Non-Payment of Never Events: Implications for Practice

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This discussion of the origin and types of events referred to as never events, and their anticipated financial effect on hospitals, will offer recommendations for hospitals and physicians as they prepare to address this major change in healthcare reimbursement.

The National Quality Forum (NQF) and the LeapFrog Group fueled the initial interest in never events. Starting in 2002, the NQF has developed a list of twenty-eight never events, defined as adverse events that are deemed by these groups as preventable events that should never occur in the hospital setting. These advocacy groups publicly questioned the Centers for Medicare and Medicaid Services' (CMS') reimbursement of such events. The LeapFrog Group endorsed the NQF's list and encouraged hospitals, among other things, to waive all costs for healthcare required due to a never event.

CMS has applied the never events concept to healthcare reimbursement by promulgating regulations stating that hospital-acquired conditions (HACs)—which are very much like the twenty-eight never events identified by NQF—will no longer be reimbursed by Medicare for hospitalized patients unless the HAC was present upon the admission of a patient. Effective October 1, 2008, reimbursements to hospitals could be drastically reduced as a result of this policy. A hospital will not receive additional payment for cases in which a HAC was not present on admission and then occurred during the hospital stay. The case will be paid as though the secondary diagnosis was not present.

But consider the following hypothetical situation:

Marge is a seventy-nine-year-old female admitted for an irregular heartbeat and swollen lower extremities. She lives alone and her primary caregiver is her daughter. She has smoked two packs of cigarettes a day for forty years. She has little interest in eating and is frail and underweight. Cardiac tests reveal a fast atrial fibrillation unresponsive to medication. An ablation procedure and placement of a cardiac pacemaker is recommended. Marge undergoes the procedure without complication and
Two nights after the procedure, Marge becomes disoriented and agitated. She insists that she wants to go home but that she is being held prisoner. The nurse determines that Marge is at risk for falls and institutes appropriate fall precautions. The nurses reassure Marge and give her a sedative to encourage sleep. The hospitalist evaluates Marge and determines that there is no apparent medical reason for Marge's confusion. The working diagnosis is “Sundown Syndrome”—a condition seen at times in hospitalized elderly patients. The condition presents with nighttime confusion that lessens during daylight hours.

At around 3:00 a.m., Marge decides to take matters into her own hands and proceeds to climb over the bed rails. Marge falls over the bed rails, hitting her head and breaking her hip. The head injury results in a subdural hematoma requiring surgical evacuation. Marge's broken hip is pinned during a second surgery.

The postoperative course is complicated by a prolonged need for ventilator support. Smoking predisposes Marge to pneumonia, which ensues within forty-eight hours of the fall. Marge also needs an indwelling urinary catheter. Mobility is limited due to the neurosurgery, hip pinning surgery, and the ongoing ventilator support.

The nursing staff gets Marge up in a chair as ordered. During a transfer from Marge's bed to a chair, the newly implanted pacemaker wire becomes dislodged, necessitating another trip to the cardiac catheterization lab and a lengthy procedure to reposition the wire. During the procedure, a central venous catheter is inserted into the right subclavian vein. A small pneumothorax is created during the procedure. It is treated immediately and resolves without sequelae. Marge develops a small but deep decubitus on her bony tailbone.

During the remainder of Marge's hospital stay, she develops a urinary tract infection despite the routine care of the catheter as set forth by hospital procedures. Because of the antibiotics used to treat Marge's pneumonia and urinary tract infection, Marge develops clostridium difficile and intractable diarrhea. After approximately a four-week stay in the hospital, Marge is discharged home to the care of her daughter. She has stopped smoking but continues to have a poor appetite.

Now think about these questions (answers will be provided at the end of this article):

1. When did the first potential never event occur?
2. What are all of the potential never events in the above scenario?
3. What is the approximate cost to the hospital in uncompensated charges attributed to Marge's never events?

Not reimbursing hospitals for never events is part of CMS' transformation from a simple payor of health services to a well-informed purchaser of only quality healthcare services. In April 2007, CMS first identified some HACs that might be subject to no reimbursement effective for discharges on or after October 1, 2008. The HACs that ended up on this list are:

- Foreign object retained after surgery;
- Air embolism;
- Blood incompatibility;
- Stage III and IV decubitus ulcers;
- Falls and trauma resulting in fractures, dislocations, intracranial injuries, crushing injuries, burns, and electric shock;
- Catheter-associated urinary tract infection;
- Vascular catheter-associated infection; and
- Surgical site infection—mediastinitis after coronary artery bypass graft surgery (CABG).

CMS estimates that these eight conditions cost Medicare approximately $21.3 billion annually. The most prevalent conditions are stage III and IV decubitus ulcers, with 257,412 cases reported under the current reimbursement codes at an average cost of $43,180 per hospital stay. The most costly condition is mediastinitis following a CABG with sixty-nine cases reported at an average cost of $299,237 per hospital stay.

On April 14, 2008, CMS announced nine other conditions that it is considering for the same reimbursement elimination effective in 2009. The additional HACs include:

- Certain surgical site infections following elective procedures (e.g., total knee replacement, laparoscopic gastric bypass and gastroenterostomy, and ligation and stripping of varicose veins);
- Legionnaires' Disease;
- Glycemic control conditions;
- Iatrogenic pneumothorax;
• Delirium;
• Ventilator-associated pneumonia;
• Deep vein thrombosis (DVT)/pulmonary embolism (PE);
• Staphylococcus aureus septicemia; and
• Clostridium difficile-associated disease.11

On July 31, 2008, CMS announced that three of these proposed conditions—certain surgical site infections, glycemic control conditions, and DVT/PE following certain procedures—would be considered an HAC effective October 1, 2008. CMS reserves the right to revisit the remaining six conditions at a later date.12

CMS estimates that these additional nine conditions cost Medicare approximately $21.76 billion annually.13 The most prevalent condition is DVT, with 140,010 cases reported at an average cost of $50,937 per hospital stay. The most costly condition is ventilator-associated pneumonia, with 30,867 cases reported annually at a cost of $135,795 per hospital stay.14

These seventeen HACs considered to date by CMS cost an estimated $43 billion annually,15 reflecting only Medicare expenditures and not those of private insurance. Thus, actual costs potentially attributable to these never events are likely substantially greater. The $43 billion is approximately 1.8% of the estimated $2.3 trillion spent on all healthcare in 2007 in the United States.16

This idea of not reimbursing hospitals for care that results from a never event has quickly found support. A significant number of public and private sector payors have decided not to reimburse hospitals for healthcare that flows from a never event. In November 2007, the BlueCross BlueShield Association, which represents insurance plans that insure over 100 million people, announced that it would phase in non-payment for never events.17 Cigna and WellPoint recently made similar decisions.18 Sixty-one Massachusetts hospitals will stop charging for nine of the NQF never events. Nationally, approximately 1,300 hospitals intend to waive all costs directly associated with never events.19

States also are embracing the idea. For example, the New York Medicaid program recently announced that it will deny reimbursement for fourteen never events.20 Minnesota hospitals have decided that patients and health plans should not pay for any of the NQF’s twenty-eight never events.21 Massachusetts will no longer pay for care related to the twenty-eight NQF never events for the 1.6 million patients covered through four state agencies.22 CMS recently sent a letter to state Medicaid directors encouraging the adoption of the CMS non-payment policies.23 The economic impact of this trend among CMS, states, hospitals, and health insurers is staggering.

Granted, the occurrence of some never events is hard to comprehend—instances of wrong surgery, wrong patient, or wrong site still occur.24 Tying payment to quality makes sense and is standard in many industries. Quality healthcare is also something we all want both in our professional and private lives. However, the concern with the burgeoning CMS list of never events is that it includes known complications of receiving good healthcare—especially when healthcare delivery is coupled with, among other things, patient behavior, drug side effects, or indwelling catheters. Many healthcare providers, and their legal counsel, would agree that at least some of the HACs are not aberrant enough to be categorized as a never event as that term is defined by NQF or CMS. Unfortunately, some never events can occur as unpreventable side effects of healthcare delivery.

For example, in Marge’s case, the delirium arguably was a side effect of the sedative or was a confusion sometimes seen in elderly hospitalized patients. The fall over the bed rails and its consequences could be attributed to Marge’s behavior despite the hospital’s recognized precautions to prevent the fall. Forty years of smoking could predispose a person to pneumonia. A pneumothorax is a small but known complication of a central venous catheter.25 These circumstances eliminate four of the current or potential HACs.

So what is a hospital to do? And what role do physicians play in this effort?

Work as a team. A hospital would be wise to involve hospital physician leadership and the medical staff in any efforts to address never events. The hospital provides the place, staff, and equipment for healthcare, but a physician oversees the delivery of healthcare to patients who come to the hospital. The financial loss to hospitals caused by the lack of reimbursement of care that flows from never events will eventually affect the resources available for healthcare. The interdependence between physicians and hospitals will be impacted by the financial burden of never events.

Be proactive. Gather stakeholders—physicians, nurses, ancillary staff—and study the CMS list of seventeen no-pay HACs and the twenty-eight never events on the NQF list. Stay abreast of other never events CMS is considering. Develop standing orders and algorithms to address factors that could contribute to a HAC.

Address and mitigate the potential for a “blame game” between hospitals and physicians. Think about it: many of the never events could inadvertently flow from either physician orders (insertion of a urinary catheter) or physician actions (insertion of a central venous line). The hospital staff then follows the physicians’ orders along with hospital policy and procedures. Adverse events will likely occur (for example, an infection with an indwelling urinary catheter). This sets up a never event and the hospital risks nonreimbursement.

Who is to blame, or is anyone to blame? Will never events require legal counsel for physicians to review indemnification provisions in any contracts with hospitals? Will hospital legal staff want to cost shift the lack of reimbursement for any secondary care that flows from an adverse event? Hospitals and physicians should now work collaboratively to address these explosive issues head-on.

Develop thorough admission forms and heightened documentation. Document such factors as mental status, skin condition, risk factors for immobility, and poor health habits such as smoking. Go even further and document—perhaps through another admission checklist—the preexisting conditions that predispose patient to a HAC. Have a physician evaluate the patient and then sign off on the admission checklist. Document the known side effects of drugs and treatment in the medical record—for example, in Marge’s case, among other things, chart that delirium may be a side effect of a sedative and an iatrogenic pneumothorax is a complication of a central venous catheter.
Physician Organizations

Importantly, this documentation may prove helpful in the future because CMS is considering comments it received about “enhancement options” for the payment issues related to HACs. For example, CMS discusses the idea of “risk adjustment” at the individual or subpopulation level that would take into account certain predispositions toward the development of HACs in hospitalized patients. Physician documentation in the medical record of preexisting conditions, comorbidities, and potential side effects will be critical as a hospital attempts to make the case for reimbursement for a HAC.

Revise informed consents. Include language acknowledging the complications, such as HACs, that can occur during a hospital course. Tailor informed consent forms to allow the inclusion of information about a patient’s preexisting conditions that could predispose the patient to a HAC. Have the patient acknowledge in the informed consent form the existence of such preexisting conditions or past medical history. Use the informed consent and the other documentation described above to appeal the nonpayment.

Consider the nexus between gain-sharing and the prevention of never events. The Department of Health and Human Services Office of Inspector General issued two advisory opinions recently that provide guidance for hospitals and physicians to work together to develop programs that save costs. Study these advisory opinions—and perhaps even seek an advisory opinion—about the synergy possible in collaborations between physicians and hospitals implemented to prevent certain never events.

Utilize existing tools to try to improve quality and address HACs. For example, the NQF publication Safe Practices for Better Healthcare: PowerPoint-Centers provides thirty practices that a hospital could institute to try to mitigate a HAC occurrence. The Surgical Safety Checklist, developed by the World Health Organization and currently being piloted by eight locations worldwide is another resource for hospitals and surgeons to consider.

Study safety intensive industries. The airline industry may provide guidance for healthcare. For example, at Beth Israel Deaconess Medical Center, a Harvard University-affiliated teaching hospital, the obstetrics unit reduced adverse events by 25% by borrowing practices from the airline industry such as implementing “crew resource management,” which defines rules for communication and requires increased awareness of the distribution of patients within the unit. The unit staff has frequent “huddles” to discuss workload and unit status.

Become an expert in the Medicare and private payor appeal and payment process. Use the admission forms, informed consent forms, and heightened documentation to argue for reimbursement of a HAC or never event. Learn from the denials of the appeals to argue the next appeal for payment. Move HAC and never event reimbursement decisions from a carte blanche denial of payment to a fact and circumstance balancing test.

Never events—and importantly the appeal of a denial of payment for a never event—is uncharted territory. Indisputably, the financial impact of the nonpayment of never events will affect a hospital’s bottom line. In addition, the litigation aspects of never events are an additional concern. Come October 1, 2008, reimbursement in healthcare will undergo drastic changes—and more is to come if CMS includes or expands on NQF’s twenty-eight never events. If there ever was a common cause for hospitals and physicians to come together and address in unison, it is never events.

Answers:

1. When did the first potential never event occur? Delirium.
2. What are all of the potential never events in the above scenario? Delirium, fall over the side rails resulting in intracranial trauma and hip fracture, ventilator-associated pneumonia, catheter-associated urinary tract infection, iatrogenic pneumothorax, potential stage III decubitus, and clostridium difficile-associated disease.
3. What is the approximate cost to the hospital in uncompensated charges attributed to Margés never events?

<table>
<thead>
<tr>
<th>Hospital Acquired Condition</th>
<th>Cost per Hospital Visit</th>
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<tbody>
<tr>
<td>Delirium</td>
<td>$23,290</td>
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<td>Fall over the side rails resulting in intracranial trauma (1) and hip fracture (2)</td>
<td>$33,894 for each HAC</td>
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<td>Ventilator-associated pneumonia</td>
<td>$135,795</td>
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<td>Catheter-associated urinary tract infection</td>
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<td>Iatrogenic pneumothorax</td>
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<td>Potential stage III decubitus</td>
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<td>Clostridium difficile-associated disease</td>
<td>$59,153</td>
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<td>Total HACs: 8</td>
<td>Total unreimbursed costs: $448,428³²</td>
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2 Id.
3 CMS Fact Sheet, Incorporating Selected National Quality Forum And Never Events Into Medicare’s List Of Hospital-Acquired Conditions, April 14, 2008, available at www.cms.hhs.gov/apps/media/fact_sheets.asp. (Note: for purposes of this article, the terms never events and HACs will be used interchangeably.)
6 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, Final Rule, 72 Fed. Reg. 47130 (August 22, 2007); see also, CMS Fact Sheet, FY 2008 Inpatient Prospective Payment System Proposed Rule Improving the Quality of Hospital Care, April 13, 2007, available at www.cms.hhs.gov/apps/media/fact_sheets.asp.
7 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009, 73 Fed. Reg. 23528 (issued April 30, 2008); see also, CMS Fact Sheet, CMS Proposes Additions to List of Hospital Ac-
The total amount of estimated costs was obtained by multiplying total charge for a patient discharge by total number of cases annually.

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Clinical Integration: Lessons Learned or The Good, the Bad, and the Ugly

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There are two kinds of people in the world, my friend. Those who have a rope around their neck and those who have the job of doing the cutting.

— Tuco, The Good, the Bad, and the Ugly

Preface

In our June 2006 article in this newsletter, "Clinical Integration: Collective PPO Contracting as a Catalyst for Quality Medicine," we discussed how clinical integration (CI), coupled with collective negotiation by an "interdependent" network of otherwise independent physicians, could work to free healthcare from the economic and quality challenges that threaten to close like a noose around the practice of medicine. As we examined the prevailing state of antitrust law and enforcement policy at the time, we foresaw a number of potential hazards that could have strangled the development of CI: hostility from the payor market, skepticism from employers, and heavy-handed prosecution by the Federal Trade Commission (FTC).

But that hasn't happened. Instead, a growing number of physician networks, frequently (and most successfully) in collaboration with hospitals and health systems, have embarked on the trail to CI. And they've done so in a way that engages health plan participation; enhances value for employers as healthcare purchasers; and embraces the consistent, flexible framework provided by the FTC since 1996.

So, with apologies to Sergio Leone, we bring you this update from the CI frontier in all its nuanced glory—good, bad, and ugly.

The Good

There are two kinds of people in the world, my friend. Those with loaded guns and those who dig. You dig!

— The Man with No Name

Antitrust Enforcement Policy

Let's begin with the many "good" things that have happened regarding CI—not the least of which is the evolution of antitrust law and enforcement policy as it applies to collective negotiation by physicians.

Throughout the 1980s and 1990s, independent physicians engaged in legitimate, collective negotiations with health plans by effectively managing quality and cost under capitated and other "risk" arrangements. However, as health plans steadily continue to retreat from risk contracting, physicians can have the greatest impact on cost and quality if they learn to apply the tools and processes they developed to manage care under capitation to the growing fee-for-service population. By doing so in an effective and conscientious manner, these physicians will likely find that they meet the legal definition of a "clinically integrated network" as it was first established by the FTC along with the U.S. Department of Justice (DOJ) in their 1996 joint Statements of Antitrust Enforcement Policy in Health Care:

[An] active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.

According to the Joint Statements, and every other pronouncement by the FTC since 1996, such integration affords a network of independent physicians the ability to have its collective negotiations escape per se illegal treatment by the FTC, instead to have its joint contracting evaluated according to the so-called "rule of reason"—a balancing test that considers the anticompetitive effects of the arrangement against its potential to achieve procompetitive efficiencies.

Integral to this balancing test is the concept of ancillarity (i.e., a determination that the joint contracting is "reasonably necessary" to achieve the efficiencies promised by the joint conduct). Through at least 2002, however, many healthcare organizations found this "reasonable necessity" formula somewhat disquieting. Did it really mean that a group of physicians who had already worked with their hospital to improve care was effectively barred from commencing collective negotiations with health plans? Would ancillarity give the FTC an insurmountable prosecutorial advantage and lead to an enforcement environment too harsh and hostile for physicians and hospitals to engage in CI?

Since that time, the FTC has published consent decrees and advisory opinions that are extremely helpful in answering any question about "overenforcement" and ancillarity. These include the two MedSouth advisory letters (from 2002 and 2007), the
Suburban Health Organization (SHO) advisory letter (2006), the Greater Rochester Independent Practice Association (GRIPA) advisory opinion (2007), and the consent decrees with Brown & Toland Medical Group (2005) and Advocate Health Partners (AHP; 2006).

Further, the FTC and DOJ held a series of public hearings in 2003 on the topics of clinical integration and joint physician contracting (for which the authors provided significant testimony). Their findings were published in a comprehensive report entitled Improving Health Care: A Dose of Competition, including a lengthy discussion of CI along with a list of questions that the FTC uses as a “due diligence” list when considering whether a physician network is operating in a lawful manner.2

While any of these FTC documents can provide invaluable insights toward answering the “what is CI?” question, three of the most recent examples offer a particularly dramatic illustration: AHP, GRIPA, and SHO.

On December 29, 2006, the FTC concluded its four-year investigation of AHP, a 3000-member physician network in the greater Chicago area affiliated with the eight-hospital Advocate Health Care Network. Unlike previous consent decrees, the settlement between AHP and the FTC specifically permitted AHP to continue its collective contracting activities with preferred provider organizations (PPOs) and other fee-for-service health plans under its CI program.3 Today, the newly renamed Advocate Physician Partners maintains collectively negotiated fee schedules with virtually all major health plans in the Chicago metropolitan market and annually distributes approximately $20 million in pay-for-performance incentives to its physician members.

In 2007, the FTC published an advisory opinion requested by GRIPA to evaluate its plan to conduct collective negotiations with fee-for-service plans via CI. Significantly, the FTC staff considered the “explicit admission” by GRIPA that one objective of the plan was to contract at higher fee levels for the services of physician members. Despite that, GRIPA was allowed to move forward with collective negotiation.

So what do we learn from the AHP Order and the GRIPA Advisory Opinion? The FTC, at this point in time, is not engaged in overenforcement. AHP was allowed to continue collective negotiation and GRIPA was given permission to begin collective negotiation. So what do these public statements by the FTC say about the “ancillarity” issue (i.e., the requirement that joint contracting must be “reasonably necessary” for the CI program’s success)? Well, let’s consider what the FTC said specifically about this concept.

Ancillarity, or the lack thereof, was the crucial factor in the FTC’s negative advisory opinion from March 2006 to SHO, a “super physician network” composed of eight physician networks affiliated with a number of competing hospitals and hospital systems throughout the Indianapolis metropolitan area. This opinion, issued in March 2006, rejected SHO’s proposed CI program for primary care physicians employed by SHO’s affiliated hospitals. In arriving at this conclusion, the FTC identified both a lack of “interdependence” among the primary care physician groups and

the ability of the employing hospitals to influence the practice patterns of these physicians without resorting to the joint negotiation of fees with health plans.4

By allowing physician networks like MedSouth, Brown & Toland, GRIPA, and AHP to contract collectively on behalf of their physician members—and by withholding this privilege from SHO—it is clear that the FTC is maintaining a consistent approach to finding ancillarity in programs that require physicians to follow closely identified real initiatives with a “likelihood of improvement” in the quality and cost of care. Clearly, such physician networks must demonstrate that these initiatives and likely improvements are different from what they were doing previously, and in a manner that performance is measured, monitored, and enforced. Both AHP and GRIPA argued that, in order for these programs to be sustainable, there had to be a series of incentives afforded to physicians the ability to collectively negotiate and the ability to ask payors to fund pay-for-performance bonuses for physician compliance.

“Good” Health Plans

Other “good” occurrences include the response of the payor market or at least some of the payor market (see “Ugly” below). A solid, sustainable CI program needs validation in the marketplace through a contract with those health plans that recognize and reward physician efforts. There are three components to a true CI contract: (1) an articulation of the purposes and the initiatives included in the arrangement; (2) a recognition by the payor that this is a new and different type of arrangement; and (3) a payment methodology that recognizes the value of the program and its need for sustainability.

Sustainability means that the payors recognize that the program will reduce cost through better prevention and management of illness and reimburse physicians for their efforts. In many instances, this long-term reduction in healthcare costs is driven by CI contracts with physicians who provide a 10–30% increase in per-unit fee schedule reimbursement. In this regard, health plans have shown a great willingness to invest in the long-term capabilities of a physician network’s CI program by contributing incentive and infrastructure support funds.

“Good” Hospitals

Also in the “good” category is the willingness of many hospitals and health systems to work closely with their medical staff members to develop new physician networks and support the development of CI programs that drive better hospital quality and cost-effectiveness. These programs allow hospitals to broaden their physician alignment strategies beyond a rigid focus on employment models and create a relationship among the medical staff and the hospital that sees the physicians working in an interdependent manner—in many cases, for the first time. Further, organizations like Advocate Physician Partners are developing a body of published work on the value of such an intensive hospital physician collaboration through CI in reducing cost and enhancing quality.5
The Bad

Angel Eyes: People with ropes around their necks don’t always hang.

Woman on stagecoach: What do you mean?

Angel Eyes: Even a filthy beggar like that has a protecting angel.

There is a lot less to say about the “Bad” than there is about the “Good.” Nonetheless, it bears mentioning that some lessons learned are not pleasant.

“Bad” Hospitals

Hospitals are in a position to be the greatest asset or the biggest challenge in the development of a successful CI program. Hospital administrators and boards sometimes fail to recognize the benefit of CI to the institution and the community and resist or rebuff opportunities to provide encouragement, project management, and financial support to clinically integrated physician groups—which, if structured properly, do not cause Stark or Medicare fraud problems.

Some shortsighted hospital administrators will even deny the usefulness of cooperating with the network of independent physicians on CI initiatives to improve hospital performance on core measure compliance, patient safety efforts, and cost-savings and efficiency projects. In such cases, the hospital administrator may even try to subvert any efforts by physicians toward developing a CI network due to a belief that it will undermine the administrator’s efforts to own and control physicians through employment and thereby the physicians’ referrals.

“Bad” Physicians

Last but not least: the physicians themselves can become their own worst enemy. Also an obstacle are physicians who do not see the need to change what they are doing because they are either afraid or cynical or just do not see interdependence and quality as the future. Then there are others who simply have a vested financial interest that renders them opposed to the development of such a CI program.

Because of this chronic issue of physician inertia, it is important to develop a leadership group of physicians who are fully briefed with all the information on CI, and train them to expand their numbers in a grassroots-style organizing campaign. These efforts culminate in a series of roundtable and town-hall meetings where the doctors become more aware and trusting, as well as fully committed to the CI process.

The Ugly

I have a system, very much like yours. Only difference is I don’t shoot the rope, I shoot the legs off the stool. Adios.

— Tuco

“Ugly” Health Plans

There is even less to say about the “Ugly” than the “Bad.” Nonetheless, negative payer reactions top the list. It is important to remember that we started this century with certain payors actively engaged in overt and covert attempts to break up physician networks (independent practice associations [IPAs], physician hospital organizations [PHOs]) by using the antitrust laws. For example, United HealthCare pioneered the distribution of opportunistic “CI questionnaires” among numerous IPAs and PHOs nationwide—often using the physician networks’ uneducated responses to form leading questions to raise antitrust concerns. With their oft-stated preference to “deal directly” with the physicians, it is hard to ignore the likelihood that United and other health plans employing this tactic wish to use their significantly greater leverage to achieve better financial terms.

There are still many payors who would prefer to ignore CI efforts and act as “free riders,” enjoying the benefit of CI collaborations among physicians and hospitals without having to pay for it. After all, when physicians begin managing quality and cost in an interdependent manner, they begin applying these techniques to all their patients. So, while one or two payors recognize the efforts of a CI physician network with a better fee schedule and a contribution to a pay-for-performance physician incentive fund, the other payors may ignore their community responsibility and take the advantage for free. When that happens, the physicians, aligned with the participating hospital or health system, should approach the employers in their community and make this lack of health plan responsibility well known. CI is a dramatic change in the provision of healthcare. The community needs to get behind it.

Conclusion

CI fosters collaboration among independent physicians and hospitals in a way that both increases the quality and efficiency of patient care—and, as such, the concept of CI has expanded its usefulness to hospitals and networks of physicians well beyond that of mere antitrust compliance. By virtue of properly structured, responsibly implemented CI programs, physician networks can assert themselves forthrightly in collective negotiations with PPO health plans. Simultaneously, CI offers hospitals and physicians a highly potent business and clinical strategy—providing them with the ability to thrive in the advent of consumerism, pay-for-performance, and quality report cards.

1 See www.ftc.gov/reports/hlth3s.html#8.
3 See www.ftc.gov/opa/2006/12/ahp.htm.
4 See www.ftc.gov/bc/adops/gripa.pdf.
5 See www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf#search=%22suburban%20health%20organization%22.
The Centers for Medicare and Medicaid Services (CMS) has been testing the recovery audit contractor (RAC) program since 2005. Instituted under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the program is intended to analyze and audit reimbursement claims, employing private contractors to identify whether the government overpaid or underpaid hospitals, physicians, and other providers for the services they provided. RACs are unique in that they are the only Medicare auditors who are paid a contingency fee based on the amount of improper payments they identify and collect. The RAC program was first introduced in Florida, New York, and California, and then expanded to include Massachusetts, South Carolina, and Arizona.

RACs corrected more than $1.03 billion in improper Medicare payments during the three-year demonstration project, while only reviewing claims in five states at a minimal cost to the government. An overwhelming majority of the improper payments identified by RACs—approximately 96% ($992.7 million)—were overpayments collected from providers, while only 4% ($37.8 million) were overpayments paid back to providers. Nearly half of the overpayments were related to incorrect coding and about one-third were claims that did not meet Medicare’s criteria for medical necessity. Other types of errors identified include insufficient documentation, duplicate claims, and fee schedules followed incorrectly. While physicians have been affected by the RAC demonstration program, the bulk of the identified overpayments (85%) were to hospitals.

RAC claims review activity has grown quickly over the past several years, a trend which will likely continue. Of the $1.03 billion in improper payments corrected by RACs so far, approximately 4% occurred in 2006, 34% occurred in 2007, and 62% occurred during the first half of FY 2008. Further, the RAC program will soon be rolled out nationwide. While the demonstration program ended in March of this year, the Department of Health and Human Service (HHS) is required by law to create a permanent, national RAC program by January 1, 2010. The program is expected to be phased in, with additional states being added in the next four months.1

The incentive-based nature of the RAC program has many members of the healthcare sector—particularly hospitals, physicians, pharmacies, and laboratories—expressing concern that the RACs are focusing their activities nearly exclusively on recovering overpayments to providers with little or no attention given to instances in which providers were underpaid for the services they delivered. The program continues to be the subject of much discussion in the medical community.

On May 14, 2008, the House Committee on Small Business, Subcommittee on Regulations, Healthcare and Trade, heard testimony on the RAC program from a wide range of healthcare providers. In a statement following the hearing, Rep. Charlie Gonzalez (D-TX), who chairs the subcommittee, commented: “CMS is right to seek an efficient payment system, but that doesn’t mean it should only correct the errors that favor the agency. In the current economic climate, many small providers are struggling to stay afloat. If CMS owes them money, they should be paid.”

Representing the American Medical Association, William A. Dolan, MD, noted that roughly 53% of physician practices have fewer than three physicians and 75% have fewer than eight physicians. Dr. Dolan cited the regulatory burdens associated with RAC reviews and the impact of the time and expense of the reviews on small practices. Dr. Dolan questioned the value of the reviews, stating that “although little data has been released by CMS concerning the average alleged overpayments RACs collected from physicians, the 2006 data suggest that the average was as little as $135 per provider in Florida and $216 per provider in California.”

“These collections are nominal compared to the time and effort required to process them,” Dolan said. “The best way to reduce common billing and coding mistakes is through target education and outreach, rather than onerous audits performed by outside contractors provided with incentives to deny claims.”

Dolan also said that the RAC program is redundant in the face of other audit processes currently in place, such as the Comprehensive Error Rate Testing Program (CERT), the employment of Fiscal Intermediaries (FIs), Medicare Administrative Contractors (MACs), and Quality Improvement Organizations (QIOs) that already oversee Medicare payments.

Other witnesses shared similar concerns with the subcommittee. Speaking on behalf of the Alliance of Specialty Medicine, a coalition of thirteen national medical specialty societies representing more than 200,000 physicians, Michael C. Schweitz, MD, characterized the RAC program as an uncontrolled bounty hunter. Schweitz provided several specific examples of problems that
The RAC’s findings to the fiscal intermediary must do so within thirty days from the date on the notice letter. If an appeal is not initiated in time, the RAC will simply recoup the alleged overpayments, leaving the provider with no other avenue of recourse. The appeals process can be daunting. It often involves reviewing each claim and its corresponding medical record individually, as well as developing a case one claim at a time. Furthermore, there are potentially five levels of appeal available to providers—the process could involve a significant time commitment.

Providers in the demonstration states have voiced a number of concerns with the RAC program. The greatest concern was that claims reviewers did not always seem well versed in Medicare policy and often applied the wrong standards to claims or simply applied the standards incorrectly. Providers were equally troubled by the fact that RACs often began recouping alleged overpayments immediately, before the appeals process was resolved. In addition, RACs were allowed to keep their contingency payment as long as they won the first level of appeal, even if they subsequently lost the appeal at a higher level.

CMS has said that it will make significant improvements to the permanent RAC program in response to some of these concerns. For example, RACs will now be required to have “certified coders,” although it is not clear how many or to what extent they will be involved. In contrast to the demonstration program, the permanent program will place a mandatory limit on the number of medical records a RAC can request at one time, although the exact number is not yet known. In the future, RACs will be required to repay their contingency fee if they lose at any level of appeal. Additionally, a new Medicare appeal rule slated to take effect on July 1, 2008, will prohibit RACs from recouping alleged overpayments from providers who have appealed the audit findings until the first two levels of appeal have been completed.

What Is Next?

On July 11, 2008, CMS issued a report on the RAC demonstration program. The report speaks to the success of the program as well as describes changes that are expected to be made to the RAC program going forward. A copy of the report is available online. According to CMS, it has returned almost $700 million to the Medicare Trust Funds from the inception of the demonstration project through March 27, 2008. This amount takes into account the cost of the program (approximately twenty cents for each dollar collected) and any monies CMS paid back to providers as a result of overpayments collected from providers, as well as any monies related to claims overturned on appeal. Overall, 14% of providers appealed the process, with 4.6% of those decisions being overturned.

The permanent RAC program is intended to be used by CMS to ensure that payments to healthcare providers are accurate and proper, and that the number of errors in Medicare claims continues to decline. In an effort to be responsive to complaints regarding the demonstration project, CMS proposes the following changes to improve the permanent RAC program including:

- Requiring each RAC to hire a physician medical director and certified coders;
- Changing the claim review period from four years to three years;
- Adding a maximum look-back date of October 1, 2007;
- Requiring each RAC to get a claim review in the first year, although that may not be the case in the first year.
- Increasing the number of overpayments recycled from 10% to 20%.
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RAC audits occur through two different processes: automated review and complex review. Complex review is required when the RAC determines that a billing error has occurred but cannot be sure without reviewing the medical record. The RAC will send a letter to the provider requesting medical records, and the provider will have forty-five days to respond. The RAC will then review the medical record to determine if the claim was coded correctly or if the treatment was medically necessary. Providers will receive determination letters informing them of overpayments, underpayments, or no errors.

Automated review is used to detect obvious errors, such as duplicate billing, that do not require review of the medical record. Because there will be no request for medical records, a provider will not know it is the subject of an automated review until it receives notice of overpayment or underpayment. Once a RAC has identified potential billing errors, a provider must act quickly to appeal. Providers who choose to appeal the RAC’s findings to the fiscal intermediary must do so within forty-five days to respond. If an appeal is not initiated in time, the RAC will simply recoup the alleged overpayments, leaving the provider with no other avenue of recourse. The appeals process can be daunting. It often involves reviewing each claim and its corresponding medical record individually, as well as developing a case one claim at a time. Furthermore, there are potentially five levels of appeal available to providers—the process could involve a significant time commitment.

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- Adding a maximum look-back date of October 1, 2007;
• Requiring the RACs to pay back contingency fees when an improper payment determination is overturned—at any level of appeal;
• Requiring RACs to offer a web-based application by January 1, 2010, to allow providers to see the status of cases; and
• Having all new issues a RAC wishes to pursue for overpayments validated by CMS or an independent RAC validation contractor and to share the upcoming new issues with provider organizations.

Now is the ideal time for providers to set up procedures to effectively deal with RAC audits, rather than waiting until you are subject to an audit.

**Tips for Responding to RAC Audits**

1. **Don’t be an easy target.** Make sure your coders, management team, billing department, physicians, and anyone else involved with billing is kept up-to-date of appropriate coding and billing practices. Inappropriate use of code modifiers is one area that RACs have focused on repeatedly. Medical necessity is another dangerous area for providers since RACs have the ability to retrospectively second-guess admission and treatment decisions. It is critical for providers to keep detailed medical records and take steps to ensure that medical records contain the appropriate documentation as required by current regulations. Additionally, providers should perform internal audits on a regular basis and consider periodic external audits.

2. **Assemble a response team.** It is important to designate one person to act as the primary point of contact to be responsible for coordinating all communications in connection with the audit. The provider’s RAC coordinator should consult with multiple departments—including billing, compliance, medical staff, and legal departments—and alert the RAC team as soon as he or she becomes aware of the audit.

3. **Be skeptical.** Providers should review every claim for recoupment and never simply assume that the RAC audit was performed correctly.

4. **Be prepared to appeal.** Both statistical and anecdotal evidence from the demonstration programs shows that providers who appealed RAC audit findings were quite often successful. RACs have made errors in the past, and appealing RAC audits may be well worth the investment.

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1. For a state-by-state breakdown of the proposed roll-out, see *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration*, p. 53 (June 2008).
Prospective providers and suppliers of services to Medicare beneficiaries that require Medicare certification may have to be more patient and diligent in the future in order to receive initial certification by Medicare. No longer will state survey agencies be able to conduct Initial Surveys of new providers while other survey and certification work remains to be completed.

While physicians do not need to be certified for Medicare, physicians and physician groups are increasingly involved in other ancillary providers such as labs, imaging facilities, hospitals, and other facilities required to obtain Medicare certification. Physicians interested in, solicited to invest in, or owning facilities that require Medicare certification should consider the additional cost and time involved in obtaining accreditation from accreditation organizations (AOs) rather than from state survey agencies (SAs).

The Social Security Act provides for the establishment of a quality assurance system for the Medicare Program, the basis of which is onsite surveys by both federal and state surveyors.1 Each state has a designated state SA charged with ensuring and maintaining the quality of services and items provided to Medicare beneficiaries through certification, recertification, and the investigation of complaints (Survey and Certification) regarding Medicare providers in their jurisdiction. Certain Medicare providers—including hospitals, critical access hospitals, ambulatory surgery centers (ASCs), labs, home health agencies, and hospices—must be Medicare certified prior to receiving reimbursement for services to Medicare beneficiaries, for which a survey (Initial Survey) is required to be provided at no cost to the provider. For several years, Initial Surveys have been delayed in several states due to resource limitations.

In order to expedite the Initial Survey process, some states have attempted to make alternative arrangements. Louisiana passed legislation allowing new providers to voluntarily pay the cost of the Initial Survey to the Louisiana Department of Health and Hospitals, the state SA, to conduct the Initial Survey on a priority basis. Louisiana recently received instructions from the Centers for Medicare and Medicaid Services (CMS) that this practice is not acceptable and that Initial Surveys were not to be performed unless higher priority Survey and Certification work was completed first.2 This notification followed a national policy change by CMS that reprioritized the agency’s Survey and Certification activities.3

These recent changes by CMS have altered the landscape of Survey and Certification activities for new providers and suppliers who, for the first time, seek certification to provide services to Medicare beneficiaries and be reimbursed for those services. CMS has directed SAs to reprioritize Survey and Certification activities to emphasize further the recertification of existing providers, as well as the investigation and resolution of complaints against such providers. For the first time, the Initial Survey of new providers has been placed at a lower priority, with specific CMS instructions to the SAs not to conduct any Initial Survey until all recertification and investigation of complaints pending before the SA are resolved. This reprioritization applies to all providers who are subject to CMS certification. Unfortunately for new providers who were planning for an Initial Survey by an SA, the backlog of other Survey and Certification actions is likely to prevent any SA from conducting an Initial Survey unless and until longstanding underfunding of survey activities is resolved.

In the national policy change, CMS created “Tiers,” notifying SAs that Initial Surveys have been placed in Tier 4, behind other required survey activities (i.e., recertification and investigation of existing Medicare providers). Tier 1 priorities are statutory mandates, such as surveys of existing nursing homes and home health agencies and investigations of complaints with a high potential for immediate jeopardy. Tier 2 consists of complaint investigations, surveys of a 10% targeted sample of end stage renal disease (ESRD) centers and surveys of 5% of the remaining provider types identified to CMS as facilities most at risk of providing poor care. Tier 3 includes surveys of other providers that a SA determines are most at risk of quality problems. Although CMS has deemed Tier 4 priorities (including the survey of new providers) to be important, the agency also determined accomplishment of these activities to be reasonable only if other higher priority work can be accomplished within budgetary restraints.
CMS changed policy due to limitations in resources and funding, other survey responsibilities, and the large number of new providers seeking certification. For example, since 2002 CMS has seen a growth of almost 50% in rural health clinics, and almost 40% in ASCs and hospices, seeking to participate in Medicare.

CMS did allow for exceptions and higher priority for providers in certain circumstances where alternate methods of achieving certification are not available. Providers may apply for an exception to the priority assignment in cases where the provider can show that lack of initial Medicare certification would result in significant access-to-care issues for beneficiaries. Additionally, CMS provided that ESRD facilities, transplant centers, and hospitals without an option for accreditation—such as those seeking certification with special psychiatric hospital conditions of participation or distinct psychiatric or rehabilitation unit of a critical access hospital—will be a Tier 3 priority.

CMS also made special provisions for rehabilitation hospitals, and rehabilitation and psychiatric units of a hospital, which are seeking exclusion from compliance with the Inpatient Prospective Payment System (IPPS) under 42 CFR § 412. Rather than a survey, hospitals seeking IPPS exclusion for the first time may submit an attestation and a completed Form CMS-437, 437A, or 437B as applicable. Hospitals whose IPPS exclusion has been removed must wait twelve months and then be subject to a survey by an SA under Tier 4 priority.

All is not lost for other providers and suppliers who want to participate in the Medicare program for the first time. In addition to SAs, CMS recognizes accreditation by certain private AOs. CMS will certify facilities and providers that obtain accreditation from an approved AO as a Medicare-certified provider without additional survey or certification by an SA. Among the approved AOs are The Joint Commission, American Osteopathic Association, Community Health Accreditation Program, Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Commission for Health Care Inc., American Society for Histocompatibility and Immunogenetics, College of American Pathologists, Commission on Office Laboratory Accreditation, and American Association of Blood Banks. Each AO has been approved for certain types of facilities which may include hospitals, critical access hospitals, ASCs, labs, home health agencies, and hospices.

However, certain providers and suppliers not eligible for accreditation (and not designated as a Tier 3 priority) are considered Tier 4 and will have to wait for a survey by an SA unless approved for an exception based on critical access-to-care problems. These providers include comprehensive outpatient rehabilitation facilities, long-term care units of hospitals, non-Medicare-participating nursing homes, outpatient physical therapy, and rural health clinics.

While most prospective providers have the option of obtaining accreditation by an AO, there may be some consequences of Medicare change in Survey and Certification priorities that must be considered when assessing future plans to develop facilities required to obtain Medicare certification. Traditionally, Initial Surveys were conducted by SAs contemporaneously with licensure surveys, and thus there was little delay between the start of operations and being able to seek reimbursement for services to Medicare beneficiaries. Now providers may have to be operational for several months before a survey for certification by an AO can be completed, while being prohibited from seeking reimbursement from Medicare. For providers who seek accreditation by The Joint Commission, for example, a preliminary survey can occur as early as two months prior to opening, with a second survey conducted onsite approximately six months after the first survey. Medicare certification cannot occur until the second survey is completed. Thus a facility could be operational for over six months before certification by Medicare is obtained. There will be additional costs to obtaining accreditation from a private AO that were not present when obtaining an Initial Survey from an SA. There is also a perception in the provider community that accreditation surveys are more time consuming and intensive than Initial Surveys and require more planning and preparation by the facility.

Developers of healthcare facilities must consider these consequences when evaluating and planning the development of hospitals, ASCs, labs, and other facilities that require Medicare certification. Appropriate financial projections, budgeting, and financial resources will be important for the success of any such project. Professional advice and experience in developing healthcare facilities will also become a necessity. These changes may also make the acquisition of existing providers more attractive. Only time will tell whether these changes reduce the number of new Medicare providers.

1 Social Security Act Section 1864, 42 U.S.C. 1395aa.
2 Letter dated April 15, 2008, from the CMS Division of Survey and Certification, Region VI, to the Health Standards Section of the Louisiana Department of Health and Hospitals.
3 CMS Memorandum, November 5, 2007, Ref S&C-08-03.
4 Id.
5 Appendix A to Memorandum S&C-08-03.
6 Id.
7 Appendix C to Memorandum S&C-08-03.
Peer Review Hearing Guidebook focuses on the peer review hearing process, including steps that should be taken long before a medical staff hearing is contemplated to assure that procedures are in place to facilitate an effective and fair hearing. This Guidebook discusses not only the legal issues involved in peer review hearings, but also focuses on the practical steps that can be taken to improve the peer review and hearing processes. Sample forms, checklists, Medical Staff Bylaws, and fair hearing provisions are included on the CD-ROM, and can be customized for your clients.

**ABBREVIATED TABLE OF CONTENTS**

**Overview of Applicable Law:** The Health Care Quality Improvement Act of 1986 (HCQIA); Immunized Participants; Standard for Professional Review Actions; Furtheance of Quality Healthcare; Adequate Notice and Hearing Procedures; Pre-hearing Motions.

**When Is a Hearing Required?** When a Hearing Is Required? Right to Hearing Following Summary Action.

**Notice to Practitioner:** Notice of Hearing; Notice of the Hearing.

**Role of Legal Counsel:** Involvement of Attorneys; Attorney’s role as an Advisor or Observer; Exclusion of Attorneys from the Hearing; Right to Counsel before Hearing is Requested; Representation of Medical Staff and Hospital.

**Use of Hearing Officer:** Importance of Having a Hearing Officer; Selection, Role and Responsibilities of the Hearing Officer during and after the Hearing; Pre-hearing Procedures.

**Composition and Selection of Hearing Committee:** Size of Hearing Committee and Selection of Committee Members; Communications with Hearing Committee Members; Voir Dire and Challenges to Panel Members.

**Pre-Hearing Procedures—Discovery:** Scheduling; Pre-hearing Discovery and Exchange of Information; Pre-hearing Motions.

**Burden of Proof and Evidentiary Standards:** Burden of Proof and Applicability of State Administrative Procedure Act; Subpoena Power.

**Making a Hearing Record:** Form of the Record; Special Considerations for Public Hospitals; Public Disclosure; Applicability of State Administrative Procedure Act; Subpoena Power.

**Conduct of Hearing:** Right to Call, Examine, and Cross-Examine Witnesses; Witness Immunity; Sequestration of Witnesses; Witness Questioning Style; Questioning by Hearing Committee Members; Closing Written Statements.

**Hearing Committee Decision and Report:** Hearing Officer Participation in Deliberations; Hearing Committee Report.

**Proceedings After Hearing Committee Report:** Copy of Report and Notice Provided to Practitioner; Practitioner Response to Hearing Committee Report; Review of the Hearing Committee Report by Medical Executive Committee; Appellate Review by the Governing Body; Appearance Before Appellate Review Body.
Upcoming Teleconferences

**Red Alert—Red Flag Rules May Apply to You**
Wednesday, October 1, 2008
Co-sponsored by the Health Information and Technology and Hospitals and Health Systems Practice Groups

The Federal Trade Commission (FTC) recently issued a reminder notice of the November 1, 2008, deadline for compliance with its “Red Flag Rules.” The Red Flag Rules require the implementation of identity theft prevention programs by certain creditors. At this time, it has been concluded by the FTC and health lawyers that healthcare providers may be considered creditors and thus, covered by the Rules.

This teleconference will identify healthcare providers covered by the Rules and outline the process for implementing a proper identity theft prevention program. Experts from a variety of perspectives will provide not only a legal analysis of the Rules, but also practical guidance for addressing and implementing the proper program for your facility.

**Poliner Post Mortem: Implications for Hospitals and Medical Staff Members**
Thursday, October 2, 2008
Co-sponsored by the Hospitals and Health Systems; In-House Counsel; Medical Staff; Credentialing, and Peer Review; and Physician Organizations Practice Groups

The matter of Poliner v. Texas Health Systems will be discussed in depth including the facts of the case developing prior to the time of its filing through the time of its reversal upon appeal. The panel will discuss the practical application of the Poliner decision, as well as the Health Care Quality Improvement Act of 1986. The particular factors cited by the Fifth Circuit Court of Appeals in reversing the trial court’s Poliner holding will also provide topics.

Tuesday, October 28, 2008
1:30-3:30 pm Eastern
Co-sponsored by the Fraud and Abuse; Hospitals and Health Systems; Physician Organizations; and Regulation, Accreditation, and Payment Practice Groups

A two-hour interactive discussion of several real-world scenarios focused on new Stark Law changes and how they apply in the client counseling context. Materials and scenarios to be distributed in advance, including AHLA Stark Law Member Briefing.

**Health Plan Contracting: Hot Topics and Contracting Strategies for Payors and Providers**
Part I
Thursday, October 30, 2008
Co-sponsored by the Payors, Plans, and Managed Care and Hospitals and Health Systems Practice Groups and AHLA’s Professional Resources Department

- State Regulator Presentations—Hot Topics in State Regulatory Enforcement Relating to Health Plan Contracting
- Panel Discussion on Top Ten Current Hot Contracting Issues
- Question and Answer Session

**Part II**
Wednesday, November 19, 2008
- Continuation of Hot Contracting Issues Discussion
- Fact Pattern Analysis—Strategic Contracting Issues—Round Table Discussion

**Unless otherwise noted, all teleconferences are held 1:00-2:30 pm Eastern.**

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