CMS Taking Action on Adverse Events

An Inside Perspective on Medicare’s Nonpayment for Never Events

There has been a constant buzz ever since the Centers for Medicare & Medicaid Services (CMS) announced its plan to withhold reimbursements for eight potentially preventable adverse events. These events include hospital-acquired conditions such as infections, pressure ulcers and various types of injuries, as well as serious preventable “never events” such as an object left in a patient following surgery (see “List of Eight Events”). Traditionally, Medicare paid more to cover the treatment of patients who acquired these types of conditions during hospitalization. With this new plan, it will pay only if the hospital can demonstrate it did not cause the condition—that is, that the condition was present on admission (POA).

To support this process, the CMS created Medicare severity diagnosis-related groups for more complex coding. This includes a POA payment category to identify patients with a secondary diagnosis, i.e., adverse condition(s) that exist at the time of admission. While hospitals must transition to these new reporting requirements by October 2008, actual payment changes will not take effect until January 2009.1

With this plan to stop reimbursements for select adverse events, the CMS hopes to spark hospital quality improvement and patient-safety initiatives to prevent and/or eliminate adverse events. This measure represents an ongoing effort. The CMS is considering adding at least six more conditions to the original list, including ventilator-associated pneumonia, *staphylococcus aureus* septicemia, deep vein thrombosis/pulmonary embolism and wrong-site surgery, among others. Industry reaction has been mixed.2 As numerous states, and even some large insurers, look to emulate the CMS plan (see “States Follow Suit”), some quality improvement experts question the plan’s ability to actually drive change. At issue is the “preventability” of some events, the impact on current safety initiatives and the potential changes in care necessary to determine POA.3

To gain an insider’s perspective, *infocus* discussed these CMS reform issues with Joel Perlman, Executive Vice President, Chief Financial Officer and Dr. Rohit Bhalla, Chief Quality Officer, at Montefiore Medical Center, New York.

---


---

Joel Perlman
Dr. Rohit Bhalla

*continued on page 2*
**States Takes Action**

A mandate from the Centers for Medicare & Medicaid Services (CMS) that cuts reimbursements for eight adverse event seems to have sparked new state initiatives concerning billing for adverse medical events as well as efforts to improve patient safety reporting systems.

According to the National Academy for State Health Policy (NASHP), a not-for-profit group that assists states with health care policy and practices, more than half the states (26 plus the District of Columbia) currently support adverse event reporting systems. Although many states started reporting as a means to enforce licensing measures, today the emphasis rests more on improving health care quality. Of the states participating, 13 report on all 28 adverse events on the National Quality Forum (NQF) list. Many systems also require hospitals to provide data showing they analyzed and identified why the adverse events occurred. This root cause analysis is used as the basis for improving the quality of care. New York hospitals report adverse events through the New York Patient Occurrence Reporting Tracking System (NYPORTS) which covers similar conditions as the NQF list (see “New York Gets to Work”).

Some states have moved beyond posting adverse event statistics on their Web sites. Minnesota has pledged to stop billing for the 28 NQF adverse events. Others, like Massachusetts, are starting with a smaller number. Also, state hospital associations from Michigan to Vermont have either enacted or are actively evaluating nonbilling policies for adverse events.

---

**INFOCUS: For perspective, can you give us a quick sketch of Montefiore Medical Center?**

PERLMAN: Montefiore is the university hospital for the Albert Einstein College of Medicine and is a multi-campus, integrated delivery system with annual revenues of nearly $2.5 billion. With more than 1,100 beds and 70,000 admissions, Montefiore is the largest provider of acute care services in the Bronx. Additionally, the medical center has one of the nation’s largest ambulatory care programs and partners with numerous health plans in capitated managed care arrangements. Our medical staff numbers about 2,000 and we train more than 800 full-time equivalent residents and fellows annually. Montefiore serves a diverse patient population and has one of the highest Medicare/Medicaid payer mixes of any academic medical center in the nation.

BHALLA: Montefiore has a long history of leadership in quality improvement, health information technology (HIT) and patient safety. We have been recognized by the Leapfrog Group as one of the safest hospitals in the United States, based on having systems such as computerized physician order entry (CPOE) and intensive care staffing and based on our care processes, safe practices and outcomes.

**INFOCUS: What were your initial reactions to CMS’s plan to cut reimbursements for adverse events?**

PERLMAN: Adverse events have come to define two very different categories of medical circumstances. One, the so-called “never events,” relates to errors that often result in serious harm to the patient. Examples include wrong-site and wrong-patient surgery. Medicare, and increasingly other payers, intend to deny reimbursement for such events. The Medicare “never events” are rare and as such should not cause significant financial consequences to hospitals. Furthermore, it represents a reasonable approach to accentuating the overarching goal of promoting safety and error prevention in our nation’s hospitals. A principal concern is that “never events” be limited to circumstances that are fully within the control of providers to prevent, that they receive appropriate input from medical professionals and that they be consistent across payers. There is the risk that the list of “never events” may be misused by certain payers and that hospitals could be penalized inappropriately.

The second category of adverse events is being applied to certain medical complications that occur during a patient’s hospital stay. The concept is that these events are avoidable and Medicare should not reimburse the added costs associated with treating these complications. Examples include urinary tract infections and pressure ulcers. Medicare has established a policy that these complications will only be reimbursed if the hospital can document that the condition was not acquired in the hospital. It is requiring hospitals to document POA status for these complications to avoid risk of payment reductions. This category raises other concerns for the hospital community. One concern is that Medicare, or other payers, may overreach and penalize hospitals for medical circumstances that are not entirely within the hospital’s ability to control. Many patients admitted to hospitals today are frail and are afflicted with chronic or other compromised health conditions which make them susceptible to medical complications. Nursing home patients are an example of a cohort of patients who are often frail, sickly and have

---

**List of Eight Events**

The CMS plan calls for withholding added reimbursements for these conditions:

**Serious Preventable Events**

- Air embolism
- Blood-type incompatibility
- Object left in patient during surgery

**Other Adverse Events**

- Catheter-associated urinary tract infections (UTIs)
- Hospital injuries (fracture, dislocation, intracranial injury, crushing injury, burn, fall)
- Pressure ulcers (decubitus ulcers)
- Surgical site infections (mediastinitis after coronary artery bypass graft [CABG] surgery)
- Vascular catheter-associated infections

Source: CMS 42 CFR Parts 411, 412, 413, 489 (CMS-1533-FC)

compromised immune systems which subject them to higher risks of medical complications.

Reimbursement as well as pay-for-performance and value-based purchasing programs can make an important contribution to focusing attention and aligning incentives targeted at quality of care improvements. However, these policies and payment practices must be crafted prudently, with input from the knowledgeable sources in the medical community, and applied consistently by all payers.

BHALLA: From the quality end, we support transparency and accountability. When it comes to patient safety, of course we would like to eradicate all adverse events. However, my initial concern is that this new policy has the public thinking that all hospital-acquired events are synonymous with these rare events that should never happen. While rare events such as wrong-site surgery should never happen, hospital-acquired events such as pressure ulcers and falls are driven by many underlying factors associated with a patient’s illness, treatment and health status. At Montefiore, a primary focus has been on the more prevalent, preventable events such as ICU deaths and medication errors. From a population health and health care systems-change perspective, these areas offer some of the greatest potential for impact on patient safety improvement and risk reduction. For example, our policy of 24-hour-a-day, seven-day-a-week critical care physician presence across our entire acute care division has helped us reduce overall inpatient mortality by nearly 40 percent over the past decade. Similarly, by introducing CPOE, we cut prescribing errors by nearly 90 percent. Patient safety experts and health services researchers have estimated that if all non-rural US hospitals adopted ICU staffing standards, more than 50,000 lives could be saved annually. And if these same institutions introduced CPOE systems, we could potentially avert more than 500,000 serious medication errors each year.

INFOCUS: What have you been doing to prepare for this new plan?

BHALLA: We brought together an interdisciplinary group to analyze the projected clinical and financial impact of the new policies on the organization and to formulate an appropriate plan. Many are concerned with non-payment for an entire stay, but based on at least CMS’ specifications, the revenue implications are related to whether or not the event results in assignment to a higher coding category and the associated “premium.” As a result, we are doing some revenue modeling. Beyond finances, we are evaluating the plan from all angles, with coders looking at workflow and clinicians and physicians considering clinical practice implications such as changes to test ordering and provider documentation patterns. The idea is to identify the events that are most prevalent among our patient population and target key areas for effective intervention.

PERLMAN: We are working diligently to prepare for the POA requirements. This requires staff training, additional workflow steps and, in some cases, more patient testing to identify and document that a condition is present on admission. As noted, at Montefiore, we treat a diverse and complex patient population, many of whom are admitted through our emergency department. The POA requirements add yet another intervention in an already taxed emergency department environment. It is important that Medicare and other payers establish POA policies that

continued on page 4

New York Gets to Work

With other states taking action on adverse events (see “States Follow Suit”), New York’s Department of Health (NYSDOH) has announced plans to limit Medicaid payments for preventable adverse events and to stop paying for certain “never events.” Although it may seem as if the state is a bit behind, in fact, it currently supports an extremely robust hospital reporting system for adverse and “never events.” For this New York Patient Occurrence Reporting and Tracking System (NYPORTS), New York earned kudos as one of the few states with a Web-based reporting system, according to the 2007 Guide to State Adverse Event Reporting Systems, a state health policy survey report by the National Academy for State Health Policy (NASHP).

The Greater New York Hospital Association (GNYHA) is also bucking the trend of other state hospital groups that are urging members to stop billing for certain adverse events. Instead, GNYHA is taking a proactive approach, joining the United Hospital Fund (UHF) in co-sponsoring initiatives to improve patient safety and care quality. These collaboratives encourage hospitals to implement evidence-based preventive practices and share results to reduce central line-associated bloodstream infections (CLABs), hospital-associated infections such as Clostridium difficile, and critical care learning. Another committee is merging efforts to analyze the “big picture,” looking at clinical experiences, economic outcomes and research, and reimbursement and payment policies to develop new quality and safety initiatives.
Physicians Proactive on Near-Miss Events

While state hospital associations across the country are making commitments to stop billing for adverse events and serious medical errors, a group of physicians in New York is looking to preempt these problems altogether by identifying near misses. In a voluntary program, the New York chapter of the American College of Physicians (NYACP) has teamed with the New York State Department of Health (DOH) to collect and analyze near misses in an effort to prevent medical errors. Near misses are defined as events that could have harmed patients but did not. More than 4,700 internal medicine residents have volunteered to report their near-miss events to the DOH’s Patient Safety Center. The three-year trial is expected to yield valuable information and collaborative solutions to support hospitals’ efforts to improve the quality and safety of health care systems. The program brings a new layer of transparency to data available as a result of hospital reporting through the New York Patient Occurrence Reporting and Tracking System (NYPORTS) and patient care quality and performance reporting for the Centers for Medicare & Medicaid Services (CMS).


CMS Taking Action on Adverse Events continued from page 3

are flexible and not rigidly applied. There are circumstances where adverse medical complications that are not preventable by the hospital will occur post admission. It is essential that POA policies be adapted to recognize this reality.

INFOCUS: Do you have any specific concerns regarding implementation?

BHALLA: I hope we do not lose the forest of common and serious patient safety issues through the trees of extremely rare “never events” and POA documentation efforts. The prevention of nosocomial infections, whether catheter, central line or ventilator associated, thromboembolic disease and other highly prevalent events, including those that we discussed earlier, remains a significant issue for facilities across the US and for the public as a whole. It would be a shame to see that organizational energy shifted, especially when we all have fixed resources.

INFOCUS: Do you have any final thoughts on the impact of this CMS plan?

PERLMAN: It ultimately becomes a matter of proper oversight and flexibility on the part of policymakers and other stakeholders to ensure that Medicare applies adverse events policies and practices fairly, consistently and with input from knowledgeable health care professionals. The goal of improving quality and patient safety and ensuring hospital accountability is clearly a national health care priority. There are many encouraging initiatives underway throughout the hospital industry to improve processes and standards of care. Significant progress in error prevention, patient safety and improved outcomes are being achieved today and more will come in the near future. The current focus on adverse events presents the risk of payer emphasis on less than optimal measures.

We applaud the government’s quality agenda, and certainly we will seek to be fully compliant with these CMS measures. However, we hope that this does not encourage quick fixes, which may cause stakeholders to take their eye off the ball and miss opportunities to capitalize on other quality initiatives that offer the potential for far greater long-term benefits to our health care system. Dr. Bhalla has already described some of these promising initiatives. Hospital industry leaders working collaboratively with government and other stakeholders offers the best opportunity to establish evidence-based national standards, practices and policies that will contribute to long-term sustainable patient care improvement. (For more on this, see “New York Gets to Work.”)

BHALLA: From a policy perspective, in this arena I think it is important to remember the distinction between payment and public reporting. Current efforts such as the Hospital Quality Alliance and value-based purchasing include public reporting on quality measures for certain medical and surgical conditions. In these efforts, financial disincentives and public reporting have gone hand-in-hand. But we must think carefully about public reporting of “never events” and hospital-acquired complications. This may have the opposite of its intended effects. On the one hand, we are calling for greater accountability in publicly reporting complications. On the other, we are trying to institute a health care culture of safety, to promote information sharing and to learn from one another’s mistakes.

It would also be helpful to have a universal preventable “serious events” list. Like other facilities in New York, we are adhering to, or have seen, a number of different adverse event and quality reporting standards. These include the New York Patient Occurrence Reporting and Tracking System codes, the National Quality Forum serious events list, the Joint Commission Sentinel Events and these new CMS conditions. Private payers have also released their own iterations of these events lists. This fragmentation may dilute both purpose and policy. In the end, rather than each managing to measure or rushing to implement the Medicare proposals, we would be better served by thinking about all of the mandates and determining which set would achieve the greatest good and promote the most health care systems learning.

2 Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 411, 412, 413, and 489 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Final Rule, Federal Register, August 22, 2007, 72.
4 The Leapfrog Group, “ICU Physician Staffing (IPS).” Fact Sheet, April 9, 2008, 1.
The first part of the law took effect this January and requires physicians, physician assistants and specialist assistants to report adverse events related to office-based surgical procedures. The second part, which becomes effective July 14, 2009, requires practices performing OBS to be accredited by one of three approved agencies. Under this legislation, the New York State Department of Health (NYSDOH) defines OBS as “any surgical or other invasive procedure performed outside of a hospital, diagnostics and treatment center or other Article 28 facility in which moderate sedation or deep sedation or general anesthesia is utilized to provide comfort to the patient in order to perform the procedure.”

**Adverse Event Reporting Is Here**
Starting this year, OBS practices must report any OBS-related adverse events to the DOH Patient Safety Center within one business day. Adverse events are defined as serious or life-threatening events that patients experience after OBS, specifically, death within 30 days, an unplanned transfer to a hospital, an unscheduled transfer or hospital admission within 72 hours of OBS that lasts longer than a day, or any other serious or life-threatening event that results in temporary or permanent physical loss or mental impairment.

Who is required to report? Any physician, physician assistant or specialist assistant directly or indirectly involved with the OBS procedures must report a subsequent adverse event. This reporting requirement also applies to other physicians, physician assistants or specialist assistants who may later see the patient and believe a condition or complication is related to a prior OBS procedure. While not mandated, hospitals and staff aware of OBS-related adverse events are also encouraged to report to the Patient Safety Center. This reporting requirement is totally separate from the hospital’s responsibilities to the New York Patient Occurrence Reporting and Tracking System (NYPORiTS).

**Reporting Remains Confidential**
To report adverse events, download the reporting form (DOH-4431) and completion instructions from the NYSDOH Web site (www.nyhealth.gov/professionals/office-based_surgery). For tracking and confidentiality purposes, forms must be sent via certified mail to the designated NYSDOH address. Confidentiality and nondisclosure are understandably prevalent concerns for physicians facing new levels of transparency and adverse event reporting requirements. With this law, OBS practices can rest easy, as these reported adverse events fall under the Public Health Law section 2998-e confidentiality provisions. This means reported data can only be shared internally within the DOH and is not subject to disclosure under Article 6 of Public Offices Law or Article 31 of Civil Practice Law and Rules.

**OBS Accreditation Countdown Begins**
With one year left before OBS accreditation becomes mandatory, it is no surprise that the DOH has been inundated with questions regarding the law’s applicability. As a result, the DOH issued a comprehensive online list of answers to frequently asked questions on OBS (www.nyhealth.gov/professionals/office-based_surgery). The list is updated periodically. Highlighted areas of concern include which doctors and procedures are impacted and how the accreditation process works, as well as issues of confidentiality and reimbursement.

The fundamental question for OBS practitioners is, “Does this law apply to my practice?” If you are a physician, physician assistant or specialist assistant who performs OBS procedures with more than minimal sedation and operate outside of a hospital, continued on page 6.
diagnostic and treatment center, or other Article 28 facility, the answer is yes. The law does not apply to dentists, podiatrists or other professionals who are regulated by an entity other than the NYSDOH (see “When Other OBS Regulations Apply”). However, if a dentist is dually licensed as a physician and performs applicable OBS procedures, then the law and accreditation requirements pertain.

A wide range of procedures fall under the OBS umbrella, but only one—liposuction of greater than 500cc of fat—is singled out for specific inclusion in this law. For all other OBS procedures, the need for practice accreditation is based on the definition and type of procedure and the level of sedation required. Thus, offices that perform OBS procedures using moderate sedation/analgesia, deep sedation/analgesia and general anesthesia, as defined by the American Society of Anesthesiologists (www.asahq.org), must be accredited. Offices performing only minor procedures or procedures requiring minimal sedation, such as most botulinum toxin injections and minor integumentary procedures, are excluded. While endoscopy, colonoscopy, rhinoplasty, and augmentation or reduction mammoplasty are just a few procedures to which the law applies, other procedures require closer examination.

While Magnetic Resonance Imaging (MRI) procedures are typically excluded from the law, MRIs requiring contrast and those that use moderate to deep sedation are considered invasive procedures and therefore require accreditation. Recognizing that patients respond differently to sedation, the DOH also emphasizes that it is the intended impact on the patient (level of sedation) that matters most in the determinations. It expects practitioners to be able to control sedation and rescue patients from a deeper level of sedation than intended.

### Accreditation Agencies Process

After a lengthy screening, the DOH approved three agencies for accrediting OBS practices: the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) and The Joint Commission. OBS practices that are already accredited by one of these agencies will simply be required to maintain their accreditation. However, if your OBS procedures qualify for inclusion under the law and you are not accredited, you must apply for accreditation by one of these three agencies. For example, most plastic surgery practices are currently “Quad A-verified,” that is, accredited by the AAAASF. Ultimately, the choice of accrediting agency is up to the individual practice. The DOH recommends that OBS practices research the application process, accreditation standards, agency costs and so forth before making a selection. This can be a very time-consuming process; one agency estimates the process can take anywhere from six weeks to six months. To meet the July 14, 2009, deadline, practices are advised to submit their accreditation applications as soon as possible, or by December 2008 at the very latest (see box for agency contact details).

### OBS Practice Accrediting Agencies and Contacts

*Check the various agency Web sites for training, worksheets, pricing and other information on accreditation.*

**Accreditation Association for Ambulatory Health Care**  
5250 Old Orchard Road, Suite 200, Skokie, IL 60077  
www.aaahc.org

**American Association for Accreditation of Ambulatory Surgery Facilities**  
5101 Washington Street, Suite 2F, Gurnee, IL 60031  
www.aaaasf.org

**The Joint Commission**  
One Renaissance Boulevard  
Oakbrook Terrace, IL 60181  
www.jointcommission.org/AccreditationPrograms/Office-BasedSurgery

---

**Ten Years in the Making**

Ten years after the original Committee on Quality Assurance in Office-Based Surgery first convened to discuss the issue, the office-based surgery (OBS) law has arrived. Despite its lengthy history, the bill was met with surprise from legal advisors and OBS practices alike when it sped through the legislature last summer. That may have been because the NYSDOH’s 2001 OBS guidelines initially were struck down in court. However, the Court of Appeals ruled against the challenge by nurse anesthetists and determined that DOH did indeed have the authority to regulate OBS. This opened the way for the DOH to release revised guidelines in 2004, which established standards of professional care for OBS. The new legislation moves this forward, translating standards into requirements and mandating accreditation of OBS facilities by July 2009.

As of 2007, at least half of the states, including New York, have adopted laws or regulations governing OBS (see State by State OBS Laws & Regulations at www.aaaasf.org). This activity was prompted by the rapid growth of OBS procedures combined with a notable void in related safety standards, such as those required of hospitals and ambulatory surgery centers.
The actual accreditation process entails examining your physical office location to ensure it meets standards for everything from size and sterilization facilities to emergency power. For new accreditations, you must notify the agency of all procedure rooms and office locations used for OBS procedures. If you perform nonaccredited and accredited OBS procedures and wish to maintain separate procedure rooms, the agency can provide the necessary requirements for compliance. This process could require added financial investments to upgrade facilities for regulatory compliance.

As a second step of accreditation, the agency must ensure your practice is operating as a legal entity. Under New York law, physicians may legally practice under different types of entities—that is, sole practitioner, general partnership, registered limited liability partnership, professional corporation or professional limited liability company. With any of these entities, the key distinction is that all personnel responsible for the practice must be physicians. For example, if you have a professional corporation, your directors, officers and shareholders must all be physicians. Similarly, the name of your practice must also follow certain legal requirements (for more, see “What’s in a Name?”).

**What’s Next?**

By now, all OBS practices in the state should have received the “Dear Doctor” letter issued from the NYSDOH regarding this amendment to Section 230-d of the Public Health Law. Perhaps you have even read subsequent literature describing these regulatory changes. Hopefully, your OBS practice is already on board with the new guidelines for reporting any adverse events that may have occurred. The final step to full compliance under this law is determining your status as an OBS practice and, if required, taking the necessary steps to be accredited.

Unless otherwise noted, this article was compiled based on information on the New York State DOH Office-Based Surgery Web site (www.nyhealth.gov/professionals/office-based_surgery).

---

**When Other OBS Regulations Apply**

Though many types of facilities and practices perform office-based surgery (OBS), some are governed by laws and licensing measures outside the recent OBS regulations. These include ambulatory surgical centers and diagnostic and treatment centers. While these facilities may also perform invasive procedures under various forms of sedation, they fall under Article 28 of the New York State Health Code, requiring strict licensing procedures. Similarly, dentists, podiatrists and other professionals who perform invasive surgery or use conscious sedation must adhere to completely different sets of practice guidelines based on their respective professions. These guidelines are overseen by the New York State Education Department (www.op.nysed.gov).

**What’s in a Name?**

A rose is a rose is a rose is a rose. That may work for a rose, but in the accrediting process, names make a definite difference. During office-based surgery (OBS) accreditation, the accrediting agency scrutinizes how the practice is set up as a legal entity, and this includes looking at the practice’s name. The agency looks for two words, “center” or “clinic,” which are both off-limits to OBS practices. Why? Essentially, this prohibition was established to prevent confusion between Article 28-licensed surgical centers and OBS practices. The intention was to provide a distinction between the two types of facilities and to protect consumers from paying higher professional or facility fees for a facility that is not licensed. The exact wording under Article 28 of the Public Health Law states, “It shall be prima facie evidence that a diagnostic or treatment center is being operated when any provider of medical health or health services describes itself to the public as a ‘center’ or ‘clinic’” (Section 600.8, New York Compilation of the Codes, Rules, and Regulations). To avoid being mistaken for an Article 28 facility (and any potential fraud related to that), make sure that “center” or “clinic” are not part of your OBS practice’s name.
Case Details
A 43-year-old female approached the defendant plastic surgeon to request liposuction of the abdomen, knees, thighs, and buttocks. She was an exotic dancer and believed appearance was important for her livelihood. Her surgical history included three Cesarean sections, liposuction of the hips and thighs and breast implants. She was a non-smoker, five-feet, four-inches tall, 148 pounds and exercised regularly. The defendant discussed options, risks and expected outcomes with the patient, including the possibility for further liposuction. The defendant also advised the patient that skin redundancy in her lower abdomen might occur due to abdominal skin that lipped over the Cesarean scar.

In October 2001, the defendant performed liposuction of the abdomen, knees, thighs and buttocks in the office surgical center without complications. Post-operatively, the patient complained of dimpling in the left lower abdomen, and requested further liposuction of the knees and thighs. The defendant advised the patient to wait at least three months for any revisions.

In January 2002, the patient returned to request further liposuction of the knees and thighs. She complained of excess skin above the Cesarean scar and wanted it removed. The defendant documented in writing: “Skin excision with excision of contributing scar was given as alternative to patient. Patient agrees and would very much like to have the excess skin removed….risks, benefits discussed with the patient.” The signed written consent for the surgery lists the planned procedures as “revision of liposuction and scar revision of abdomen.” However, the patient has a copy of the signed consent with only liposuction documented as the planned surgery. This discrepancy is the basis of the lawsuit. The patient alleges she never consented to a scar revision.

In January 2002, the patient returned after removing the dressing herself. On exam, there was a four-centimeter separation of the right lateral abdominal incision. The defendant placed steri-strips over the separation, reinforced the dressing, and instructed the patient to leave the dressing in place. Despite the instructions, the patient removed the steri-strips herself and returned to the office five days later. On exam, the separation was now down to the deep dermis. Steri-strips were reapplied to the separation, and the patient was advised the wound might now heal wide with thickening at the site of separation. A follow-up appointment was scheduled, but the patient never returned.

The patient transferred her care to another plastic surgeon who continued the wound care. In June 2002, a subsequent provider performed flap advancement and closure of the deficit. A 2006 independent medical exam (IME) by a plastic surgeon revealed the abdominal scar was a fine line, well healed, and the right and left side appeared equal with no deficit in contour.

Allegations
The plaintiff alleged she did not consent to the scar revision. As well, she alleged that surgery was improperly performed and as a result caused excessive bleeding, infection and a permanent indentation in her abdomen.

Investigation and Case Development
Two plastic surgery experts reviewed the case, and were supportive of the surgical technique and the post-operative management. The amount of fat removed during the initial surgery was within the standard of care, and it was appropriate to wait three months before doing further surgery. The January 2002 surgery was the appropriate procedure to address the excess abdominal skin and scar lipping, and the technique was correct. Post-operative bleeding was a known risk of the procedure and the bleeding was not excessive. Wound dehiscence was a known complication and the patient’s own removal of the dressings may have contributed to it. The allegation of infection was not supported in the medical records from the subsequent provider.

The experts were much less supportive about the consent issue. They agreed the defendant’s pre-operative notes clearly indicate the plan for scar revision, including risks and benefits discussed with the patient, and that the patient agreed to the revision. Nonetheless, the discrepancy in the signed consent forms was a significant obstacle to defending the case, and the patient’s testimony compounded it. She insisted she was told the revision did not involve cutting or sutures.

Investigation identified sloppy office practices at the root of the consent discrepancy. The defendant routinely delegated to the...
office secretary the job of obtaining the signed surgery consent form. The secretary completed the fields on the form, including the planned procedures, and witnessed the patient’s signature. The defendant was inconsistent in her review and initialing of the consent form. The office had an informal pre-procedural checklist; there was no protocol for verification of the written consent by a member of the surgical team.

In this case, the secretary listed the planned January 2002 procedure as revision of liposuction, but not scar revision. The patient signed this consent, and asked for a copy, which was provided. A time out to verify agreement for the planned surgery was not done before the surgery began. The secretary realized scar revision was not written on the consent. She added it later to the original signed consent. There was no documentation by the defendant on either version of the consent. The anesthesia consent form was also completed by the secretary, and listed the planned surgery as liposuction and scar revision. However, scar revision appears to have been written in after surgery commenced. Even though the nurse anesthetist signed the anesthesia consent form, she often signed the form intra-op or post-op. The nurse anesthetist had no recall about this case.

Documentation problems continued in the post-operative period. Different notes exist for the same visit. Although the contents differ, the notes are not contradictory; however, a plaintiff attorney might easily sway a jury to believe there was a cover-up. The defendant could not explain why she wrote multiple notes for the same visit. She theorized that when she saw the patient the chart was not available and she documented on a loose progress note. The chart was available on the next visit, but the loose note was missing, so she rewrote the note in the chart. The defendant also recalled documenting a note that the patient reported using a vacuum the evening of surgery. This activity could have caused the bleeding and contributed to the subsequent dehiscence. However, this note could not be found. Lastly, there were out-of-sequence notes, and the defendant’s explanation on the reason why remained open to question.

Resolution
The clinical management of the patient was considered defensible, but the documentation irregularities drove the decision to settle. The claim settled for $37,500 prior to trial.

Conclusion
The disorganized documentation practices and loose pre-operative verification of consent provided the foundation for this suit. A well-documented record may not prevent a lawsuit, but haphazard documentation and record keeping will always create obstacles to the defense of one. An office-based surgical center must apply the same standards as a hospital operating room for insuring all aspects of patient consent reconcile and are complete. A thorough pre-operative verification protocol would have alerted the defendant to the consent issue. In addition, a time out to ensure everyone was in agreement with the planned surgery would have been another opportunity to identify the problem. The recent New York State Public Health Law § 230-d Office-Based Surgery mandating accreditation and adverse event reporting by office-based surgical centers demonstrates the awareness that non-hospital surgical sites present the same challenges to patient safety as do hospital operating rooms.

Three Risk Reduction Strategies
Responsibility for Obtaining Consent
The attending physician has a non-delegable responsibility to obtain the informed consent from a patient. This includes not only the discussion of the risks, benefits and alternatives for the planned surgery, but also the documentation related to the process. It is not appropriate for clerical staff to obtain informed consent. Delegation of some aspects of the paperwork may be done, but it is ultimately the attending’s responsibility to ensure any delegated task is correctly executed. In this case, neither the defendant nor a member of the surgical team reviewed the surgery consent form pre-operatively with the patient. In addition, the nurse anesthetist’s routine did not include a consistent pre-operative review of the anesthesia consent with the patient.

The secretary’s actions resulted in there being two different versions of the surgical consent form, and the defendant was unaware this occurred until the patient initiated the lawsuit. If a written consent is altered or illegible, it should be re-done and re-signed by all parties. This must occur before any sedation, analgesia or anesthesia is administered. Both copies of the consent should be maintained in the record, as well as an explanation of the need for the second consent. It is a good idea to include documentation guidelines in the orientation of all new office staff, as well as to reinforce the “do’s and don’ts” in an annual staff education program, to ensure everyone is aware of proper documentation requirements.

Pre-operative Procedures
The loose pre-operative verification and lack of a time out were also factors in why the consent problem was not identified. These types of lapses place an office surgical center at increased risk for “wrong patient,” “wrong site,” and “wrong procedure” surgery. Measures to prevent these errors include a systematic pre-operative verification process for all patients. There are many distractions in a busy surgical suite, and a clinician performing a mental check list may overlook a requisite item. A written protocol and checklist will ensure each step of the verification process is consistently completed. Prior to starting any surgical or invasive procedure, a final verification must be done. At this “time out,” all members of the surgical team engage in positive identification of the patient, the intended procedure and the site and side of the procedure. If there is any discrepancy, it must be resolved before proceeding.

Coherent Medical Records
In this case, there were multiple notes with differing content for the same post-operative visit. This was likely due to an inconsistently available medical record. Documentation on pages separate from the medical record should be avoided. Office clinical staff should know how to find the medical record whether secretarial staff is available or not. Loose pages are too easily lost, and it appears notes were lost in this case. There should be a protocol to deal with loose pages, including placement in a designated location and scheduled frequency for filing them into the official record.

In conclusion, the defendant entered an out-of-sequence note in the record. Out-of-sequence notes expose a clinician to the accusation of dishonesty. Additions or addendums should be made infrequently and only if the information is important to the patient’s medical care. If an addition of pertinent clinical information is warranted, it should be labeled as an “addendum,” and dated using the date the addition is written. An addendum written after an adverse occurrence or unanticipated outcome is generally considered self-serving and defensive. Confer with the sponsoring hospital’s risk manager prior to writing an addendum.
Does Reporting Impact Provider Choices?

In today’s era of transparency, hospitals and physicians regularly report everything from “never events” and near misses to a wide range of critical care interventions and clinical practices. And thanks to convenient Web access, consumers can easily view volumes of this quality and safety data and numerous report cards. How does all this information impact a patient’s choice of providers? According to a study in the Annals of Internal Medicine, “Systematic Review: The Evidence That Publishing Patient Care Performance Data Improves Quality of Care” (January 15, 2008), these reporting systems are often more confusing than helpful. This consumer confusion stems from a combination of poor format and irrelevant measurements. The use of medical nomenclature can also be problematic. The study showed that medical error reporting can be useful in encouraging hospital improvement efforts, but no data was available showing the impact on physicians’ efforts. And while there was a “modest association” between consumer choice and health plan ratings, the study found little consistency in linking hospital and individual physician reporting to consumers’ health care decisions. Report cards and reviews may be popular for choosing everything from appliances to schools, but they are rarely used for selecting hospitals and physicians. As the National Academy for State Health Policy moves ahead with efforts to standardize and consumerize reporting content, perhaps comparative shopping for health care providers will become the new norm.

From Coast to Coast, Physicians Report In

Former New York City Mayor Ed Koch was famous for shouting, “How am I doing?” to his constituents. Today, figuring out how we are doing has become a part of life in the health care field.

Not only are the three R’s—ranking, rating and reporting—a part of doing business for hospitals, but they are increasingly popular with consumers. Just witness the interest in annual health care rankings appearing in publications such as U.S. News & World Report. By contrast, assessments of physicians’ performance have received less public scrutiny. At the heart of these performance measures is the Healthcare Effectiveness Data and Information Set (HEDIS), a tool first released in 1993 to enable consumers to compare health plan performance using national and regional benchmarks (Wikipedia). These standards continue to be updated each year by the National Committee for Quality Assurance (NCQA). By NCQA estimates, more than 90 percent of the health plans across the country support HEDIS measures of patient care and service. Performance is based on data collected through surveys conducted by NCQA-approved organizations. It is also based on medical chart and related insurance claim information submitted by health plans (see HEDIS & Quality Measurement pages at www.ncqa.org). A visit to the NCQA Web site (www.ncqa.org) lets consumers view HEDIS ratings and create their own health plan report cards, com-

Physicians’ Perspective on P4P

In 2005, the Centers for Medicare & Medicaid Services (CMS) started a voluntary pay-for-performance (P4P) program for physicians. This program offered 10 large physician group practices a bonus of 1.5 percent of their Medicare fees for meeting quality and cost measures. Despite this incentive, only two earned the bonus. Some attribute these early results to poor project design with no feedback to guide the groups in meeting program goals. After tweaking the program for 2007 and increasing the physician quality measures from 66 to 74, about 99,000 health professionals (16 percent of those eligible) opted to participate in the Physician Quality Reporting Initiative (PQRI). A recent CMS release indicates that this time’s the charm: more than half of the groups are eligible for bonus payments for 2007. Physicians should receive $36 million in bonus payments by August 2008. This turnaround may be attributed to better CMS program implementation with groups such as the American Society of Anesthesiologists. Still, some counter that more change is needed, including raising the 1.5 percent bonus amount to encourage greater PQRI participation. (D. Trapp, “Medicare Quality Reporting Called a Promising Start,” AMNews, March 17, 2008, accessible at www.ama-assn.org)

A survey by the Medical Group Management Association (MGMA), a national coalition of medical group practices, found PQRI participation takes an administrative toll in terms of time and cost. Of 190 groups (representing more than 3,000 physicians) responding, 44 percent participate in the PQRI. These respondents cited numerous concerns, including a need for billing addendums for reporting purposes (35 percent), increasing staff (22 percent), and raising staff salaries (17 percent). When asked about PQRI measures and quality care improvements, only 16 percent of respondents cited good or excellent improvement rates. And the PQRI received below-average marks in bringing benefit and satisfaction to practices. (MGMA press release, “Administrative Burden, Costs Come with Participating in Medicare Quality Program,” October 29, 2007, accessible at www.mgma.com)

Despite these negatives, the PQRI has been extended through 2008 and will require participating groups to report on up to 119 quality measures from July through December. While the CMS expects the program to continue into 2009, its future will depend on postelection health care reforms.
paring results for health maintenance organizations (HMOs), preferred provider organizations (PPOs) and similar organizations.

Controversies arise when individual health insurers set their own rankings for physicians’ performance and quality of care by combining HEDIS measures with a small sampling of claims data. The result is that physicians can find themselves scoring at the top for one insurer and near the bottom for another.1 A similar unevenness in physicians’ ratings prompted the Massachusetts Medical Society to sue the Group Insurance Commission, the agency overseeing health insurance for many public employees across the state. At issue is the methodology the commission uses to rank physician cost and quality measures.2 In an attempt to remedy this situation, several initiatives have been proposed at both state and national levels to establish standards for health plans’ physician ratings. By adopting these guidelines, health plans essentially agree to follow standard principles for measuring and reporting physician performance (see “Spotlight on Physician Ratings”).

At the local level, the New York Business Group on Health (NYBGH), a not-for-profit organization devoted to employer health benefits, introduced its Multi-Payer HEDIS Project. This project uses aggregated claims data from nine large insurance plans, such as Aetna, Empire and UnitedHealth, to provide a more accurate view of physicians’ practices. The program, which began in 2006 with 800 primary care physicians, continues to expand (www.nybg.org/initiatives/multipayer.html). According to a Crain’s Health Pulse report (March 10, 2008), this year 3,500 doctors received personalized performance feedback reports based on HEDIS clinical measures and claims data for close to 614,000 HMO patients insured by these commercial plans. In response to physicians’ comments, the NYBGH has initiated efforts to improve its data accuracy by having a select number of practices and hospitals compare claims data to medical charts. As with other ratings, the intent is to eventually post physician performance data online for consumer use.

While New York continues to refine physician measurements, a program in California serves as a model for success. The Pacific Business Group on Health (PBGH), a business coalition focused on health care, introduced its Physicians Performance Project in 2003 to measure physician performance based on clinical care quality, efficiency and patient experience. Its goal is to help physicians improve quality and efficiency, assist consumers in finding quality care, and design pay-for-performance systems to reward physicians who make improvements. The PBGH Web site (www.pbgh.org) cites project studies that demonstrate how implementing performance measures improves physician efficiency and quality, as well as provides opportunities for potential cost savings. Results from these studies are being used to drive quality improvements for the measured physicians and to model health care cost savings for commercial insurers. The PBGH is also actively linking efforts with similar groups nationwide to develop standards for physician performance measurement. Finally, the PBGH provides consumers with online report cards listing performance results on medical groups across the state (see the California Office of the Patient Advocate’s Web site at www.opa.ca.gov).


Spotlight on Physician Ratings

Physician ratings and rankings have been in the spotlight lately. Just last year, the New York state legislature codified a bill, the Doctor Model Ranking Code, which sets guidelines for physician rating programs. These adopted guidelines were developed with assistance from the American Medical Association (AMA), the Medical Society of the State of New York and the Consumer-Purchaser Disclosure Project (an umbrella organization of consumer groups) from standards first proposed by Attorney General Andrew Cuomo. This bill has won the support of health plans across the state, including the New York State Conference of Blue Cross and Blue Shield Plans (NYSCOP), MVP Health Care and its affiliate Preferred Health, Group Health Incorporated (GHI) and Health Insurance Plan of Greater New York (HIP). It has also been endorsed by many of the nation’s largest health insurers, including CIGNA Healthcare, Aetna, Wellpoint, United Healthcare and Oxford.1

In April 2008, the Consumer-Purchaser Disclosure Project introduced the Patient Charter for Physician Performance Measurement, Reporting and Tiering Programs (or Patient Charter) in an effort to standardize principles for the measurement and public reporting of physician performance. Financed by the Robert Wood Johnson Foundation, this initiative is supported by physicians, leading health insurers, labor organizations and industry groups, including the American Academy of Family Physicians and the American Medical Association. The Patient Charter addresses several areas of improvement. First, it attempts to create uniform standards and a methodology for health plans across the country to use in evaluating provider performance. This would create a more consistent system of ratings and allow for health plan data to be aggregated on a national scale. Once the actual ratings are developed, the Patient Charter also provides physicians with opportunities to correct errors in the reported data. By improving the reliability, validity and fairness of health plan ratings, these standards can play a key role in enhancing health care quality for patients. And with full disclosure through public reporting, the Patient Charter can help consumers make informed health care choices based on physician quality and cost.2


A New Tool to Enhance Practices

There’s a new tool to help physicians enhance their practices. The Risk Management Handbook for Physicians’ Offices is designed to assist physicians in developing and improving their office policies, procedures and practices. This practical guide also includes insights on human resource and employment law issues, office safety and emergency procedures, medical records management, and various risk management challenges. The handbook is available in electronic format on a CD-ROM for convenient downloading and use. The CD-ROM contains a PDF version (print only) and a Microsoft Word version, which can be edited to meet a practice’s particular needs. If you are interested in receiving a copy of this resource, please contact Glenn Slavin at gslavin@fojp.com for more information.