

BECKER'S ORTHOPEDIC & SPINE

PRACTICE REVIEW

Business and Legal Issues for Orthopedic and Spine Practices

10 Knee Specialists to Know

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Dr. Cole specializes in arthroscopic shoulder, elbow and knee surgery. He has a specific interest in arthroscopic reconstruction of athlete's shoulder (rotator cuff, instability and arthritis), elbow and knee. He is the principal investigator for numerous FDA clinical trials and regularly performs basic science research.

He has authored and edited several hundred peer-reviewed publications, including highly recognized orthopedic textbooks on arthroscopy, sports medicine and cartilage transplantation. His publications also include nearly one thousand book chapters, technique papers, and presentations describing the techniques and results of shoulder, elbow and knee surgery. Dr. Cole lectures and teaches the techniques of cartilage restoration and shoulder arthroscopy on a national and international level. He is a member of numerous national

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10 Interesting Statistics and Facts About Orthopedic Practices

Here are 10 interesting statistics and facts about orthopedic practices, as gathered by the American Academy of Orthopaedic Surgeons.

1. Private practice makes up the majority (81 percent) of orthopedic practice settings. Within the private orthopedic setting, 60 percent are in orthopedic group practice, 31 percent in solo practice and 9 percent are in a multi-specialty practice. The remaining 19 percent is split between seven additional practice settings: academic practice (9 percent), hospital/medical center practice (4 percent), military practice (2 percent), pre-paid plan/HMO practice (2 percent), public institution, non-military (1 percent) and other setting (2 percent).

2. Here are the top 10 fellowships (with the percent of members with the fellowship in parentheses).

- Sports medicine (28.4 percent)
- Hand surgery (20 percent)
- Spine surgery (14 percent)
- Total joint (9.6 percent)
- Adult knee (9.1 percent)
- Pediatric orthopedics (8.8 percent)
- Adult reconstruction (8.5 percent)
- Adult hip (7.6 percent)
- Trauma and fractures, including Ilizarov (7.6 percent)
- Shoulder and elbow (7.3 percent)

Most orthopedic surgeons (86 percent) report completing one fellowship; 12 percent reported they have completed two fellowships; 1 percent reported completing three. The remaining 1 percent reported completing more than three fellowships.

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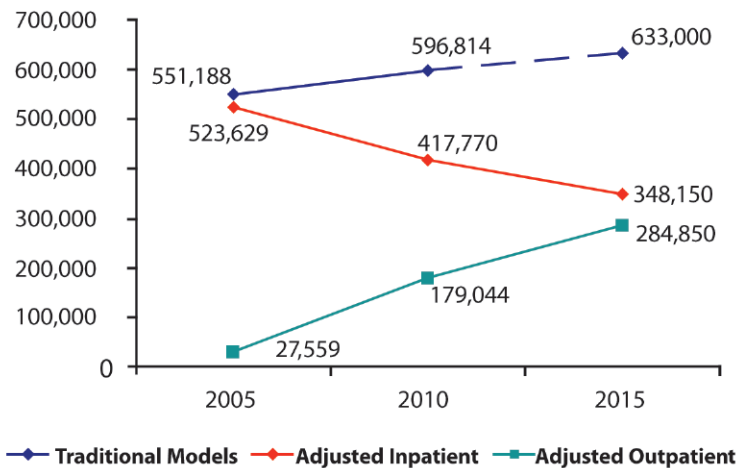
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PRACTICE REVIEW

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Letter from the Editor

2009 will be a challenging year for orthopedic and neurosurgical practices nationally. There are a handful of core considerations that parties should take into consideration as they make their plans for the coming year.

1. **Decrease in procedures.** There will be some deceleration in orthopedic and spine procedures as parties are more cautious regarding spending money on co-payments and about concerns regarding being off of work for some period of time. This will lead to some slowdown in the number of procedures. In fact, some commentators have already indicated that after cosmetics, the largest area of deceleration for hospital procedures is in the orthopedic space.

2. **Payors and patients will slow down on payments.** In addition to the deceleration of procedures, payors and patients will be slower on their payment of amounts due.

3. **Increased patients on Medicaid.** This will reduce overall average payments per procedure.

4. **Core concepts to improve profitability.** Much of the plans for next year will center on improving and applying some core concepts and blocking and tackling to retain and keep profits where they should be. These can be clarified to five core concepts.

- **Keep debt low.** This is a good time not to be over leveraged. In fact, overleveraging has led to many of the problems throughout the nation's economic system as a whole.
- **Redouble efforts to improve managed care contracts.** This may be a good time to review managed care contracting and to see if it makes sense to try and reopen negotiations. Unfortunately, managed care payors are themselves benefiting from increased consolidation and are facing more pressure to reduce healthcare costs.
- **Careful on head count.** This is a time to be very careful about staffing and overstaffing to ensure that your offices and surgery centers, if applicable, are staffed at the right amounts and not overstaffed.
- **Improvements in collecting.** A good deal of improvements, in terms of profitability, is often in billing and collections. This is a good time to allocate people to improve collecting and to examine better ways to improve your billing and collecting.
- **Improved marketing.** This is a terrific time to double-down on inexpensive marketing types of efforts that may lead to more patients and more follow-through with patients and referral sources.

We see 2009 as a challenging year. While fortunate to be in the healthcare area, it is still an area where there will be efforts made to bring down costs nationally and it is an important time to redouble the efforts to improve the profitability of orthopedic practices and neurosurgical practices.

Should you have any questions, please contact Scott Becker at (312) 750-6016 or sbecker@mcguirewoods.com.

Very truly yours,

Scott Becker



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10 Knee Specialists to Know (continued from pg. 1)

societies and serves on the board of the American Academy of Orthopedic Surgeons and assumes many high level positions on society organizing committees.

John D. DiPaola, MD. Dr. John DiPaola is founder of Occupational Orthopedics and a partner at East Portland Surgical Center in Portland, Ore. After 12 years practicing general orthopedics, Dr. DiPaola established Occupational Orthopedics, the only specialty practice in the United States providing personalized care exclusively for injured workers. He is the current medical director for Oregon Health Systems and Montana Health Systems. Dr. DiPaola regularly speaks about injured workers' care at regional and national meetings.

Jack Farr, MD. Dr. Jack Farr is the medical director for the Cartilage Restoration Center of Indiana. Over the past 20 years, following his completion of his orthopaedic surgery residency at Indiana University Medical Center, Dr. Farr has continued to focus his practice in sports medicine and knee restoration. His numerous appointments and affiliations include a clinical associate professorship in orthopaedic surgery at Indiana University Medical Center and a board position with the Cartilage Research Foundation.

Freddie H. Fu, MD. Dr. Freddie Fu is the David Silver Professor of Orthopaedic Surgery and chairman of the department of orthopaedic surgery at the University of Pittsburgh School of Medicine and University of Pittsburgh Medical Center, where he was previously the department's executive vice chairman. Dr. Fu has been the head team physician for the University of Pittsburgh Department of Athletics since 1986 and holds secondary appointments at the university as professor of physical therapy and health physical and recreational education. Dr. Fu is known worldwide for his pioneering surgical techniques to treat sports-related injuries to the knee and shoulder and his extensive scientific and clinical research in the biomechanics of such injuries.

Scott Gillogly, MD. Dr. Scott Gillogly is founder of the Atlanta Knee and Shoulder Clinic and formed a sub-specialty group of the clinic, the Atlanta Sports Medicine & Orthopaedic Center. Dr. Gillogly specializes in cartilage restoration, complex knee disorders, biologic knee reconstruction as well as sports and shoulder injuries and serves as the head team physician and orthopaedic surgeon for the Atlanta Thrashers hockey team and the Atlanta Falcons football team. Dr. Gillogly completed a distinguished military career in the Army Medical Corps with the rank of lieutenant colonel. He is currently the director of sports medicine training for the Atlanta Medical Center Orthopaedic Residency Program.

E. Marlowe Goble, MD. Dr. Marlowe Goble has been a pioneering knee surgeon for the past 30-plus years and is perhaps best known in orthopedics as one of the top surgeons in ACL reconstruction and meniscal allograft transplants. He performed what may be the first minimally invasive knee replacement procedure and holds more than 70 patents. He currently practices at Salt River Orthopedics in Afton, Wyo., serves as the director of the Utah State University medical device testing laboratory in the department of animal science and is an adjunct professor in the department of orthopedic surgery at the University of Utah. His previous work included founding several companies, including MedicineLodge, an orthopedic technology development firm; Facet Solutions, a facet arthroplasty device company; and Frontier Biomedical, a leader in comparative medicine. Dr. Goble has had several other notable achievements including serving as a lead surgeon for Zimmer on the prosthetic ACL development and as Utah State University team physician.

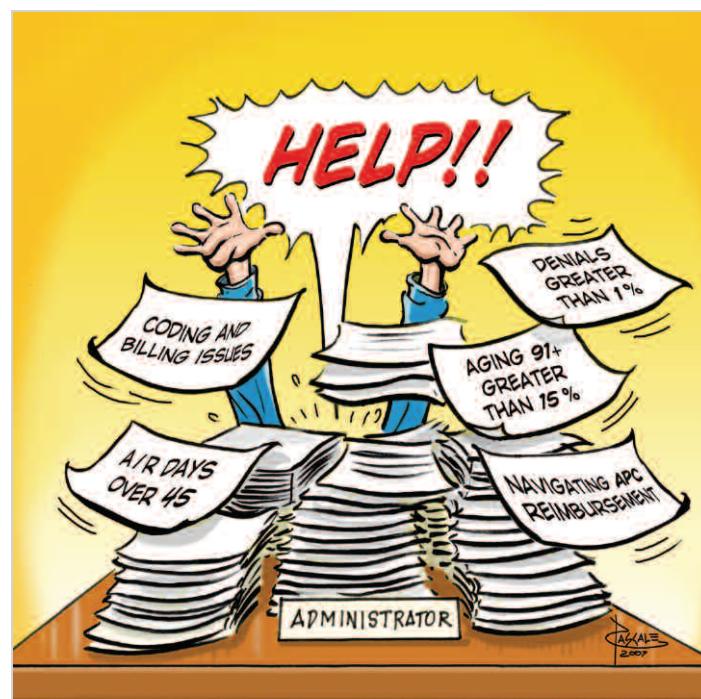
Timothy E. Kremchek, MD. Dr. Timothy Kremchek serves as the Cincinnati Reds baseball team medical director and chief orthopaedic physician. He performs the bulk of his surgical practice at the Summit Surgery Center in Cincinnati. He currently serves as the director of sports medicine for the TriHealth System of Good Samaritan and Bethesda hospitals. Dr. Kremchek began private practice in orthopaedic surgery and sports medicine in Cincinnati in 1993, when he completed a one-year orthopaedic sports medicine fellowship at the Alabama Sports Medicine Institute in Birmingham, Ala.

Frank R. Noyes, MD. Dr. Frank Noyes is founder of the Cincinnati Sportsmedicine and Orthopaedic Center and director of The Noyes Knee Center. Dr. Noyes is an internationally recognized authority on the diagnosis and treatment of complex knee problems. In 1975, he joined the department of orthopaedic surgery at the University of Cincinnati and started Cincinnati's first sports medicine program. He also established the Noyes-Giannestras Biomechanics Laboratories within the University of Cincinnati College of Aerospace and Mechanical Engineering, and today serves as a clinical

professor with the school's department of orthopaedic surgery and an adjunct professor with the department of biomedical engineering.

Michael B. Purnell, MD. Dr. Michael Purnell is an orthopedic surgeon at Orthomed Center in Modesto, Calif. He specializes in sports medicine with a focus on the knee and shoulder and has more than 19 years of clinical practice experience. His clinical interests and expertise include computer-assisted knee arthroplasty, complex reconstruction of knee instabilities including ACL, PCL and dislocations, treatment of meniscus and cartilage abnormalities. He also has extensive experience in shoulder arthroscopy and reconstructive shoulder surgery. He is a graduate of University of Iowa College of Medicine, did his residency at Boston University Affiliated Hospitals Program and completed a Sports Medicine Fellowship in Sydney, Australia. Dr. Purnell is the team physician for the *Modesto Nuts*, the Class A affiliate of the Colorado Rockies baseball team, and a team physician for California State University, Stanislaus and Modesto Junior College. He serves as a consultant for DePuy Orthopaedics and Advanced Bio-Surfaces and is a member of the editorial staff for the *American Journal of Sports Medicine*.

David Raab, MD. Dr. David Raab is a senior partner and one of the founding members of Illinois Bone and Joint Institute, one of the country's largest orthopaedic and musculoskeletal practices. He has been in practice for 17 years as a board-certified orthopaedic surgeon in suburban Chicago. His practice is focused on surgical and non-surgical management of the knee, shoulder and hip, as well as sports medicine and work-related injuries. Dr. Raab's surgical specialties include arthroscopic knee, shoulder and sports medicine surgery, as well as total knee and hip replacement. He also serves as the president of the Illinois Sports Medicine and Orthopaedic Surgery Center. Dr. Raab completed his medical training and residency at Northwestern University Medical School and completed a fellowship in sports medicine at the Minneapolis Sports Medicine Center in Minnesota. ■



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10 Interesting Statistics and Facts About Orthopedic Practices (continued from pg. 1)

3. Orthopedic surgeons perform an average of 32 orthopedic procedures each month. Among 12 frequently performed procedures, arthroscopy of the knee was reported by more surgeons than other procedures, and with greater frequency. Spinal fusion or re-fusion was reported by the second largest number of surgeons. Rotator cuff repair was the second most-frequent reported procedure, followed by release of carpal tunnel.

4. Orthopedic surgeons report that 19 percent of their patient payment came from private sources, including private insurance and self-pay. Managed care accounted for 33 percent of payment, split between HMOs (8.5 percent) and PPOs (24.2 percent). Government patient payments are primarily Medicare patients (24.8 percent), with only 7.1 percent coming from Medicaid. Workers' compensation patient payments accounted for nearly 12 percent of the total, while 4 percent of service time was considered pro bono.

5. Surgeons younger than 40 comprise less than 15 percent of all members. The proportion of surgeons who remain active past the age of 70 represented 5 percent of the total orthopedic workforce in 2006. Surgeons 70 and older report performing an average of 19 procedures per month. The highest average number of procedures performed monthly (35) is by orthopedic surgeons in the 40 to 49 age bracket.

General orthopedic surgeons report an average of 28 procedures performed per month, while specialists report 33 procedures per month.

6. Here are the top 10 states in terms of number of orthopedic surgeons (with number in parentheses).

- California (2180)
- New York (1183)
- Texas (1141)
- Florida (1035)
- Pennsylvania (764)
- Illinois (689)
- Ohio (629)
- New Jersey (558)
- North Carolina (545)
- Massachusetts (495)

7. Here are the 10 states with the highest orthopedic surgeon density per 100,000 populations (with density in parentheses).

- Wyoming (12.17)
- Montana (10.69)
- District of Columbia (9.81)
- Alaska (9.64)
- Vermont (8.67)
- New Hampshire (8.40)
- Connecticut (8.09)
- Rhode Island (8.08)
- Maryland (7.82)
- Massachusetts (7.74)

8. Here are the 10 states with the lowest orthopedic surgeon density per 100,000 populations (with density in parentheses).

- West Virginia (4.18)
- Mississippi (4.38)
- Michigan (4.39)
- Oklahoma (4.96)
- Texas (4.99)
- Arizona (5.07)
- New Mexico (5.08)
- Kentucky (5.18)
- Arkansas (5.22)
- Nevada (5.22)

9. On average, orthopedic surgeons took 4.3 weeks of vacation in 2005, spent 8.9 days at CME events and 8.2 days at professional meetings. The number of days spent at CME events and professional meetings varies substantially by practice setting, with surgeons in a military setting spending the least days (7.7 CME and 6.7 meetings), while surgeons in a private academic setting spend the most (11.4 CME; 13.6 meetings).

10. On average, full-time practicing orthopedic surgeons spend 86 percent of their time in clinical practice, which includes office, surgical, and patient rounds time. Approximately 16 percent of full-time surgeons report spending 100 percent of their time in clinical practice. The remaining time is split between administration (7 percent), teaching (4 percent), research (2 percent) and other related activities (2 percent). ■

Read the *American Academy of Orthopaedic Surgeons* report at www.aaos.org/Research/stats/2006opus.pdf.



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Spine Surgeon Dilemma: Standalone Practice or Join Orthopedic Group

By Rob Kurtz

The dilemma between whether to start a standalone practice or join an orthopedic group is one that many spine surgeons face during their careers. Both options have their merits, and both can bring challenges and obstacles to success. Without careful planning and an understanding of what makes these choices appealing and unappealing, the decision could very quickly prove to be a mistake.

Here are many of the pros and cons of both scenarios, and some practical guidance to help tackle the challenges of each option.

Standalone practice

While a standalone practice may offer many perks — you essentially determine your income, control your staff and dictate your on-call relationships — it also carries with it many challenges, including developing a good referral base, negotiating managed care contracts, and then there's the small issue of overseeing a business and doing so successfully.

• Financial autonomy

Probably the most obvious benefit of a standalone practice is the financial autonomy.

“What you kill is what you eat, basically,” says James Hansen, MD, founding member of Austin (Texas) Neurosurgical & Spine Institute and a partner at South Austin Surgery Center. Assuming you have access to cases, “you can determine your own income.”

But such autonomy also presents significant challenges.

Taking time off — for vacations or an illness — effectively ends your income while you are out of the office, says Dr. Hansen. It may take significant time to build up enough revenue that you can afford and feel comfortable bringing in no revenue for a few days.

There are also other ramifications to consider, such as what will happen to referrals sent your way that you cannot accept because you are out of the office. If the referring doctor isn't willing to wait for your return and sends another physician the case, you may risk losing the referral if another physician accepts and delivers an impressive outcome.

• Developing referral sources

Perhaps the most critical questions a spine surgeon must answer before deciding to make the leap and go solo is where his or her patients are going to come from at the start, and what avenues exist to build a strong referral base to ensure a steady stream of patients.

“Maybe (the surgeon is) employed by a local hospital and there is the built in referral base for his spine surgery,” says Chris Shoup, a group vice president

at Nueterra and former CEO of Spine Hospital of South Texas in San Antonio. “But if he's not employed, and decides to go standalone, what kind of referral base is he going to have going forward to garner cases?”

Tip: The surgeon must then put in a great deal of work and communication to develop a strong referral base from the medical community, Mr. Shoup says.

“He has to go out, do a lot of legwork,” he says. “A spine surgeon must make an effort to reconnect with their referral patterns to ensure that the primary care and specialists remain in the loop. For example, an orthopedist sends a patient over for a lumbar laminectomy. I'm going to go back and tell the orthopedist what I did, thank (him or her) for the business, and try to build referral patterns that way.”

Tip: It is also important to not pose a threat to surgeons who are willing to refer cases to you, says David Abraham, MD, a founder of the Reading Neck and Spine Center in Wyomissing, Pa.

“If you can prove to referring orthopedic surgeons that you in no way compete with them — most general orthopods don't want to think about the spine — and that you respect the territorial nature of the spine as opposed to the rest of orthopedics, then you should be able to get to the point (where the cases come to you),” Dr. Abraham says. “The individual has to prove to the local orthopedic community that he is not a threat, and typically that is obvious because when you're on-call, you give hip fractures away; you give ankle fractures away; you give general orthopedic care to people who are likely going to be your good referrals.

“About 80 percent of my surgical referrals are coming from orthopedic offices, and the orthopedists don't ever see back pain anymore, don't see neck pain anymore; they simply call my phone number,” he says.

• Prepare to negotiate

It's great to have referrals, but they're only good if you can get paid for the work you perform.

“That's another factor a doctor has to consider: How am I going to get paid for what I do? How do I get on the managed care plans?” says Mr. Shoup. “A standalone practice will have to negotiate every individual managed care contract, especially if you're in a large market.”

Since you cannot piggyback on an existing contract, standalone surgeons must be prepared for potentially lengthy negotiations, have a strong understanding of what they want to be paid for their procedures and also understand how to read a contract and identify potentially undesirable clauses that payors may try to include.

Tip: This is often where the services of a healthcare consultant or lawyer may be worth exploring, but these services are an expense that can come at a time when a surgeon is looking to stick to a tight budget as the business launches.

• Ready to run a business?

Running a standalone practice requires more than just a surgeon and patients. It's a business like any other medical practice, and requires a building, staff (and salaries and benefits), supplies for the staff, supplies for procedures and the many other financial investments.

“If you start picking apart the different aspects to the business model — drug and medical supplies, salary costs, managed care contracting, cash flow — there are so many roads that trickle off of that that they have to think of,” so surgeons must consider whether they are prepared for and want to shoulder such a time-consuming challenge, Mr. Shoup says.

A common mistake made by a standalone surgeon, or even those in a small group, that can make running the business more difficult is hiring the wrong personnel.

“One big problem I see ... is hiring an office manager that is a friend of a friend or has minimal education,” Mr. Shoup says. “That person is handling multimillion dollars' worth of your money and they don't picture it as the business for what it is. You bill out millions of dollars every year; who is handling your collections billing and expense management?”

It may seem financially logical to keep expenses low when starting a practice, and spending less on salary is one way to do so. But skimping on staff who handle your billing or those who will negotiate contracts for drug and medical supplies can cause a practice to lose more money than it gains in salary savings.

Tip: Make sure to set aside time to find the right personnel, and then expect to pay more for the experience and value they will bring to your practice.

“Prepare for the cash outlay you have to pay for salary and benefits for somebody of a high level of professionalism,” Mr. Shoup says.

The good news is that as a standalone surgeon, problems with staff members are easily resolved as you have the say about who stays and who goes, a luxury not always found in a group practice, says Dr. Hansen.

Tip: Before starting your own standalone practice, learn some basic business skills and try to gain a better understanding of the business of medicine,

even if it requires delaying the start of your stand-alone practice for a few years, Dr. Hansen says.

“My first recommendation is to take some time and learn some basic business skills, even if it means to be taking a night course,” he says. “I took every college course I could, every AMA ‘starting your practice’ course that I could. Learn some basic business skills, and learn the business of medicine just so that, particularly, if you’re on your own, you can maximize your earnings, you don’t make bad business choices, you don’t get the most expensive office and you’re able to make your rent payments.”

• **Call rotation flexibility**

As a standalone surgeon, you can choose to take emergency calls where you want to and with which organizations you want to affiliate yourself, a situation that may be determined for you if you were to join a group.

“The large group may have affiliations with a hospital system or a surgical hospital ... and then you’re in a position where you have to do your (cases) over there,” says Mr. Shoup.

On the downside, there’s no one to cover for your calls if you go away for vacation, which may limit how comfortable you feel taking time off.

• **Reputation is yours**

Your successes (or failures) determine the reputation of your practice. You do not have to worry about a poor decision made by a partner drastically

affecting your ability to run a successful business in the community.

“Your reputation stands by you,” says Dr. Hansen. “Your practice’s reputation is made by you; you don’t have to worry about someone else hurting your practice.”

Group practice

The work and stress needed to overcome the challenges of standalone practice can easily convince spine surgeons that a standalone practice is not in their interest and that joining an orthopedic group practice would be a better choice. While this scenario certainly alleviates some of the stresses of starting a practice, a spine surgeon interested in joining such a group must carefully weigh the benefits of this option and ensure the partnership they are considering allows enough freedoms and successes to make it a worthwhile alternative to entrepreneurship.

• **Reliable referral sources**

When you join a group, some of the stresses of forming strong referral relationships are instantly alleviated.

“There’s safety in numbers,” says Mr. Shoup. “Your referrals are such that another doctor is not going to change his referral patterns because he likes someone (outside of the group) better. The big group that you’re in has a vested interest in maximizing the billing opportunities for you to maximize the

partnership’s cash. There’s an intrinsic built in mechanism to go back and forth.”

Tip: You may still want to reach outside your group to establish relationships and receive referrals from other sources. If you do so, you will want to let the orthopedic surgeons in your group know that these referrals are not intended to help boost the orthopedic side of the practice.

“You’re going to want to say to your partners, ‘if Doctor Jones across the way sends me a spine, it’s very obvious that I’m going to send that patient back to Doctor Jones so he can understand that we’re not stealing his practice,’” says Dr. Abraham. “Spine is such a small fragment of overall orthopedic care that the group should not in any way be interested in using spine to market general orthopedics.”

• **Managed care piggybacking**

Oftentimes, one of the perks of joining a practice for a spine surgeon is the ability to gain access to the practice’s managed care plans, and therefore, have the ability to perform procedures immediately and get paid a good rate for the cases. Whether this is the case is an important question for the surgeon to ask when interviewing with a group.

“If I’m a neurospine guy and I’m looking to join a group, how quickly can I gain access to their managed care plans?” asks Mr. Shoup. “If I’m a new guy coming into town, will I be able to piggyback on their managed care plans?”



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• Getting paid fairly

The primary reason an orthopedic group will bring in a spine surgeon will be to keep in the spine business the surgeons were referring out. Spine surgery can be a very lucrative specialty, and a group can financially benefit by keeping the procedures in-house. How much it benefits is a potentially big issue of contention.

“The spine orthopods may be making considerably more than the general orthopod,” says Dr. Hansen. “There could be jealousy issues or they could be trying to average your income into theirs, which is not going to sit well for very long. The upfront issue of asking how the pay arrangement is going to be figured out is very, very important.”

When spine surgeons interview with a group practice, Dr. Hansen says it is important to ask financially relevant questions including the following:

- How do you get paid, and how is payment set up?
- Does everybody share the income? Is it pure productivity or some blended formula?
- What's your vacation time?
- What are your benefits?
- Are benefits weighted more toward the older guys? As you become the older guy, do you get some more benefits?
- What happens when someone retires? Does he or she get a payout? Are the remaining people expected to buyout the people who are leaving?

Tip: If a spine surgeon is displeased with the financial arrangement proposed by the group practice, it is not uncommon for him or her to receive an income guarantee that meets financial expectations but still lets the group reap the rewards of keeping the procedures within the practice.

If such an arrangement is acceptable for both sides, the spine surgeon may want to solicit the services of a lawyer to ensure a clear understanding of the components of the contract.

“Get yourself an attorney who is versed in health-care practices to review the contract,” says Dr. Hansen. “I would strongly recommend a contract so there's no misunderstanding and so it has enough details. If you're not interested in hiring an attorney, I would go to a much larger practice with younger guys, because they're more likely to have looked into those issues than if you're just joining one other guy who may want to take advantage of the younger guy. I think it becomes a lot more important to have an attorney if you're joining a much smaller group.”

While it is important for a spine surgeon to understand what he or she can expect as a base income, it is important not to overlook the value of joining a group practice and the costs that come with this partnership.

For example, with your increase in expenses, you can expect benefits that are going to be a little more generous for you and your staff.

“You can negotiate better arrangements with insurances, better arrangements with staff benefits because there are more of you and you have more buying power,” says Dr. Hansen.

There are also the benefits of joining a team that should already have well-qualified staff in place to handle essential processes such as billing and purchasing supplies.

“If I'm part of a big group, my drug and medical supply expenses are pretty much a given because they're already accounted for, somebody is already managing that need,” says Mr. Shoup.

• Understanding your costs

When running a standalone practice, the costs of running the business are fairly easy to understand and estimate since it's all limited to operations of a single surgeon and the staff. But when joining a group, trying to determine how much of a surgeon's income will go toward running the group practice's business is a little more challenging.

“When you get into a large group, you get into multiple layers of shared costs,” says Mr. Shoup. “I've heard numerous times from many different practices that shared costs have gone up incrementally because Doctor (Smith) has an entourage of people in satellite offices. I am an in-house surgeon at the main office without any satellite offices, and yet I have to share in the whole expense of the group.

“You need to look into and really estimate your costs,” he says. “While they may feed you your business, how much of it is going to get sucked out because of their operating expenses?”

Tip: It is essential to understand business when starting a standalone practice, but some knowledge in this area can also be of great benefit when joining a practice.

“Somebody in a group practice has to be a business man, and that person may not be around all of the time or may not want to do it, so it kind of behooves you to at least understand the business aspects for your own protection,” says Dr. Hansen. “If you don't want to be a business man, you don't necessarily have to, but it's a little risky not knowing anything.”

Taking some time to better understand the business of medicine can help spine surgeons make wiser decisions concerning their own work, and can also allow for better monitoring of the practice's expenses, which likely affects a portion of their incomes.

• Know your partners to determine creative flexibility

Joining a practice means more than just sharing office space. It also means that you're going to share a reputation with your new partners, and some of your partners may have particularly strong feelings about the types of procedures you should or should not be performing and the surgical methods you employ.

“You need to know your partners, know their reputation,” says Dr. Hansen. “Do they do things that you do? Are they going to be comfortable with you

doing something differently from how they're trained if you came from a different program? You should get to know the philosophy of the group, what they expect of you, what freedoms you are going to have to do your own procedures.”

If your partners have strong beliefs about how they perform procedures and expect you to emulate their methods, you may be able to learn from their techniques. The downside is that you may find yourself abandoning some of your training to conform, making you feel like a resident again, with your partners as the attending physicians, says Dr. Hansen.

Tip: The only way to gain an understanding of your partners' expectations is to interview all of your potential colleagues, says Dr. Hansen.

“Bring up those issues because that's not something that comes out in the open when you're talking,” he says. “Can you be more cutting edge and try new things? Ask what kind of procedures they do because some people do certain things, others do not. How do they do certain procedures (if there's more than one way)?”

Tip: If you want to develop a spine niche in a group practice and essentially become a sub-specialist, Dr. Hansen suggests looking for a strong group that already has sub-specialists in different areas so your vision is more likely to be understood and accepted.

• Call rotation inflexibility?

If you join a group practice that already has spine surgeons, determining coverage for you when you go away shouldn't be a big headache. But if you are the only spine surgeon in a practice and are interested in traveling for an extended period of time, requesting that your orthopedic partners cover for you may cause problems.

“If you're an orthopedic/spine fellow joining a general orthopedics group, you need to determine how coverage is going to be handled, because not all of these orthopods may be comfortable covering some spine procedures,” says Dr. Hansen. “If you're gone for vacation for two weeks and you're the only spine guy, they may not be comfortable handling it.”

Another challenge a spine surgeon joining an orthopedic group practice may face is that the orthopedic surgeons may view the spine surgeon's arrival as another body to take on some of the orthopedic call responsibility. If this is not something the spine surgeon intends to do, this issue must be discussed before the surgeon's joining the practice. ■

Contact Rob Kurtz at rob@beckersasc.com.

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4 Observations on Orthopedic and Spine Devices and Equipment

By Stephanie Wasek

Here, John Cherf, MD, MPH, MBA, one of the nation's leading orthopedic surgeons, discusses his thoughts on purchasing orthopedic and spine devices and equipment in four areas.

1. Total joints. "Orthopedics companies have become very consolidated," says Dr. Cherf. "In terms of the joint replacement hip and knee business, three companies have 70 percent of the market share: Stryker, Zimmer and DePuy. Add two more companies — Biomet and Smith & Nephew — and you're at 95 percent. Total joints are historically perceived as commodity products; new technologies have been heavily promoted, such as alternative-bearing and resurfacing.

"But I think we're going to enter a new era in which providers really focus on usability and cost of service. And the reason is that there's no good data to differentiate these products."

The takeaway is that you should focus on ease of use, and get your physicians to agree, ideally, on one vendor whose product provides this, so the administrator can focus on keeping costs low.

2. Sports medicine. "On the sports medicine side, Arthrex is very innovative, and technology-driven, always pushing the envelope, and as a result dominates the space," says Dr. Cherf. "On the knee side, there's the all-inside arthroscopic technique with minimal incisions for ACL and PCL reconstruction. Arthrex also has some interesting shoulder technology: The TightRope, which was originally designed for ankle surgery, is an innovation for minimally invasive shoulder surgery."

3. Spine. "On the spine side, Medtronic has over 55 percent of market share, but this area is really the wild, wild west," says Dr. Cherf. "There's a lot of new technology, the long-term data is limited, and the utilization of procedures is growing extensively. The payors are likely to continue to examine these new technologies in terms of cost and utilization. Moving forward, I think MIS is kind of a mature sector, and we're going to see a lot of activity focusing on pain management and making patients comfortable as an adjunct to spine procedures."

4. Biologics. "I also think we're going to see increased activity on ortho-biologics and other methods for targeting disease earlier," he says. "Even though there's not a lot of data supporting it right now, biologics is the future, and that's where we're going to see the greatest dividends over the next decade." ■

Dr. Cherf (jcherf2002@kellogg.northwestern.edu) is a board-certified orthopedic surgeon who maintains a multidisciplinary practice focusing on musculoskeletal medicine with a focus on knee and shoulder disorders at the Neurologic and Orthopedic Hospital of Chicago.

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 ambulatory surgery centers (ASC) 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 5,800 ASCs in the United States. Of these, approximately 900 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 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

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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 overutilize 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 recent 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 Jan. 2008, the New Jersey Board of Medical Examiners elected to move forward on an emergency rule in response to these recent cases.

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 has been protected by both the 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).

With that said, the change in the make-up of the House, the Senate and the White House is not beneficial to 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

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5 Business Challenges Orthopedic Practices Face

By Scott Becker, JD, CPA, and Stephanie Wasek

Don Love, the CEO of an orthopedic practice in Roanoke, Va., and Ken Austin, MD, an orthopedic surgeon in Ramsey, N.J., share their insights on key business challenges orthopedic physicians are currently facing. Five of the largest challenges facing orthopedic practices include (1) decreasing Medicare and Medicaid reimbursement; (2) decreasing third-party reimbursement; (3) difficulty recruiting physicians and staff; (4) increasing hospital competition and recruitment; and (5) the need to develop ancillary services and revenues.

1. Medicare and Medicaid practice payment cuts. Physicians are facing drastic impending cuts to their professional fees.

Medicare's sustained growth rate which is used to calculate payment rates is flawed," says Mr. Love. "We have faced these incredible cuts in reimbursement that have been delayed over the last several years, but the formula is still in place. What's more ... there will be double-digit reductions for professional fees. The impact of those reductions will be very significant, especially for Medicare and Medicaid."

Mr. Love says a potential effect statewide and nationally is that physicians may limit the number of Medicare and Medicaid patients they're treating or opt out of Medicare altogether. There will also be a ripple effect on commercial payor contracts if they are tied to the federal rates, he reminds.

This decrease will make it all the more important to separately focus on the increasing number of patients who are taking part in high-deductible health plans as part of the push for consumer-driven healthcare.

"We are investing more in overhead and labor hours to prepare, because this movement puts the onus on us to screen thoroughly for treatment," says Mr. Love. "The patient must understand what his financial responsibility will be with regard to payment — especially to payment up front — so that he isn't hit with an unexpected bill and we ensure payment for services when they are rendered. We're also making use of technology to ensure we capture our charges accurately and bill appropriately and stay in compliance with our contracts.

"Purely from a billing point of view, it's more complex and your coders have to be more astute to ensure your practice is not missing charge opportunities when physicians perform services."

2. Contracting with third-party payors. Orthopedic and surgical practices are again facing significant challenges from large payors. Large payors are making aggressive efforts to "rebalance" payments. In practice, this means they are attempting to pay less to proceduralists and more to those who

provide evaluation and management services for independent orthopedic practices, where a great percentage of revenues come from procedures.

This renewed effort, combined with increasing payor leverage in many markets, has the ability to greatly decrease orthopedic revenues in the short and long run.

3. Recruiting clinical and business office staff. "Recruitment is always a challenge," says Mr. Love. There are a sufficient number of physician assistants to meet the demand for the present, but "there are fewer orthopedic physicians nationwide, and hiring a physical therapist or physical therapy assistant is just about impossible these days. It's an ongoing challenge to have skilled support staff, coders and insurance billers, reception and front desk staff — you need good people all the way down the line."

In addition to demonstrating to prospective physicians, clinical staff and business office employees that your practice employment is dynamic and growing — adding ancillary services, for example — offering training support is good for recruiting and retaining, as well as key for keeping your facility on the cutting edge.

"Training is becoming more critical for providing staff with the skill sets to be successful, and to give patients excellent care and service," says Mr. Love. "For example, we embarked on EMR a couple years ago, and it's been filled with challenges; but you have to pay to train staff in order to implement new technology and keep their skills and your facility up to par."

4. Changing relationships with hospitals; achieving détente with hospitals. Hospitals are again flexing their muscles in their relationships with physician practices. Over the last two to three years, hospitals have refocused their energies on acquiring and employing orthopedic and neurosurgical practices. Here, the efforts are more directed today on focused, high-revenue practices as opposed to primary care practices. This effort, in many markets, has come with the attitude implied or explicit that there is no longer room or will not be in the long run room for truly independent practices.

"For a long period of time, hospital administrators were not attentive to the needs of surgeons; they took what we did and how we did it for granted, which led to a great deal of frustration," says Dr. Austin. "When we had an opportunity to set up our own facility with our own protocols and oversight, we jumped at it. And it's worked out better than we possibly could have imagined. It proved we could do what we wanted more efficiently."

Hospitals have not always taken well to these kinds of practice driven successes. However, as time has

gone on and outpatient surgical facilities have become more integrated in healthcare, hospital administrators are "starting to get it, and understand how ambulatory surgery centers (ASC) can be beneficial to them," he says.

While the opening of an ASC can alter the relationship between hospitals and surgeons to become more competitive in nature, it doesn't have to be that way if each side recognizes what the other brings to the table.

"There are still a lot of orthopedics cases that can only be done in the hospital, that require appropriate post-op monitoring, such as joint replacements, fractures, traumas — these just aren't geared for the ASC," says Dr. Austin. "The ASC doesn't answer all the needs of the medical community. We have different functions, different efficiencies, and as long as those are realized and appreciated, each can thrive in its own area. From our perspective, the hospital is not considered a competitor, but an ally and a complement.

"As a result, we support the hospital regularly, donate to causes, present at charity functions. We could not do what we do without a hospital, which is a necessary element of any community — the stronger the hospital is, the stronger we are."

5. Developing ancillary services. Orthopedic groups are increasingly looking to offer a range of integrated services to their patients, including MRI and physical therapy, under the same umbrella as the practice. Ancillary services may also include ASCs and physician-owned hospitals.

"With the professional fees component going down, other revenue sources, such as PT, MRI, ASCs, durable medical equipment sales, bone density screening and others are increasingly important, but development of those ancillary income streams come with their own challenges levied on them," says Mr. Love. "For groups such as ours in certificate of need states, it can be very costly to pursue [a CON to add services] only to be turned down. And, in some states, the physical therapist association has been effective in getting physician-owned PT practices banned."

Roanoke Orthopaedic Center's ancillary services include an osteoporosis program that includes bone density testing, physical therapy, dispensing durable medical equipment, and it continues to explore further options.

"Some groups doing durable medical equipment sales are taking it to the next level: A group in Charlotte, N.C., is doing retail DME," says Mr. Love. ■

Contact becker@beckersasc.com.

New Report Examines Hospital-Physician Relationships and Arrangements to Secure Successful Alignment With Physicians

A new report examines the trends driving a shift in hospital-physician relationships and profiles the arrangements that can be adopted to secure successful, long-term alignment with the physician workforce.

The report is the result of a collaborative effort between Sg2, a leading international, future-focused healthcare intelligence company providing expert-led resources, tools and education to enhance maximize clinical effectiveness, and McGuireWoods, a leading law firm with one of the largest healthcare departments in the country.

The report, *Accelerating Hospital-Physician Collaboration 2008*, offers steps for developing each arrangement, and the benefits and challenges of each arrangement are summarized. It also presents leading practices and lessons learned from successful alignment initiatives.

The collaborative effort was led by Jillian Addy and Bill Woddson from Sg2, and Tom Stallings, JD, Kristian Werling, JD, Elissa Moore, JD, Scott Becker, JD, CPA, and Amy Nolan from McGuireWoods.

Request a copy of the report at by emailing Scott Becker at sbecker@mcguirewoods.com.

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3 Hot Spine Device Trends

By David Abraham, MD

New technology in the spine market is expanding faster than the size of the universe. There are three main areas of focus.

1. Interspinous process devices. These devices treat lumbar spinal stenosis; they are placed between the spinous processes to separate the bones and indirectly decompress the stenotic lumbar spinal canal. Lumbar spinal stenosis produces the symptoms of intermittent neurogenic claudication, which usually appears in elderly patients and is clinically characterized by difficulty with prolonged standing and walking, relief upon sitting down, and improvement in symptoms with lumbar spinal flexion (the so-called shopping cart position).

These new devices are a hot topic at the national spine meetings and are attracting much enthusiasm and financial support. Clinically, the only device that's currently FDA-approved is the X-Stop produced by Kyphon, which was recently acquired by Medtronic Danek for \$3.9 billion (yes, with a B). This company's only other product is the Kyphoplasty Balloon, which is used to expand osteoporotic compression fractures in the elderly.

These interspinous process devices are being marketed as "minimally invasive" in that they typically require only a 1-in. incision and are completed in less than 30 minutes. The brochure describes performing

the surgery under local anesthesia, although I don't know of anyone who does this. The technique involves separating the paraspinal muscles down to the level of the lamina, inserting the device between the bones and securing it with a fixation wing.

Other companies are trying to develop percutaneous devices, but none have sought FDA approval. Within 36 months, I expect there to be three to six devices that will be the second generation of this technology.

2. Artificial cervical disc. Cervical degenerative arthritis is a very common clinical problem, and artificial cervical disc technology stands to offer significant treatment options for people who suffer from cervical radiculopathy. The current standard of care for a cervical herniation involves an anterior cervical discectomy and fusion, usually using a plate and allograft. In 2007, a cervical disc was approved by the FDA for use. A recent prospective randomized trial comparing a cervical fusion to the cervical artificial disc demonstrated similar clinical improvements by the two treatments. The hope is that long-term studies will prove that preservation of motion will lessen the wear and tear on the discs next to the surgical area; this may take a decade to prove.

The cervical disc may have difficulty gaining approval from private payers, since the technology is

theoretically related to its cousin, the artificial lumbar disc. The lumbar disc had high expectations when it was launched in 2005, but estimates about its sales volume were off by 90 percent. Insurance companies simply are not allowing patients to have access to this lumbar technology, and I'm not sure they will allow access to cervical discs, citing concerns about long-term durability and use.

3. Dynamic spine stabilization devices. Finally, the issue of dynamic stabilization of the spine must be mentioned in this discussion. I admit I have great difficulty discussing this topic with enthusiasm, because I do not believe in the technology or in the language used to support its use. Basically, the technique consists of surgeons' placing elastic devices after decompressions to stabilize the motion segment but not fuse it — they use the term "soft fusion." While this topic has garnered a lot of press and titled many meetings, I don't think it will come to fruition as widespread clinical practice. In fact, a recent article in the journal *Spine* discredited its use after follow-up studies evaluated the high frequency of post-op device complications. ■

Dr. Abraham (abrahamatrnsc@aol.com) is a spine surgeon at the Reading Neck and Spine Center in Wyomissing, Pa.



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3 Spine Products to Know With Neurosurgeon Dr. James B. Macon

By Rob Kurtz

James B. Macon, MD, a neurosurgeon based in Framingham, Mass., who performs surgical procedures at several west suburban Boston hospitals and whose practice is dedicated to spine and pain surgery, discusses three new spine products which have benefited his practice.

1. Holmed Swivel Port System

The Holmed Swivel Port System, designed by South Easton, Mass.-based Spine Surgical Innovation (with Dr. Macon serving as the design consultant), was developed to give spine surgeons minimally invasive access to the spine while cutting down on potential morbidity associated with some muscle dilator tubular access systems, Dr. Macon says.

In other systems, “the initial placement of the dilator — in order to achieve access to the spine — usually involves putting a sharp K-wire down to the spine,” he says. “That K-wire, if it’s not watched very carefully under x-ray control with fluoroscopy, can get pushed into places you don’t want it to go such as into the spinal canal or into a nerve root. Also, the inner dilator is fairly small — small enough to go into the spinal canal and cause nerve root or spinal cord injury.”

The Swivel Port System eliminates both the use of the K-wire and dilators and improves spinal access, says Dr. Macon. The way the device works is that following an incision, a blunt instrument such as a Penfield dissector is used to split the muscle, as opposed to the use of a K-wire. After the dissector has reached the spine, biplane fluoroscopy confirms the proper level and trajectory for the port placement. Once the muscle is split, a Cobb periosteal elevator is inserted to scrape the muscle and ligament off the intended docking area for the port that will provide access to the spine for the surgeon.

The Swivel Port System works like a hand-held retractor when closed and becomes a tube when opened. The retractor is placed through the muscle split down to the bone. What makes the Swivel Port System different from other systems is that rather than using dilators to obtain access to the spine, this system uses blades that are opened by rotating (swiveling) the port base. The blades on the port have a flange which prevents the port from migrating out once positioned, Dr. Macon says.

“We open the port by turning the blade at the port base using a ring-type device that fits over the port,” he says. “Once the port is open, then we put in expander blades, and they allow increased exposure and minimize muscle creep so we can see more than just a straight cylindrical tube and yet you have eliminated the dilator and the K-wire problems, so it is safer and very fast to insert. You just split the muscle, put it in and you open the port with the ring. It’s both safe and provides excellent exposure.” In addition, the port can be fixed to the operating

table with the handle attached to a flexible arm. This arm can then be firmly attached to an operating table, allowing a surgeon to position the trajectory of the port in different angles, even changing the trajectory angle during a procedure. This allows a surgeon to perform procedures such as multiple-level decompressions through one port placement, Dr. Macon says.

The Swivel Port System includes a number of retractors with blades of varying sizes which allow for a wide range of procedures, he says. These include minimally invasive posterior decompressions in the lumbar spine such as microdiscectomies and foraminotomies as well as large decompressions such as two-level laminectomies or fusions and pedicle screw fixations from the postlateral approach.

While the long-term outcome might not be different from other open approaches, Dr. Macon has found that the minimally-invasive approach has much less morbidity in the short term. He also notes that a particularly interesting trait about the Swivel Port System is that it actually has greater benefits for obese patients. “In the Swivel Port technique, there’s no change in the incision size — the port just gets longer to accommodate the depth of the incision,” he says. “Those patients who are larger benefit the most from this particularly procedure because they have much smaller incisions and less risk of wound problems than when standard open exposures are used. It’s really a paradox that the larger the patient the smaller incision is better. This is one of the surprising benefits of the minimally invasive approach to the spine.”

2. SpineJet HydroDiscectomy

The SpineJet HydroDiscectomy was developed by HydroCision, which is based in North Billerica, Mass. This device essentially allows a surgeon to make incisions using a water jet. “The SpineJet MicroResector can be placed in a disc space for removing discs either percutaneously through a cannula or through the Swivel Port,” he says. The SpineJet MicroResector will perform a microdiscectomy through a very small incision with a minimal annulotomy.

“The HydroCision discectomy is an interesting adjunct for a surgeon wanting to perform outpatient spine surgery for contained lumbar disc protrusions,” Dr. Macon says. “I have successfully used this technique for lumbar microdiscectomies.”

Dr. Macon also finds the use of HydroCision’s SpineJet XL curette beneficial. He uses this device to prepare the disc space for receiving an inter-body fusion when performing lumbar transforaminal interbody fusions through the Swivel Port.

“There are several different handles which you can use for different parts of your operation,” he says. “I

developed a bayonet handle for the curette and microdiscectomy device which allows use through the Swivel Port without obscuring your vision. Initially, their system was just a straight handle that blocked your vision when used with tubular access systems.”

3. Allen Spine System

The Allen Spine System developed by Allen Medical Systems in Acton, Mass., is an extension attachment that connects to a standard operating room table and allows a surgeon to perform spine procedures in an optimal position with no interference of the fluoroscopic imaging required for accurate placement of the Swivel Ports, Dr. Macon says. The Allen Spine extension attachment also offers excellent padding for patients which decreases the likelihood of pressure sores and other complications of lying in a prone position for spine procedures.

“The Allen Spine System is a very good product for an outpatient center because it is cost-efficient for the facility,” Dr. Macon says. “Because it’s not a whole table and can be attached to the operating table we already have, it is less expensive than competing products.” ■

Contact Rob Kurtz at rob@beckersasc.com.

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At a Glance: 6 Top Orthopedic Device Companies

Here are brief profiles of six manufacturers that are among the world's largest medical device companies; in addition, these six (listed alphabetically) are those from which orthopedic-driven ASCs and hospitals purchase much of their orthopedics-surgery related products.

DePuy Orthopedics (a division of Johnson & Johnson)

The largest and most diversified of the world's healthcare companies, Johnson & Johnson was founded in 1886. Today, with operations in 54 countries, and sales in more than 175 countries, it is the premier purveyor of more than 200 medical devices, including orthopedic and spinal products. J&J is also a global leader in the sales of pharmaceuticals and packaged consumer healthcare goods. Its stock is traded on the New York Stock Exchange (NYSE) (symbol: JNJ). During fiscal 2007, Johnson & Johnson acquired two healthcare companies: Conor Medsystems, a cardiovascular device company with new drug delivery technology, and Robert Reid, a Japanese orthopedic product distributor. In Oct. 2008, Johnson & Johnson acquired HealthMedia, an online health counselor. DePuy's U.S. headquarters is in Warsaw, Ind.

Medtronic

Founded in 1949, Medtronic is one of the leaders in innovative medical technologies and surgeries, with focus on diagnosis, prevention and monitoring of chronic conditions. Among the firm's innovations of special interest to orthopedic surgeons are its bone graft and Minimal Access Spinal Technologies and image-guided surgical navigation procedures. The firm, headquartered in Minneapolis, Minn., sells its products in more than 120 countries. Its stock is traded on the NYSE (symbol: MDT). In Oct. 2007, the Company launched the CD HORIZON LEGACY Anterior Spinal System and in July 2008, Medtronic completed the acquisition of Restore Medical, manufacturer of devices to treat sleep-disordered breathing.

Siemens Medical Solutions

Siemens Medical Solutions provides a comprehensive mix of consulting services, including a variety of orthopedic-related devices and equipment. Among the innovative "firsts" developed by Siemens are the first x-ray tube patent, the first hearing aid with amplification adjustability, the

first real-time ultrasound, the first whole body fast volume Spiral CT and the first PET-CT hybrid scanning system. Based in Erlangen, Germany, the firm was founded in 1877. Siemens AG stock is traded on the NYSE (symbol: SI).

Smith & Nephew

Smith & Nephew's orthopedics division is a global provider of leading-edge joint replacement systems for knees, hips and shoulders, as well as devices for orthopedic trauma procedures. The specialist market helps drive the company's annual \$3.4 billion in sales, according to the company, by continuously developing new materials and techniques to meet the growing demands of procedures and facilities for tougher, long-lasting implants and less-invasive, faster-to-heal surgical products for use across patient populations. Smith & Nephew was founded in 1856 and is headquartered in the United Kingdom. It is now the UK's largest medtech company and one of the top companies in its field in the world. Their units jointly offer over 1,000 product ranges. It is traded on the NYSE (symbol: SNN).

Stryker Corp.

Stryker Corp., another industry leader, manufactures and sells a diverse product mix of medical and orthopedic devices in the domestic and global marketplace, including hip, knee and upper extremity replacement prosthetics, and spinal implants. The firm is also noted for its development, manufacturing and sales of video-assisted-surgical systems, powered surgical and collateral equipment and instrumentation for minimally invasive surgery. Among its innovative products is Endosuite, a functioning OR suitable for use in virtually all specialties. It has headquarters in Kalamazoo, Mich. Stryker is traded on the NYSE (symbol: SYK).

Zimmer Holdings

In 2003, Zimmer Holdings acquired Swiss-based Centerpulse, and became Europe's leading orthopedic device company. With its U.S. base in Warsaw, Ind., the company markets its products in more than 80 countries. The company specializes in the development and manufacturing of reconstructive implants and devices for spinal applications, and for knee, hip, shoulder and elbow joints, and related orthopedic surgery products. The firm is noted also for its innovation and the fast-growing spinal segment of its business. Founded in 1927, Zimmer Holdings stock is traded on the NYSE (symbol: ZMH). In April 2007, Zimmer Holdings acquired Endius, a company focused on minimally invasive endoscopic spine surgery systems, and in Nov. 2007, it acquired ORTHOsoft. In Oct. 2008, the company acquired Abbott Spine, a manufacturer of spine implants. ■

By Marc Davis, with additional research by Ariel Levine

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Office of Inspector General Issues Advisory Opinion: Physician/Hospital Orthopedic ASC Joint-Venture

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

The Office of the Inspector General recently issued Advisory Opinion 08-08. This Advisory Opinion deals with a physician/hospital joint-venture surgery center. Here, the Advisory Opinion was requested because certain physicians who invested in the joint-venture were themselves not “safe harbor” compliant. In essence, some of the physicians practice principally in an inpatient setting. The OIG, based on the number of prophylactic steps and the overall facts, determined that the joint venture would pose minimal risk of abuse under the Anti-Kickback Statute. Scott Becker, JD, CPA, and Melissa Szabad, JD, of McGuireWoods served as counsel to the requesting center. Tom Mills and Marion Goldberg of Winston and Strawn and Neal Goldstein of Much, Shelist were also instrumental in assisting the center to obtain the opinion.

It reasoned as follows:

1. Use of pass-through entity

“First, the Arrangement does not qualify for the protection of the hospital/physician-owned ASC safe harbor, because the Surgeon Investors do not hold their investment interests in the ASC either directly or through a group practice composed of qualifying physicians. Rather, the Surgeon Investors hold their individual ownership interests in the Surgeon Partnership. The Surgeon Partnership, in turn, holds an interest in the Company that owns and operates the ASC. We have previously expressed concern that intermediate investment entities could be used to redirect revenues to reward referrals or otherwise vitiate the safeguards provided by direct investment, including distributions of profits in proportion to capital investment. However, in this case, the use of a ‘pass-through’ entity does not substantially increase the risk of fraud and abuse. Each Surgeon Investor’s ownership in the Surgeon Partnership is proportional to his or her capital investment.¹ The Surgeon Partnership’s ownership interest in the Company is, in turn, proportional to its capital investment. Thus the individual Surgeon Investors receive a return on their ASC investments that is exactly the same as if they had invested directly.”

2. Four surgeons don’t pass one-third tests

“Second, four of the eighteen Surgeon Investors (the Inpatient Surgeons) fail to meet the safe harbor requirement that at least one-third of a physician investor’s income from medical practice for the previous fiscal year or previous 12-month period be derived from the performance of ASC-Qualified Procedures.² This ‘one third’ test helps ensure that the safe harbor applies only to investment income to physicians who are unlikely to use the investment as a vehicle for profiting from their referrals to other physicians using the ASC. Safe harbor protection is limited to physician-investors who, because they perform a substantial number of ASC-Qualified

Procedures, are likely to use the ASC on a regular basis as part of the medical practices.”

3. Rare referrals; all surgeons; small portion of total surgeons

“In the circumstances presented, notwithstanding that four Inpatient Surgeons will not regulatory 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 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).³ Moreover, like the other Surgeons 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 who 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 a cardiologist invests in a cardiac surgery ASC.”

4. Pain management

The OIG also comments on the fact that the physicians certified that no surgeon investor would refer patients for pain management procedures (i.e. “indirect referrals”) unless he or she personally performed the surgery.

“As noted above, the Inpatient Surgeons do have occasion to refer patients for pain management procedures that are ASC-Qualified Procedures. This raises the possibility that an Inpatient Surgeon or other Surgeon Investor might refer patients to other practitioners for pain management procedures performed at the ASC, for the purpose of generating a facility fee for the ASC. The Requestors have certified, however, that no Surgeon Investor will refer patients for pain management procedures to be performed at the ASC, unless the procedure is to be performed personally by the referring Surgeon Investor. This serves to mitigate the potential for abusive referrals, with regard to this type of procedure.”

5. Hospital prophylactic steps

The Advisory Opinion also commented positively on the steps taken to avoid the hospital driving referrals to the venture. Here, the arrangement included certain commitments limiting the ability of the hospital corporation to direct such referrals.

“Third, the Arrangement does not qualify for the safe harbor for ASCs jointly owned by physicians and hospitals, because the Hospital Corporation is in a position to make or influence referrals to the ASC and to the Surgeon Investors. However, the Arrangement includes certain commitments limiting the ability of the Hospital Corporation to direct or influence such referrals. The Hospital Corporation refrains from any actions to require or encourage Hospital-Affiliated Physicians to refer patients to the ASC or to its Surgeon Investors; it does not track referrals, if any, by Hospital-Affiliated Physicians to the ASC or to its Surgeon Investors; any compensation paid to Hospital-Affiliated Physicians is at fair market value and does not take into account any referrals Hospital-Affiliated Physicians may make to the ASC or to its Surgeon Investors; and the Hospital Corporation informs Hospital-Affiliated Physicians annually of these measures. In light of these safeguards, the ability of the Hospital Corporation to direct or influence referrals to the ASC is significantly constrained.”

6. Limitations on indirect pain management referrals; full disclosure to patients; hospital steps

This is the type of advisory opinion that a couple of years ago should have been extremely easy to attain. However, currently, the OIG has expressed great concerns with both indirect referrals and is also concerned regarding issuing advisory opinions which may serve as examples or precedent to others. Currently, it takes a great deal longer than would have otherwise been anticipated to receive an opinion.

“There are eighteen Surgeon Investors, of whom fourteen meet the following test: Each received at least one-third of his or her medical practice income for the previous fiscal year or previous 12-month period from the performance of procedures payable by Medicare when performed in an ambulatory surgery center (“ASC-Qualified Procedures”). The four remaining Surgeon Investors (the “Inpatient Surgeons”) do not meet this test. Each of the Inpatient Surgeons derives at least one-third of his or her medical practice income from procedures requiring a hospital operating room setting, but receives little or no medical practice income from the performance of ASC-Qualified Procedures. The Requestors have certified that the Inpatient Surgeons rarely have the occasion to refer patients to other physicians for ASC-Qualified Procedures, except for pain management procedures. The Requestors also have certified that none of the Surgeon Investors will refer patients for pain management procedures to be performed at the ASC, unless the pain management procedure is to be performed personally by the referring Surgeon Investor.

“The Surgeon Investors inform patients of their ownership interest in the ASC by posting notices in the two offices in which Surgeon Investors practice and through a written notice to each individual patient.

The Requestors have certified that, in the future, in the absence of exigent circumstances, such written notice to individual patients will be provided prior to the date of the procedure in the ASC.

“The Hospital Corporation is in a position to make or influence referrals to the ASC. The Requestors have certified that, in order to limit such ability, the Hospital Corporation has refrained and will refrain from any actions to require or encourage physicians who are employees independent contractors, and medical staff members (‘Hospital-Affiliated Physicians’) to refer patients to the ASC or to its

Surgeon Investors, and has not and will not track referrals, if any, by Hospital-Affiliated Physicians to the ASC or to its Surgeon Investors. The Requestors have further certified that any compensation paid by the Hospital Corporation to Hospital-Affiliated Physicians has been and will be consistent with fair market value and has not been and will not be related, directly or indirectly, to the volume or value of any referrals Hospital-Affiliated Physicians may make to the ASC, its Surgeon Investors, or the Surgeon Group. The Hospital Corporation will inform Hospital-Affiliated Physicians annually of these measures.” ■

Mr. Becker (sbecker@mcguirewoods.com) and Ms. Szabad (mszabad@mcguirewoods.com) are attorneys for McGuireWoods.

¹ We express no opinion with regard to any future sales of membership interests in the Surgeon Partnership that may result in individual investors having ownership interests that are not proportional to their investment.

² The safe harbor for hospital/physician-owned ASCs (42 C.F.R. § 1001.952(r)(4)) incorporates by reference this requirement of the safe harbor for surgeon-owned ASCs (42 C.F.R. § 1001.952(1)(ii)).

³ If this certification proves incorrect, this advisory opinion is without force and effect.

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