Shortage Area but also rural areas and an area with a demonstrated need for the physician, as determined by the Secretary of the Department of Health and Human Services. In addition, the geographic service area may include an area where at least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

7. Mission support payments

Many DHS entities make mission support payments to their affiliates in order to fulfill their missions of medical research, education and healthcare services to the community.

The Stark law provides a safe harbor for those DHS entities that meet the Academic Medical Centers exception. 42 C.F.R. 411.355(e). The AMC exception is extensive as it is complicated. Each element of the exception must be satisfied when an academic medical center makes mission support payments to a faculty practice or other affiliates. The indirect compensation exception may also be available in those cases where the support arrangement constitutes an indirect compensation as defined by the Stark law. Like the AMC exception, the indirect compensation exception entails a number of elements; each element of the indirect compensation definition and the exception must be satisfied. 42 C.F.R. 411.354(c)(2) and 411.357(p). An indirect compensation relationship may exist when at least one person or entity is interposed between the DHS entity and the referring physician. If the affiliate that is receiving the mission support payment is a physician organization and its physician employee has an ownership or investment interest in the organization, the physician-owner is deemed to stand in the shoes of the organization. As a result, arrangements that were previously treated as indirect would now be direct, and one of the direct compensation exceptions must be satisfied. 42 C.F.R. 411.354(c)(1)(ii).

A DHS entity may avoid the Stark law implications entirely if it has no financial relationship with the physician employees of the affiliate. There is no financial relationship under the Stark law if: (i) a DHS entity provides mission support payments directly to its affiliate; (ii) the affiliate is not owned by any of its physician employees; and (iii) the affiliate's compensation of its physician employees does not take into account the volume or value of referrals or other business generated by the physician employees to the DHS entity. If these three conditions are met, a DHS entity may make payments to its affiliate to keep it in good financial shape and accomplish its missions without implicating the Stark law.

8. Publicly-traded company exception

The Stark law excludes certain ownership interests in a DHS entity from the definition of the financial relationship, including ownership of investment securities that could be purchased on the open market when the DHS referral was made. These securities must either be listed for trading on the NASDAQ or a similar system, or traded under an automated dealer quotation system by the National Association of Securities Dealers. Further, the securities must be in a corporation that had stock holder equity exceeding $75 million either at the end of the corporation's most recent fiscal year or on average during the previous three fiscal years. 42 C.F.R. 411.356(a). Here, stock holder equity means the excess of the hospital's net assets over its total liabilities.

9. Isolated transactions

Physicians may engage in an isolated financial transaction with a DHS entity without violating the Stark law only if the following conditions are met. First, the amount of remuneration must be based on fair market value and not take into account the volume or value of any referrals a physician makes to the DHS entity or any other business generated by the parties. Second, the arrangement must be commercially reasonable even if no referrals are made between the parties. Finally, no additional transactions, except ones specifically excepted from the Stark law, may occur for six months after the isolated transaction. 42 C.F.R. 411.357(f). Installment payments may qualify as payment as part of an isolated transaction if the total aggregate payment is: (i) set before the first payment is made; (ii) does not take into account, directly or indirectly, referrals or other business generated by the referring physician; and (iii) is secured. 72 F.R. 51055 (Sept. 5, 2007).

10. Non-monetary compensation benefits

A physician may receive from a DHS entity non-monetary compensations up to $300 in the aggregate a year (i.e., meals, parking, training, etc.) (This amount is adjusted annually for inflation; the aggregate amount is $355 for 2009.). Non-monetary compensation cannot take into account the volume or value of any referrals or other business generated by the physician. Further, the physician must not have solicited such compensation. The compensation must also not violate the anti-kickback statute or any federal or state law. 42 C.F.R. 411.357(k). CMS recommends that hospitals implement compliance systems, such as mechanisms to track and value the provision of gifts, complimentary items and other benefits for physicians, to ensure non-monetary compensation does not exceed the annual spending limit. 72 F.R. 51058 (Sept. 5, 2007).

The Stark law does allow a hospital with a formal medical staff to throw a local staff appreciation event once a year without adhering to the spending cap. Any gifts or gratuities provided in connection with the event, however, are subject to the spending cap. 42 C.F.R. 411.357(k)(4). Finally, the recent revision to the Stark law now allows an entity to stay below the spending cap when it inadvertently exceeds the cap by no more than 50 percent and the physician repays the excess within that calendar year or 180 consecutive days from receipt of the excess compensation, whichever is earlier. The entity and the physician

may rely on the repayment provision no more than once every three years. 42 C.F.R. 411.357(k)(3).

11. Splitting profits from ancillary services within a practice

There are several ways to split profits from DHS within a group practice, so long as the given profit-splitting method is not related to the volume or value of referrals. Two profit-sharing methods that are not prohibited by Stark include certain profit-sharing arrangements between members of a group practice and certain productivity bonuses.

When a physician's group meets the Stark law's definition of a "group practice," its physicians may receive a share of the overall profits so long as the distribution is reasonable, verifiable and unrelated to the volume or value of referrals. The Stark law deems certain methods of profit sharing as not relating directly to the volume or value of referrals. The profits, for example, may be divided per member of the group. The group may also distribute DHS revenues based on the distribution of the groups revenues attributed to services that are not DHS payable by any federal healthcare program or private payor. Finally, the Stark law allows any method of profit-sharing if DHS revenues constitute less than 5 percent of the group practice's total revenues and no physician's share is more than 5 percent of the physician's total compensation from the group practice. 42 C.F.R. 411.352(i)(1) & (2).

CMS has explicitly stated that "all physicians, whether employees, independent contractors or academic medical center physicians, can be paid productivity bonuses based on work they personally perform." 69 F.R. 16067 (March 26, 2004). A physician may be paid a productivity bonus based on work personally performed by that physician, so long as the productivity bonus is not calculated in a way that directly relates to the volume or value of a physician's DHS referrals. One such method of calculating productivity bonuses is to base a physician's bonus on his or her total patient encounters or relative value units. 42 C.F.R. 411.352(i)(3). ■

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Will the Federal Government Shut Down Surgery Centers and Physician-Owned Hospitals?

By Scott Becker, JD, CPA, and Elaine Gilmer, JD

As the Democrats take control of the House, the Senate and the Presidency, many question the impact of such a change on ASCs and physician-owned hospitals. The most significant question is: Will the federal government shut down and/or restrict physician-owned hospitals and ASCs?

The short answers to this question are:

1. no, the federal government will not shut down ASCs; and
2. maybe the federal government will halt the development of new physician-owned hospitals and/or restrict the activities of and adopt new rules relating to existing physician-owned hospitals.

A story of numbers and politics

Currently, there are approximately 6,000 ASCs in the United States. Of these, approximately 1,000 are not Medicare-certified. Forty percent of all ASCs are located in five states: California, Florida, Texas, Georgia and Pennsylvania. In addition, there are approximately 200 physician-owned hospitals in the United States.

Mood in Washington, D.C., and states towards physician ownership

The mood in Washington and states towards physician ownerships is slightly more favorable than the former Bush administration's view of Iran, Iraq and North Korea. Essentially, physician ownership is viewed very negatively in Washington, D.C., and in many states.

A. Imaging. In the imaging sector, there is a common perception that supply drives demand (i.e., the more imaging facilities that are available, the more procedures that will be performed). Recently, the Wall Street Journal published an article reporting that many payors are implementing new prescreening requirements to "ensure that physicians use high-tech scans only when it is clear that patients will benefit."[1]

Insurers such as Aetna, WellPoint and Cigna Corp. have hired radiology benefits managers to monitor scans. A Government Accountability Office report found that Medicare spending on scans varied based on geographic area, suggesting that all procedures may not be necessary or appropriate. Further, the federal government is implementing a series of rules relating to (i) the designation as an independent diagnostic testing facility; (ii) the inability to lease space to other Medicare providers; (iii) the elimination of per-click relationships; (iv) the elimination of block-leasing relationships; and (v) several other requirements designed to make physician-owned imaging, as well as imaging as a whole, less costly to the federal government.

The initial reasoning behind the Stark Act (initially only applicable to physician-owned labs) was based upon an older study which found that the number of procedures performed at a facility increased when (i) a physician owned an interest in the facility, (ii) the physician was able to refer patients to such facility and (iii) the physician did not have to personally perform the procedure at the facility. In 1998, the Department of Health and Human Services, in proposing the Phase I Rule of Stark II explained:

> Both the anti-kickback statute and section 1877 address Congress' concern that health care decision-making can be unduly influenced by a profit motive. When physicians have a financial incentive to refer, this incentive can affect utilization, patient choice, and competition. Physicians can overutlilize by ordering items and services for patients that, absent a profit motive, they would not have ordered.[2]

The Stark Act continues to develop around this concept, and thus the Stark Act has traditionally restricted situations where a physician could refer a patient to a facility, such as a lab or imaging facility, but did not have to personally perform the services on the patient.

B. Physician-owned hospitals. The federal government has conducted approximately 10 different studies as to the effects of physician-owned hospitals. The vast majority of these studies have indicated that physician-ownership of a hospital is fairly benign. Notwithstanding this fact, the physician-owned hospital industry has a number of very strong opponents in Washington, D.C. These include Sen. Max Baucus, Sen. Charles Grassley and Rep. Pete Stark. For political and other reasons these individuals look very unfavorably upon physician-owned hospitals.

In Dec. 2007, The Washington Post quoted Sen. Grassley as follows:

> My motivation for seeking reforms over a long period of time is the effect that specialty hospitals have on community hospitals when specialty hospitals pass the buck on emergency care and cherry-pick based on profits rather than patient needs.[3]

Interestingly, many of these physician-owned hospitals are amongst the leaders in the country in certain quality studies. As expected, there are an extremely small number of aberrational types of physician-owned hospitals that provide a sub-standard level of care. However, notwithstanding the fact that (i) general acute care hospitals may also provide such substandard level of care and (ii) infections picked up in a general hospital are one of the leading causes of death in this country, each time a bad action occurs at a physician-owned hospital, a congressional study and investigation commences.

C. Surgery centers. Many individuals at CMS have long taken the view that, although they do not love ASCs or physician-owned hospitals, ASCs are located in so many congressional districts and such a large outcry would result if they tried to outlaw physician ownership that it will be impossible to now prohibit physician ownership of ASCs. As a result, their belief is that the ASC's ship on restriction has sailed but prohibitions may still be possible for physician-owned hospitals.

D. The New Jersey Codey Law. For nearly a decade, the New Jersey Codey Law — the state's version of the Stark Act — had been read to permit physician-ownership of ASCs. However, in cases unrelated to the Codey Law, judges have opined that the Codey Law prohibits physician-ownership of ASCs in the traditional sense.

In *Garcia v. Health Net of New Jersey, Inc.*, the court found that referrals to an ASC in which the referring physician had a significant financial interest violated the Codey Law. Due to such decisions, New Jersey may become one of the first states to prohibit and outlaw the new development of physician-owned ASCs. The compromise likely to result in New Jersey is typical of such political struggles and outcomes. In essence, those already developed physician-owned ASCs have political clout and thus will likely maintain their facilities without prohibition. In contrast, there is no one to protect the unborn ASCs.

This type of situation is precisely why many new laws include a grandfathering clause. Such a clause allows the politicians to protect themselves by allowing the existing ASCs or hospitals to survive while simultaneously pleasing their allies in the American Hospital Association or the Federation of American Hospitals by outlawing new developments. In 2009, New Jersey adopted an amendment to the Codey Law.

E. Pain management. The government has made pain management part of its work plan for 2009. In essence, much like imaging, the government believes that pain management has grown to unnecessary proportions and that the ownership and profit that pain management procedures provide has led to unnecessary procedures.

F. PET and radiation therapy ventures. CMS has extended the Stark Act to apply to radiation therapy ventures and positron emission tomography ("PET") services. Therefore, these arrangements may only operate if structured to meet an exception to the Stark Act.

G. Block leases, per-click and under-arrangements. The federal government has made negative comments on "indirect" referrals in various advisory opinions. CMS has taken action to prohibit most types of per-click leases and under-arrangements structures. It has also determined that the anti-markup rules apply to block leases. Further, in Advisory Opinion No. 08-10 issued on Aug. 19, 2008, the Office of Inspector General also raised concerns regarding block lease arrangements under the anti-kickback statute.

What will happen next?

ASCs are likely to survive largely intact. While ASCs may be challenged in some states, the outstanding work of the ASC Association and the fact that for each patient treated in an ASC, the Medicare program receives a 35 percent discount or savings for the procedure (as opposed to the procedure being performed in a hospital outpatient department), it is likely that ASCs will survive the upcoming political changes.

The physician-owned hospital situation is more challenging. Over the last year, the House and Senate have reached agreement on different types of provisions that would essentially eliminate the new development of physician-owned hospitals.

The physician-owned hospital industry had furiously been protected by both the Bush White House and a number of Republican and conservative Democratic senators who support entrepreneurial healthcare growth and service (as opposed to protecting acute care hospitals from competition).

The change in the make-up of the House, the Senate and the White House is bad for physician-owned hospitals. In many ways, it is a story of political clout. Since physician-owned hospitals are in few districts, the Congressmen and Senators in the numerous districts without such facilities may take campaign contributions and abide by the wishes of certain enemies of physician-owned hospitals (i.e., the American Hospital Association and the Federation of American Hospitals), without fear of retribution. In essence, a Congressman or Senator who does not have a physician-owned hospital in his or her district need not worry about retribution in voting positively to restrict physician-ownership. Thus, the risk of applying physician-owned hospital prohibition rules to existing physician-owned hospitals significantly rises. ■

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[1] Anna Wilde Mathews, "Insurers Hire Radiology Police to Vet Scanning." Wall Street Journal online, Nov. 6, 2008.

[2] 63 Fed. Reg. 1659, 1662 (Jan. 9, 1998).

[3] Christopher Lee, "Limits Weight on Physician-Owned Hospitals." The Washington Post, Dec. 9, 2007, p. A03's

Do Non-Procedural Sources of Income Apply to the One-Third Rule?

Q: Federal guidelines state "at least one-third of the physician's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures." Does this exclude income derived from a "non-procedural" source? An example would be ophthalmologists who own their own eye glasses shop. They receive a considerable income from the sale of eyeglasses, which adds up to more than one-third of their overall income. Are they not out of compliance with the federal guidelines as an owner of an ASC?

Scott Becker, JD, CPA: Currently, CMS has not further refined what they mean by a person's medical practice income. Hence, there is not a definite answer to this question. With regard to items or services closely related to practice, one would tend to include such income. In contrast, the less closely related to the practice that the income is (for example, lease income), the less one would believe that it must be included.

Resources

National trade associations

The ASC Association. The ASC Association is a membership and advocacy organization that provides member benefits and services; combats legislative, regulatory and other challenges at the federal and state levels; assists state ASC associations; enhances ASC representation at the state and federal levels; and established a political action committee. The other arm of the ASC Association, the Ambulatory Surgery Foundation, is an educational and research organization. To learn more, contact Kathy Bryant, president, at (703) 836-8808 or e-mail asc@association.org.

Physician Hospitals of America. PHA offers support, advocacy and educational services to the physician-owned hospital industry. PHA envisions a healthcare system focused primarily on patient care, in which physicians are involved in every aspect of delivery. For more information, visit www.physicianhospitals.org or contact Molly Sandvig, JD, executive director, at (605) 275-5349 or e-mail info@physicianhospitals.org.

Accreditation

The Accreditation Association for Ambulatory Health Care. AAAHC, founded in 1979, has become a leader in ambulatory health care accreditation with more than 4,000 organizations accredited nationwide. For more information, visit www.aaahc.org or call (847) 853-6060.

The Joint Commission: Ambulatory Care Accreditation Program. The Joint Commission has been accrediting ambulatory surgery facilities since 1975, and has more than 1,600 ambulatory organizations accredited nationwide. For more information, visit www.jointcommission.org/asc or call (630) 792-5286.

Anesthesia staffing and practice management

Anesthesia Healthcare Partners. AHP was established in 1997 as an anesthesia staffing and practice management company and provides turnkey anesthesia practices and anesthesia management services for hospitals, surgery centers and office-based practices of all sizes. To learn more, visit www.ahphealthcare.com or call (800) 945-6133.

Somnia. Somnia, founded in 1996, is one of the most experienced physician-owned and operated anesthesia management company servicing healthcare facilities nationwide, specializing in building and comprehensively managing world-class anesthesia teams that consistently deliver the highest quality of patient care. Visit Somnia at www.somniainc.com or call (877) 476-6642, ext. 3538.

Superior Medical Services. SMS is a full-service medical recruitment firm specializing in permanent and locum tenens placement of anesthesiologists, CRNAs and pain management physicians nationwide. Visit SMS at www.smsanesthesia.com or call (847) 816-9296.

Surgical Anesthesia Services. SAS delivers comprehensive anesthesia services exclusively to ASCs across the United States, with each ASC receiving a dedicated anesthesia team which does not rotate between competing facilities. Learn more about Surgical Anesthesia Services at www.surgicalanesthesia.net or call (866) 733-6231.

Back-office management, outsourcing and accounting

MedHQ. MedHQ provides accounting, revenue cycle, human resources and credentialing services to clients in 10 states. Learn more at www.medhq.net or call (708) 492-0519.

Somerset CPAs. Somerset's healthcare team is comprised of more than 20 dedicated professionals serving clients nationwide, including all types of healthcare organizations — ancillary service providers, surgery, imaging, infusion and dialysis centers, therapy facilities, other relevant ancillaries and physician groups. For more information, call (800) 469-7206 or visit Somerset CPAs online at http://healthcare.somersetcpas.com.

Billing, coding and collecting

Advantedge Healthcare Solutions. Advantedge Healthcare Solutions, an IBM Business Partner, develops medical billing technology and offers billing and A/R services for ASCs. Visit www.ahsrcm.com or call (877) 501-1611.

Alternate Medical Billing Systems. Alternate Medical Billing Systems provides a number of medical billing services including claim filing, billing statements, coding, payment posting, denials/rejections analysis and much more. Learn more at www.alternatebillingmn.com or call (866) 513-0129.

ASC Billing Specialists. ASC Billing Specialists is a billing company dedicated to the needs of the ASC market, specializing in both out-of-network and in-network facilities. For more information, call (602) 298-2653 or visit www.ascbill.com.

The Coding Network. The Coding Network is committed to provide cost effective state-of-the-industry procedural and diagnostic coding support to medical groups, academic practice plans, hospitals, ambulatory, surgery centers, and billing companies throughout the United States. Learn more at www.codingnetwork.com or call (888) 263-3633.

GENASCIS. GENASCIS provides transcription, coding, billing and collection services for all specialties; these services, coupled with MEDIBIS, the company's proprietary analytical tool, can help ASCs maximize revenue, cash flow and profitability. Learn more at www.medibis.com or call (866) 208-7348.

Healthcents. Healthcents is an ASC and physician specialty hospital contracting, software and consulting group with extensive experience helping ASCs negotiate contracts. To learn more about Healthcents, visit www.healthcents.com or call (831) 455-2695.

MediGain. MediGain is a full-service revenue cycle management company providing billing and collection services that can help ASCs and hospitals increase revenues, get claims paid faster, deploy the latest technologies, improve efficiencies and streamline their back office to better focus time and effort on patient care. Find out more about MediGain at www.medigain.com or call (214) 952-6602.

National Medical Billing Services. NMBS specializes in freestanding outpatient surgery center coding and billing, offering a cost-effective service, subject matter experts and integrity in business relationships. To learn more about NMBS, call (636) 273-6711 or visit www.asccoding.com.

Serbin Surgery Center Billing. SCB was founded in 2001 to provide solutions for ASCs' billing and collection needs. For more information, contact SCB at (866) 889-7722 or visit www.ascbilling.com.

Specialty Billing Solutions. Specialty Billing Solutions offers a cost-effective alternative to your typical in-office billing department.while positively impacting your bottom line. For more information, visit Specialty Billing Solutions at www.pinnacleiii.com/services/cbo/cbo_services.htm or call Dan Connolly, vice president of development and payor contracting, at (877) 710-3047.

Cataract outsourcing

Sightpath Medical. As a leading mobile ophthalmic services provider, Sightpath Medical's services can provide ASCs with state-of-the-art technology for cataract surgery, SLT, and YAG procedures, offering a low, capped cost-per-procedure model with no maintenance fees. To learn more about Sightpath Medical, call (800) 728-9615 or visit www.sightpathmedical.com.

Vantage Outsourcing. Vantage Outsourcing is a leading supplier of safe and effective cataract surgery services; the company can help doctors, hospitals and surgery centers perform many high-quality cataract surgeries each year with increased productivity at lower costs. Visit www.vantage-technology.com or call (217) 342-4171 to learn more.

Compounding pharmacies

JCB Laboratories. JCB Laboratories is a compounding pharmacy that serves the ASC marketplace. Contact CEO Brian Williamson, PharmD, at (877) 405-8066 or visit www.jcblabs.com for more information.

Construction and architectural firms

BBL Medical Facilities. BBL Medical Facilities is a single-source business unit with plan, design, build and development capabilities, and has been developing attractive, efficient and cost-effective medical facilities for more than 30 years. Learn more at www.bblmedicalfacilities.com or call (888) 450-4225.

Erdman (A Cogdell Spencer Company). For more than 50 years, the name Erdman has been synonymous with the delivery of innovative healthcare facility solutions. For more information, visit www.erdman.com or call (608) 410-8000.

Marasco & Associates. Marasco & Associates is a national architecture and consulting firm, dedicated to providing quality facility design and development assistance for outpatient medical facilities, private physician groups, hospitals and institutional clients. Contact the Marasco & Associates office at (877) 728-6808 or visit www.marasco-associates.com for more details.

McShane Medical Properties. McShane Medical Properties is an integrated design/build construction and real estate development firm offering comprehensive services for the healthcare industry. Contact John Daly, vice president, healthcare, at (847) 692-8616 or visit the firm's Web site at www.mcshane.com for more information.

MedBridge Development. MedBridge Development is a medical facility development and management company creating state-of-the-art healthcare delivery environments in partnership with leading physicians. For more information, visit MedBridge online at www.medbridgedevelopment.com or call (805) 679-7560.

Raymond Fox & Associates. Raymond Fox & Associates is a full-service medical architectural firm that has completed over 4,000 projects ranging from small, single-specialty offices to large, multi-specialty medical office buildings and has been involved in over 400 surgical centers. Learn more at www.raymondfox.com, call (619) 296-4595 or e-mail Raymond Fox at ray@raymondfox.com.

Consultation and brokerage of ASCs

ASCs Inc. ASCs Inc. helps physician-owners of ASCs form strategic relationships with leading ASC management companies and hospitals, and also represents physician-owners of ASCs and medical office building real estate. For more information contact Jon Vick, president, at (760) 751-0250 or visit www.ascs-inc.com.

Debt collections

Affiliated Credit Services. Affiliated Credit Services is a Colorado-based professional account receivables management firm which focuses on increasing businesses' cash flow by providing superior collection services. Learn more at www.acscollects.com or call (970) 867-8521.

Mnet Collection Agency. Mnet Financial, the preferred collection agency service vendor to United Surgical Partners and Health Inventures, is a receivables management company offering cost-effective ways to increase cash flow and reduce debt for professional services. Contact Mnet Financial at (949) 680-3335 or learn more at www.mnetfinancial.com.

Professional Finance Company. PFC is a full-service accounts receivable management company serving credit grantors for over 100 years with integrity and results. Visit PFC online at www.professionalfinancecompany.com or call (970) 352-5000.

For more information or an introduction to any of the following companies, e-mail sbecker@mcguirewoods.com, call (800) 417-2035 or fax with the company circled to (866) 678-5755.

For more information or an introduction to any of the following companies, e-mail sbecker@mcguirewoods.com, call (800) 417-2035 or fax with the company circled to (866) 678-5755.

Finance

Bank of America. Whether your need is to expand due to growth, acquisition or merger, or make a strategic investment, Bank of America offers ASCs flexible equipment finance options with competitive rates. For more information, contact balhealthcarefinance@bankofamerica.com or call (800) 835-8488.

GE Healthcare Financial Services. GE Healthcare Financial Services' outpatient finance team offers flexible solutions for physician-owned hospitals and outpatient centers. Learn more at www.gehealthcarefinance.com or call (312) 441-7705.

Physicians Capital. This Nashville-based firm provides loans based solely on the future cash flow of a surgery or diagnostic center. Learn more at www.physicianscap.com or call (615) 342-0824.

Group purchasing organizations

Amerinet. As a leading national group purchasing organization, Amerinet strategically partners with healthcare providers to reduce costs and improve quality through its Total Spend Management solutions and operational performance improvement programs, tools and services. To learn more about Amerinet, visit www.amerinet-gpo.com or call (800) 388-2638.

Health information technology providers

Amkai. Amkai is a software company with 20-plus years of experience delivering administrative and clinical solutions to ASCs, surgical hospitals and physician practices. Learn more at www.amkai.com or call (866) 265-2434.

Count Me In. Count Me In provides large enterprise time tracking tools and innovative biometric technology solutions scaled for small business needs and budgets. Find out more at www.countmeinllc.com or call (847) 981-8779.

Experior Healthcare Systems. Experior is a leading developer in software solutions for ASCs (SurgeOn) and medical practices (ExpertPM); Experior's solutions are fully integrated and interface with other third-party software products to compliment your center's needs. For more information, call (800) 595-2020 or visit www.experior.com.

GHN-Online. GHN-Online is an industry innovator in online enterprise class healthcare transaction processing. Visit www.ghnonline.com or call (214) 696-5717 to learn more.

Mavicor. Mavicor is an ASC technology management company specializing in ASC application services, systems integration and consulting services, as well as the procurement and management of hardware and software. Learn more about Mavicor at www.mavicor.com or call (888) 387-1620.

Mednet. Mednet is a software technology company, led by a group of professionals from the ASC market who understand the core of your business practice and its unique requirements. Learn more at www.mednetus.com or call (866) 968-6638.

Medtek.net. Medtek.net is a leading provider of medical transcription solutions for healthcare providers and healthcare organizations, with clients including hospitals, ASCs, clinics and physician practices. Visit www.medtek.net or call (818) 673-2900 to learn more.

ProVation Medical. ProVation Medical has created ProVation EHR, the first electronic health record designed for busy, cost-conscious ASCs. For more information, e-mail Laura Gilbert at laura.gilbert@provationmedical .com, or visit www.provationmedical.com or call (612) 313-1500.

QSE Technologies. QSE Technologies is a premiere IT systems integrator serving the ambulatory healthcare industry for more than five years. For more information, contact Marion K. Jenkins, PhD, QSE's co-founder and CEO, at (877) 236-0795, or via e-mail at info@qsetech.com or visit QSE's Web site at www.qsetech.com.

SourceMedical Solutions. SourceMedical is a leading provider of outpatient information solutions and services, collectively serving ASCs, and surgical hospitals. For more information, visit www.sourcemed.net or call (800) 719-1904.

Surgical Notes. A preeminent nationwide provider of medical transcription, coding and other related value-added information technology services for the ASC market, Surgical Notes provides transcription, coding and practice management solutions to more than 420 surgery centers and 6,300 physicians in more than 40 states. To learn more, visit Surgical Notes online at www.surgicalnotes.com or call (214) 821-3850.

zChart EMR. zChart EMR, a first-rate, intelligent, 21st-century surgical chart, was developed by dozens of healthcare professionals — administrators, office staff, nurses and physicians — at multi-specialty outpatient surgery centers. For more information, contact Kent Barber at (866) 924-2787 or visit www.zchart.com.

Imaging

Atlantis Worldwide. Atlantis Worldwide is a full-service provider of pre-owned and refurbished diagnostic imaging systems — MRI, CT scanner, C-Arm, X-ray, bone densitometer, mammograph, ultrasound and cath/angio as well as other imaging systems. To find out more, go to www.atlantisworldwide.com or call (800) 533-3356.

Insurance

Medical Protective. Medical Protective is a national leader in primary medical professional liability coverage and risk solutions to healthcare providers. To learn more, call (800) 463-3776 or visit www.medpro.com.

Managed care contracting

Eveia Health Consulting & Management Company. Founded by I. Naya Kehayes, MPH, Eveia Health Consulting & Management is comprised of a team of seasoned professionals who are experts in reimbursement management, managed care contracting and business management with a specialization in ASCs and surgical practices. For more information, call Ms. Kehayes at (425) 657-0494 or visit www.eveia.com.

Management, consulting and strategy

TRY Health Care Solutions. TRY Health provides consulting services to large healthcare systems, group practices, independent physicians and surgery centers throughout the United States. You can contact Tom Yerden, president, at (208) 865-2400 or send him an e-mail at TYerden@aol.com.

Management, development and equity firms

Ambulatory Surgery Centers of America. ASCOA is a leader in the surgery center industry, achieving exceptional quality of care and outstanding financial results. For more information, visit ASCOA online at www.ascoa.com or call (866) 982-7262.

Ambulatory Surgical Group. The Ambulatory Surgical Group team has been involved in the syndication, development and management of some of the most successful centers in the country. Learn more about ASG at www.ambulatorysurgicalgroup.com or call (973) 729-3276 (East Coast) or (310) 531-8231 (West Coast).

Blue Chip Surgical Center Partners. Blue Chip holds an equity stake in its projects and also serves as a managing partner, with several highly profitable, physician-led centers in operation around the country and a number of projects in the works. For more information, visit Blue Chip online at www.bluechipsurgical.com or call (513) 561-8900.

Cirrus Health. Cirrus Health is a health services organization, specializing in the development and acquisition of ASCs, short-stay and community hospitals, serving local communities by partnering with physicians and other healthcare providers to deliver excellence in patient care in effective, caring environments. For more information, visit www.cirrushealth.com or call (214) 217-0100.

Congero Development. Congero provides management and development services to surgical centers and other types of healthcare facilities; Congero is a minority owner in its centers and helps with the syndication and all aspects of the operating company. Visit Congero at www.congerodev.com or call (949) 429-5107.

Covenant Surgical Partners. Based in Nashville, Tenn., Covenant Surgical Partners is a privately-held owner and operator of ASCs; it was founded in 2008 by a group of successful, experienced investors, including several seasoned healthcare and financial executives, along with a prominent physician who owns his own surgery center. For more information, contact (615) 345-6903 or visit www.covenantsurgicalpartners.com.

The C/N Group. The C/N Group is a recognized leader in the development, ownership and operation of exceptional healthcare facilities, including ASCs, medical office buildings and diagnostic imaging centers. Visit them at www.thecng.com or call (219) 736-2700.

Facility Development and Management. Facility Development and Management is a for-profit company that provides consultative, developmental and managerial services for ASCs throughout the United States. To learn more, visit the Web site www.facdevmgt.com or call (845) 770-1883.

Foundation Surgery Affiliates. FSA is a healthcare management organization specializing in project development, innovative facility design, partner recruitment and facility operations for ASCs, medical office buildings, surgical hospitals and bariatric hospitals and healthplexes. More information about FSA can be found at www.foundationsurgery.com or call (405) 608-1700.

HealthMark Partners. HealthMark Partners owns and operates single and multi-specialty ASCs throughout the United States by creating joint-ventures with physicians or physicians and hospitals. Please visit the company Web site at www.healthmarkpartners.com, e-mail Senior Vice President – Development Kenny Spitler at kspitler@healthmarkpartners.com or call him at (615) 341-0701 to learn more.

Health Inventures. Health Inventures provides strategic and business planning, joint venture formation, facility development and operations management for ASCs; since 1995, it has provided support to hospitals and health systems throughout the United States and currently manages nearly 40 ASCs. Learn more at www.healthinventures.com or call (720) 304-8940.

Medical Consulting Group. MCG is a national firm specializing in medical consulting, both at the surgical practice and corporate levels; MCG provides ASC development and management solutions for single, multi-specialty and hospital joint-venture facilities. Learn more at www.medcgroup.com or call (417) 889-2040.

Medical Facilities Corp. MFC is a publicly-traded company and a leading acquirer of majority interests in high-quality specialty hospitals and ASCs. Visit MFC's Web site at www.medicalfacilitiescorp.com or contact Steven Hartley at (866) 766-3590, ext. 105.

MedStone Capital. RMC MedStone Capital combines the strength of several industry standards like Mike Lipomi, Tim Noakes and the Stanislaus Surgical Hospital of Modesto, Calif., with one of the leading real estate companies in Dallas, RM Crowe, to form a very strong team. You can see more information on MedStone at www.medstonecapital.com or call Mr. Lipomi directly at (209) 602-3298.

Meridian Surgical Partners. Meridian Surgical Partners aligns with physicians in the acquisition, development and management of multi-specialty ambulatory surgery centers and surgical facilities. E-mail Kenny Hancock, president and chief development officer of Meridian, at khancock@meridiansurg.com or call him at (615) 301-8142 for more information.

National Surgical Care. National Surgical Care is a nationwide owner and operator of ASCs, focuses on addressing the needs and problems confronting surgery centers across the country. Contact Rick Pence at (866) 866-2116 at rpence@natsurgcare.com.

National Surgical Hospitals. NSH acquires and builds freestanding, specialty surgical hospitals concentrating in orthopedic surgery, neurosurgery, and more complex general surgery cases; under the hospital license, these hospitals can also provide related services such as pain management, imaging and physical therapy. To learn more, visit www.nshinc.com or call Dennis Solheim at (312) 627-8428.

Nikitis Resource Group. Nikitis Resource Group is a new ASC development, management and consulting firm with a team that encompasses more than 100 combined years of ASC development and management experience, HOPD and hospital consultation experience and licensure and accreditation assistance to centers. To learn more, contact Dawn McLane, chief development officer, at daquay@aol.com or call (720) 320-6577.

NovaMed. NovaMed acquires, develops and operates ASCs in partnership with physicians. For more information, visit NovaMed at www.novamed.com or call (312) 664-4100.

Nueterra Healthcare. Nueterra Healthcare partners with physicians and hospitals to develop and manage community hospitals, surgical hospitals, ASCs and physical therapy centers including new development, joint-ventures, acquisitions and turnarounds. For more information e-mail Denise Mayhew at dmayhew@nueterra.com, call her at (888) 887-2619 or visit Nueterra's Web site at www.nueterra.com.

Orion Medical Services. Orion Medical Services offers a turnkey approach to ASC development and management by covering all aspects of a project from financial feasibility analysis to site and operational development. For more information, visit Orion Medical online at www.orionmedicalservices.com or call (541) 431-0665.

Physicians Endoscopy. Physicians Endoscopy develops and manages endoscopic ASCs in partnership with practicing GI physicians and hospitals. Visit the company on the Web at www.endocenters.com, e-mail John Poisson at jpoisson@endocenters.com or call him at (215) 589-9003.

Pinnacle III. Pinnacle III specializes in the operational development, management, payor contracting, coding, billing, and collecting for ASCs..For more information, visit Pinnacle III online at www.pinnacleiii.com or call Dan Connolly, vice president of development and payor contracting, at (877) 710-3047.

Practice Partners. Practice Partners in Healthcare takes great pride in the development, management and equity ownership with its physician and hospital partners. E-mail Larry Taylor at ltaylor@practicepartners.org, visit Practice Partners online at www.practicepartners.org or call (205) 824-6250.

Prexus Health. Prexus Health is a 100 percent physician-owned company that specializes in the development and management of multi-specialty, physician-owned ASCs and small hospitals. For more information, call (513) 454-1414, e-mail Prexus at info@phcps.com or visit the Web site at www.prexushealth.com.

Regent Surgical Health. As buyers, developers and managers of outpatient surgery centers and physician-owned hospitals around the country, Regent Surgical Health is an experienced developer and specialist in turnaround situations. You can learn more by visiting Regent Surgical Health online at www.regentsurgicalhealth.com or call (708) 492-0531.

Surgical Care Affiliates. Surgical Care Affiliates is one of the nation's largest providers of specialty surgical services; through its affiliation with 18 health systems and more than 2,000 physician partners, it operates 128 surgical facilities across the country. Learn more about Surgical Care Affiliates at www.scasurgery.com or call (800) 768-0094.

Surgery Consultants of America. SCA is a highly regarded company offering complete ASC development and management services nationwide. For more information about SCA, visit them at www.surgecon.com or call (888) 453-1144.

Surgical Management Professionals. With a seasoned team of healthcare professionals, SMP specializes in the management and development of ASCs and surgical specialty hospitals. For more information, visit SMP's Web site at www.surgicalmanprof.com or call (605) 335-4207.

Symbion. Headquartered in Nashville, Tenn., Symbion is a leading provider of high-quality surgical services across many specialties. Visit Symbion at www.symbion.com or call (615) 234-5900 for more information.

Titan Health. Titan is a nationwide surgery center development, acquisition and management company that partners with hospitals and physicians to develop successful, multi-specialty ASCs. Please visit Titan Health online at www.titanhealth.com; you can also e-mail D.J. Hill, chief development officer, at dhill@titanhealth.com, e-mail Kristen Franz at kfranz@titanhealth.com or call (916) 614-3600.

Texas Health Resources. Texas Health Resources is a healthcare development and management company that serves as a dedicated resource for the analysis, organizational development and operation of specialty healthcare services and hospital/physician joint-ventures. For more information about Texas Health Resources, visit www.tphrhealth.com or call (972) 392-9252.

United Surgical Partners International. United Surgical Partners International was founded in 1998 by Don Steen and the investment firm, Welsh, Carson, Anderson & Stowe, to pursue the ownership and management of ASCs in the United States and the ownership and operation of private surgical hospitals in Europe. Learn more about USPI at www.unitedsurgical.com or call (972) 713-3500.

Woodrum/Ambulatory Systems Development. Founded in 1986 by healthcare professional managers, Woodrum/ASD has offices in Chicago, Dallas and Los Angeles, and is one of oldest continuing, national ASC companies in the United States, having developed and managed ASCs in 46 states for more than 20 years. Please e-mail Joe Zasa at joezasa@woodrumasd.com, call (214) 369-2996 or visit www.woodrumasd.com for more information.

Medical devices — Implants and expedited payment options

Block Imaging International. Block Imaging International is a worldwide provider of refurbished imaging equipment, featuring refurbished digital x-ray, C-arm, MRI, CT, cath/angio, mammography and bone densitometry systems as well as CR, PACS and imagers from all major manufacturers. Learn more at www.blockimaging.com, e-mail info@blockimaging.com or call (888) 694-6478.

Implantable Provider Group. IPG works with providers, facilities, manufacturers and commercial payors to fully manage all aspects of high-cost implantable medical devices. For more information about IPG, visit www.ipgsurgical.com or call Michael Jones at (866) 753-0046.

Medical devices — Reprocessed and refurbished

Mini C Sales. Mini C Sales specializes in providing pre-owned and refurbished FluoroScan, Xi-Scan and OEC Mini C-Arms at a fraction of the cost of new systems. Visitwww.minicsales.com or call (800) 356-4000.

Northern Scientific. Northern Scientific specializes in high-end rebuilt surgical tables and surgical lighting systems, and also offer stainless instrument tables and surgical table accessories. Learn more at www.northernscientific.com, e-mail med@northernscientific.com or call (800) 669-9568.

Medical laundry

ImageFIRST Healthcare Laundry Specialists. ImageFIRST is a leading provider of laundry services for medical practices throughout the continental United States and Puerto Rico, with products including patient apparel, scrubs, lab coats, surgical gowns, bed and bath, and more. For more information, contact Michelle Loiederman, marketing coordinator, at (800) 932-7472 or visit ImageFIRST at www.imagefirstmedical.com.

Medtegrity. The Medtegrity Medical Laundry Network is a $500 million commercial laundry network comprised of one of the largest and most successful independent and family-owned laundries in the United States. Contact David Potack at (888) 546-3650 or visit www.medtegrity.us.

Outsourced medical implantable device management solutions

Access MediQuip. Access MediQuip is one of the largest and most experienced providers of outsourced implantable device management solutions to the healthcare industry. For more information, call (877) 985-4850 or visit www.accessmediquip.com.

Patient financing options

CareCredit: Patient Payment Plans. CareCredit lets your patients pay their current bills in-full immediately with the use of convenient monthly payments. Call (800) 300-3046, ext. 4519, or visit www.carecredit.com for more information.

Med-Care Solutions. Med-Care Solutions offers accounts receivable purchasing of lien-based accounts primarily for patients involved in vehicle accidents, working primarily with ASCs, hospitals, and diagnostic centers. For more information, visit www.medcaresolutions.us, e-mail kabdo@medcaresolutions.us or call (702) 870-4013.

For more information or an introduction to any of the following companies, e-mail sbecker@mcguirewoods.com, call (800) 417-2035 or fax with the company circled to (866) 678-5755.

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Patient satisfaction and benchmarking

CTQ Solutions. CTQ Solutions is a leading provider of healthcare satisfaction and benchmarking services, helping support ASC patient satisfaction targeting quality and process improvement initiatives, improving patient loyalty and meeting all industry accreditation requirements. For more information, visit www.ctqsolutions.com or call (877) 208-7605.

Surgical Outcomes Information Exchange. SOIX offers services to benchmark performance and outcomes for accreditation, risk management and quality patient care in surgery centers. Learn more about SOIX at www.soix.com or call (877) 602-0156.

Pharmaceutical waste management

PharmASC-e Consultants. PharmASC-e is a pharmaceutical waste management consulting company that works with facilities on regulatory compliance, cost control and staff satisfaction to ensure organizations are proper stewards of the environment. Learn more at www.pharmasc-e.com.

Quality

ASC Quality Collaboration. The ASC Quality Collaboration is a cooperative group of organizations and companies interested in ensuring that ASC quality data is measured and reported in a meaningful way and has taken an active role in developing quality measures for ASCs. For more information, visit www.ascquality.org or call Donna Slosburg, executive director, at (727) 867-0072.

Real estate acquisition and real estate investment trusts

McShane Medical Properties. McShane Medical Properties is an integrated design/build construction and real estate development firm offering comprehensive services for the healthcare industry. Contact John Daly, vice president, healthcare, at (847) 692-8616 or visit the firm's Web site at www.mcshane.com for more information.

The Sanders Trust. The Sanders Trust owns, acquires and develops ASC buildings and medical office buildings nationwide. To learn more about The Sanders Trust, visit www.sanderstrust.com, e-mail Bruce Bright at bbright@sanderstrust.com or call him at (205) 298-0809.

Recruitment and search firms

B.E. Smith. B. E. Smith is a leading healthcare executive search and consulting firm, supporting ASCs across the nation. To learn more, call (877) 802-4593 or visit www.besmith.com.

Kaye/Bassman International. Greg Zoch, a partner and managing director with Kaye/Bassman International, a 26-year-old executive search firm, specializes heavily in the ASC world and has served many of the industry's largest players by finding top talent at the facility and corporate level. You can e-mail Mr. Zoch at gregz@kbic.com or call him at (972) 931-5242 ext. 5290.

Manning Search Group. Roger Manning, Cathy Montgomery and their healthcare search consultant team offer middle management and executive search and recruitment with ASC-industry-specific focus. E-mail Roger Manning at roger@manningsearchgroup.com or Cathy Montgomery at cathy@manningsearchgroup.com, call them at (636) 447-4900 or visit Manning Search Group online at www.manningsearchgroup.com.

The Spring Group. Primarily focused on the ambulatory surgery industry, Joe Feldman, who brings over 35 years of healthcare experience to the recruiting industry, and his team work with corporate, hospital-based and privately owned ASCs throughout the United States. Mr. Feldman is the owner of AmbulatorySurgeryCenterCareers.com, a Web-based career board dedicated to the ASC industry, designed primarily for employers, recruiters and candidates to seek each other out at a single location. For more information, visit www.ambulatorysurgerycentercareers.com. You can reach Joe Feldman at (610) 358-5675 or e-mail him at joe@thespringgrp.com.

Surgical supply and equipment manufacturers

3M. 3M is a diversified technology company serving customers and communities with innovative products and services. Visit www.3m. com or call (888) 364-3577.

Acclarent. Acclarent is dedicated to developing innovative solutions for ENT specialists and their patients. For more information, call (877) 775-2789 or e-mail Acclarent at acclarent@acclarent.com.

Alcon. Alcon engages in the development, manufacture, and marketing of pharmaceuticals, surgical equipment and devices, and consumer eye care products to treat eye diseases and disorders. Learn more at www.alcon.com or call (800) 862-5266.

AliMed. AliMed is a designer, manufacturer and distributor of healthcare products that works with hundreds of vendors to supply more than 70,000 products to healthcare facilities and businesses all over the world. To learn more, visit www.alimed.com or call (800) 225-2610.

Allen Medical Systems. The newest innovation from Allen Medical Systems, a Hill-Rom Company, is the Allen Spine System, which manages patient skin pressure during four-post spine surgery, supports various body types, and enables the surgeon to flex the patient's spine using the power of the ORtable. Learn more about Allen Medical Systems at www.allenmedical.com or call (800) 433-5774.

Alpine Surgical Equipment. Alpine Surgical provides its clients with a wide array of both new and refurbished medical equipment for the entire ASC by working closely with many of the leading medical equipment manufacturers and specialty refurbishing companies nationwide. For more information, contact Matt Sweitzer at (916) 933-2863 or visit Alpine Surgical on the Web at www.alpinesurgical.com.

ARC Medical. ARC Medical, founded in 1990 by Hal Norris, provides ASCs and anesthesia, ICU, long term acute care and emergency areas of hospitals with products such as its ThermoFlo System, a hygroscopic condensing humidifier. Learn more at www.arcmedical.com or call (800) 950-2721.

Aspen Medical Products. Aspen Medical Products is a leader in the design, development and marketing of upper and lower spinal immobilization products. Learn more at www.aspenmp.com or call (800) 295-2776.

B. Braun. For 150 years, B. Braun has developed a rich heritage of knowledge and expertise for delivering innovative healthcare products, medical devices and programs designed to improve both patient and health-professional safety. For more information, visit B. Braun online at www.bbraun.com or call (610) 691-5400.

CONMED Corp. CONMED specializes in arthroscopy, electrosurgery, endoscopy, endosurgery, imaging, integrated systems, patient care and powered instruments that are sold worldwide through its family of companies (CONMED & Linvatec). Learn more about CONMED at www.conmed.com.

Cybertech Medical. Cybertech is the brand name of orthotic products offered by Bio Cybernetics International; its patented Mechanical Advantage products are the result of advanced technology that creates biomechanic support, patient comfort, and compliance. Learn more about Cybertech Medical at www.cybertechmedical.com or call (800) 220-4224.

Cygnus Medical. Cygnus Medical specializes in products and services for the endoscopy suite, the operating room and the sterile processing department. Learn more about Cygnus at www.cygnusmedical.com or call (800) 990-7489.

Integra LifeSciences. Through the Jarit, Miltex and Luxtec companies, Integra LifeSciences offers German-crafted quality and cost-effective surgical instruments, sterilization containers and instrument repair and refurbishment services to meet the needs of every surgery center. You can learn more about Integra LifeSciences by visiting www.integra-ls.com, e-mailing David W. Swanson, vice president of ASCs, at david.swanson@integra-ls.com or calling (800) 654-2873.

Kimberly-Clark. Around the world, medical professionals turn to Kimberly-Clark for a wide portfolio of solutions that improve the health, hygiene and well-being of patients and staff. To learn more, visit www.kimberly-clark.com or call (888) 525-8388.

McKesson Medical-Surgical. McKesson Medical-Surgical, based in Richmond, Va., is a leading distributor of medical supplies and equipment to physician practices, surgery centers, home care and extended care facilities. You can visit McKesson online at www.mckesson.com or call (415) 983-8300.

Medline Industries. Medline Industries is a manufacturer of medical supplies serving hospitals, nursing homes and home health agencies. To find out more, visit www.medline.com or call (800) 633-5463.

Medtronic. Medtronic develops and manufactures a wide range of products and therapies with emphasis on providing a complete continuum of care to diagnose, prevent and monitor chronic conditions. Learn more about Medtronic at www.medtronic.com or call (800) 328-2518.

Miltex. Miltex, a business unit of Integra LifeSciences, is a leading provider of surgical and dental hand instruments to alternate-site facilities including physician and dental offices, and ambulatory surgery care facilities. Visit Miltex at www.miltex.com or call (800) 645-8000.

PENTAX Medical Company. PENTAX, an industry leader offering detection and efficiency solutions for video and fiber endoscopy equipment and computer technology/imaging products for diagnostic, therapeutic and research applications in the GI, ENT and pulmonary fields, offers a full range of endoscopes, accessories, carts, computer hardware and software platforms, video equipment and computer software for image and data management. Learn more at www.pentaxmedical.com or call (800) 431-5880.

Progressive Dynamics Medical. Progressive Dynamics Medical manufactures six different types of warming covers to meet various requirements for the operating and recovery rooms. Learn more at www.progressivedynamicsmedical.com or call (269) 781-4241.

Spine Surgical Innovation. Spine Surgical Innovation designs and markets the Holmed Swivel Port System, which is designed for ease of use and intended for posterior or lateral lumbar surgery. Read more at www.spinesurgicalinnovation.com or call (800) 350-8188.

Stryker Corp. Stryker is one of the largest players in the $28.6 billion worldwide orthopedic market and its products are in use by medical professionals in more than 120 countries. Visit Stryker at www.stryker.com or call (269) 385-2600.

TransMotion Medical. TMM designs, manufactures and distributes a line of specialty medical procedure chairs including the TMM3 Video Fluoroscopy Chair, TMM4 Multi-Purpose Treatment Chair and TMM5 Surgical Stretcher Chair. Learn more about TMM at www.transmotionmedical.com or call (866) 860-8447.

Viscot Medical. Highlights of the product line from Viscot Medical, a provider of disposable medical products since 1974, include sterile and non-sterile surgical skin markers; sterile and non-sterile medication labels and kits for compliance with the Joint Commission requirement for labeling medications on and off the sterile field; male and female urinals; minor surgery drapes; and towels. For more information, visit www.viscot.com or call (800) 221-0658.

Valuation

HealthCare Appraisers. HealthCare Appraisers is a nationally recognized valuation and consulting firm providing services exclusively to the healthcare industry. Visit Healthcare Appraisers' Web site at www.healthcareappraisers.com or call the Delray Beach, Fla., office at (561) 330-3488 or the Denver, Colo., office at (303) 688-0700 to learn more.

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VMG Health. VMG Health is recognized by leading healthcare providers as one of the most trusted valuation and transaction advisors in the United States. For more information, visit VMG's Web site at www.vmghealth.com or e-mail Jon O'Sullivan at osullivan@vmghealth.com or call (214) 369-4888. ■

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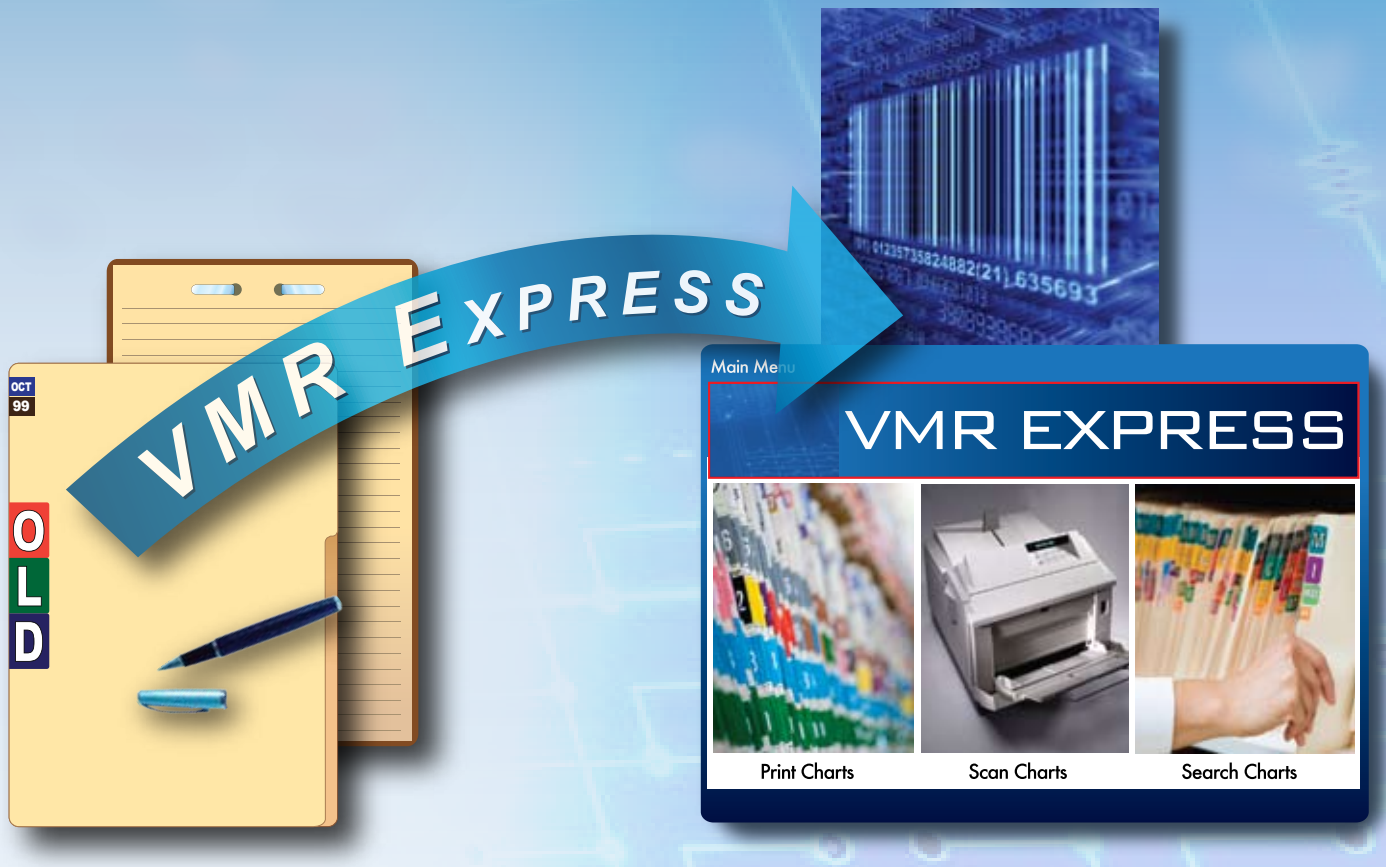

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