

THE PANEL:



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Ask the

Experts

A QUESTION & ANSWER EDITORIAL ON ISSUES RELATED TO ASCs

GIVEN THE CURRENT POTENTIAL HEALTH CARE REFORM LEGISLATION, WHAT DO YOU THINK WILL BE THE IMPACT ON ASCs IN BOTH THE SHORT- AND LONG-TERM?

LEVINE: Because of the sheer size and complexity of the health care reform legislation, I don't think anyone knows for sure what its impact on ASCs will be. However, at the very least, to the extent more people will subsequently be covered by health insurance, the potential patient population for ASCs will increase.

SABLE: In the short-term, I see little effect except for a slow decrease in the ASC's income. The impact will be worse for GI as most GI procedure ASC rates will decrease further in 2011. ASCs that are not limited to endoscopy may see some increase in payments: Orthopedics, OB/GYN, ENT and Urology. Additionally, ASCs in general must prepare for quality reporting measures in the future.

COLEMAN: With respect to the long-term impact of health care reform legislation on ASCs, there is a growing awareness among all elements of the health care community that the ASC is a more efficient venue for most cases. Given the efficiency of the ASC, there are now a large number of new cases entering the ASC arena from the hospital, especially in the area of orthopedic and spine surgery. The combination of the general consensus that the ASC is a more efficient venue, as well as the increase in new cases, bodes very well for an increase in not only total case volume of the ASC, but also in the total reimbursement. Regardless of the form of health care reform, the ASC will play a pivotal role in the reform process because, in addition to combining the aspects of efficiency and economy, the ASC setting offers a very high quality of care (patient safety, infection control, and performance improvement).

With respect to the short-term impact of health care reform legislation on

ASCs, there are three changes of direct interest to ASCs in pending health reform bills. First, the bills would reduce inflation adjustments made annually to Medicare payments, which would have the result of lowering Medicare payments to ASCs for years to come. While these adjustment reductions are relatively modest, between 1.0 and 1.5%, they come on the heels of six years of no inflation adjustments for ASC payments.

Second, the bills could require ASCs to begin submitting cost reports. Such a requirement would not only be an additional and possibly difficult administrative burden for ASCs, but to the extent the data shows ASCs with substantial margins, Congress or CMS could further reduce Medicare payments to ASCs.

Finally, the bills start a move toward value-based purchasing, where Medicare payments to facilities would be adjusted based on a facility's performance vis-a-vis its peers.

These are just the changes of direct impact. ASCs also would be less directly, but perhaps no less significantly impacted by changes to other provider-types, especially hospitals, which may alter the competitive landscape for ASCs.

WITH ACCOUNTABLE CARE ORGANIZATIONS PROMINENTLY FEATURED IN MANY HEALTH CARE REFORM PLANS, ARE ASC JVS WITH HOSPITALS BETTER POSITIONED IN THE HEALTH CARE REFORM ENVIRONMENT?

LEVINE: Whether or not they have hospital partners, ASCs have established practices and protocols which enable them to deal with quality assurance and utilization review issues more effectively than other types of practice entities. Accordingly, ASCs seem to be well-positioned to respond to the requirements of accountable care organizations.

SABLE: "ACOs" are created to encourage teamwork by providers to deliver efficient care. Many believe that the healthcare system is filled with duplication of services as well as medical procedures of uncertain value. The savings generated by teamwork would be shared by the payers, the doctors and the hospitals involved in the organizations. ACOs would be paid more if they delivered efficient, high quality care as opposed to being paid for the volume of procedures they do. Affiliations of providers such as hospitals and physician practices would allow such coordination. The joint ventures with hospitals that also have a healthcare network would allow tracking of procedures to prevent unnecessary duplication within the network and use quality indicators to ensure proper utilization.

COLEMAN: Yes. Both the House health reform bill, H.R. 3962 (Afford-

able Health Care for America Act), and the Senate version (Patient Protection and Affordable Care Act), include provisions (House Section 1301 and Senate Section 3022) establishing Accountable Care Organizations (ACOs). ACOs are provider-centric organizations focused on the costs and quality of care received by a designated population of patients over time. ACOs can consist of vertically and horizontally positioned providers, including physician groups, hospitals and ASCs. In its most basic concept, although paid on a fee-for-service basis, ACOs that meet quality-of-care targets and reduce the aggregate costs of care rendered to their patient population relative to a spending benchmark are rewarded with a share of the savings they achieve for the Medicare program.

ACOs seek to achieve the goals of improving quality and controlling costs by offering bonus payments for the achievement of cost and quality benchmarks across patient populations and care-delivery settings. ASCs that have already entered into JVs with hospitals are ideally situated to take advantage of the enhanced reimbursement opportunities that participation in an ACO may provide. These ASCs have already tackled many of the legal and operational issues related to integrating care delivery. Furthermore, they may already have relationships with third-party payers that could be converted into ACOs without significant additional investment by the JV or third-party payer. These existing relationships may make these ASCs able to act more quickly to participate in newly-created private sector ACOs or public payer ACO demonstration projects.

Regardless of whether health reform legislation is passed, providers will be increasingly challenged to adopt operating models through which they are

responsible and accountable for the quality, cost and overall care of a defined population of patients. Emphasis will be placed on clinical processes and outcomes, the patient care experience and utilization. Because the ASC operating model achieves lower costs while still providing high-quality care, ASC JVs with hospitals are ideally positioned to succeed in the current regulatory environment given the recent emphasis in controlling costs and increasing quality.

WHAT DO YOU CONSIDER THE BENEFITS AND DOWNSIDES OF MOVING FROM OFFICE-BASED PROCEDURES TO AN ASC ENVIRONMENT?

LEVINE: ASCs generally offer superior facilities, equipment, staffing and emergency response measures compared to the typical office-based surgery environment. On the other hand, some patients find them more impersonal compared to having procedures done in their physician's office.

SABLE: The benefits of moving procedures to an ASC include the ability to maintain certification in a world of ever-increasing regulation in a cost effective manner. The proper operation of an ASC also provides an increased safety level for patients. The economy of scale allows for the necessary quality management programs and for obtaining supplies at discounts based upon volume. The money needed to generate an elegant surrounding for patients and customer service is provided in this setting. The downside is the decrease in professional fees that one receives and the increase in co-pays that some insurance companies impose on patients for the facility fees. Of course, in the office setting, some of the increased professional fee is for the overhead that must be absorbed since there is no facility fee. If the physician has an ownership interest

in an ASC, the facility fee income offsets some of the professional fee decrease. If one offsets the increased office professional fee by the increased office overhead and then considers ASC ownership income, the actual income to the physician is not higher by remaining in the office setting.

COLEMAN: One of the benefits of moving from office-based procedures to an ASC environment is that there is a large reduction in liability when procedures are moved from the office to the ASC. ASCs frequently are better equipped than the typical doctor's office, as ASCs are able to invest significant amounts in new equipment that utilizes recent technological developments. ASCs typically have both an anesthesia and nursing staff, each of which will have their own liability coverage. In addition, the ASC entity itself will also have its own liability coverage. Therefore, the ASC setting provides increased liability protection due to the fact that better equipment allows for a better procedure, and the fact that the ASC is protected by a variety of liability umbrellas not found in the office setting.

One of the disadvantages of moving from office-based procedures to an ASC environment is the increased overhead involved in operating an ASC. Additionally, when procedures are moved out of the office, the doctor is faced with a "site of service differential." This differential is due to the fact that reimbursement for a procedure done in office includes compensation to the physician for some of his office space expenses. When the procedure is moved to an ASC, that extra payment is diverted to the ASC.

Another disadvantage in moving from office-based procedures to an ASC environment is that the doctor's office is often more convenient for the patient, who is accustomed to seeing

their doctor in the office setting and does not have to travel off-site for the procedure.

HEARING THE CONSTANT WAR OF POSITION STATEMENTS RELEASED BY GI AND ANESTHESIA SOCIETIES, HOW DO YOU SEE THE USE OF PROPOFOL CHANGING IN GI CENTERS IN THE NEXT 3-5 YEARS?

LEVINE: Anyone who has ever had a colonoscopy will swear by the use of Propofol. Here in New York, there was an attempt by a couple of major insurers to cut back on reimbursement for Propofol which was ultimately reversed. Hopefully, Propofol will continue to be routinely available in GI centers in the near future.

SABLE: I personally think that the liability risks, despite the statements by the professional societies, are too great to administer Propofol without an anesthesiologist or CRNA present. I find that those who have made these statements proposing administration of Propofol by non-anesthesiologists work in an area where they can call a "code" and get help within minutes and not in a setting where they may have to wait 20-30 minutes or more for assistance if they get into trouble. I think that in the absence of an anesthesiologist, Demerol (or Fentanyl) and Versed will be used. This will decrease patient satisfaction and hinder the operations of ASCs. My prediction is facility fees that bundle an extra amount for anesthesia will have to be negotiated and those funds will be used to pay for anesthesia at ASCs.

COLEMAN: A growing issue in ambulatory surgery is the safety of non-anesthesiologist-administered propofol (NAAP) for gastrointestinal (GI) procedures. According to a joint position statement issued by the gastroenterology and hepatology societies, an anes-

thesiologist can double the cost of elective GI endoscopy without improving patient safety or procedural outcome by using NAAP. This position statement issued by the four major gastroenterology and hepatology societies (American Association for the Study of Liver Diseases (AASLD), the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA) Institute and the American Society for Gastrointestinal Endoscopy (ASGE)), asserts that NAAP can be safely utilized in the ASC setting, provided that it is administered by a team of individuals who have received training specific to the administration of propofol.

The American Society of Anesthesiologists, however, maintains the position that "Diprivan, or its generic name Propofol, is a drug meant only for use in a medical setting by professionals trained in the provision of general anesthesia."

Elective colonoscopies have now become a routine screening tool, with about 50-60 million Americans electing to have the procedure every few years. Because of the large number of elective recurring procedures, the use of an anesthesiologist in the ASC setting will have an obvious impact on the cost of health care. As of right now, this issue remains on the forefront of the ASC landscape, and how this debate will be solved is largely unknown.

WHAT DO YOU SEE AS THE NEXT CMS TOPIC OF FOCUS THAT MAY IMPACT THE ASCS FROM A REGULATORY PERSPECTIVE?

LEVINE: You may see compliance plans made mandatory instead of being voluntary. On the state law side, regulators may become more vigilant with respect to enforcing the obligations of out-of-network providers to collect co-payments and deductibles from patients.

SABLE: CMS is always looking to cut fees. I predict CMS will continue to look for new ways to do so and will continue in this manner until a point is reached where ASCs and physicians will no longer accept Medicare patients.

COLEMAN: The health sector should expect that increased fraud and abuse scrutiny and enforcement will be included in any health reform package passed by Congress. Under recent proposals, providers and suppliers would be required to implement a compliance program as a condition of Medicare or Medicaid participation.

The anti-kickback statute would also be amended to provide that a person need not have actual knowledge of the law or specific intent to violate that law to establish that a violation occurred. The process for providers to voluntarily disclose violations of the physician self-referral law (Stark Law) would be re-established. While most of the proposals reflect increased scrutiny for providers, the proposal for a Stark Law self-disclosure protocol could be a significant positive development for providers that are looking for a pathway to deal with so-called "technical" Stark Law violations, where there is no fraudulent or abusive conduct, yet the statutory damages are significant.

In addition, recently updated conditions for coverage are a potential concern for ASCs. Recent compliance surveys have uncovered a number of deficiencies, which is jeopardizing program participation for many ASCs.

Joshua S. Levine is a partner at Danziger & Markhoff LLP where he concentrates in corporate, securities and health law and represents closely held business and professional corporations – primarily medical practices – on all aspects of their business dealings. He counsels clients in connection

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On an ongoing basis, he works with clients on all types of commercial and contractual matters. These include stockholder agreements, operating agreements, employment agreements, private placement memoranda for securities offerings, financing arrangements, and compliance with federal and state regulatory requirements for health care clients. In the health law area, Josh also has extensive experience in the establishment of ambulatory surgery centers and other physician-related joint ventures.

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Dr. Sable attended Albert Einstein College of Medicine and completed his internship and residency in Internal Medicine at Montefiore Medical Center. He went on to receive his training in Gastroenterology at the New York Medical College which he completed in 1978. He then began his practice in gastroenterology and along with Dr. Isadore Gutwein founded Riverdale Gastroenterology and Liver Diseases in 1981.

Dr. Sable is on the staff of Montefiore Medical Center, St. Barnabas Hospital, the Community Hospital at Dobbs Ferry and Our Lady of Mercy Medical Center. He is also the co-medical director of the Advanced Endoscopy Center.

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Ira co-authored Navigating Your Way Through the Federal Physician Self-Referral Law: A Guidebook to Stark II (Atlantic Information Services, Inc., 1995; revised 1996; second edition 1998): A Guide to Complying with Stark Physician Self-Referral Rules (Atlantic Information Services, Inc., 2004) and has authored and has been quoted in numerous articles on health law topics.

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