

# THE PHYSICIAN'S COMPLIANCE ALERT™

PROVIDING PHYSICIANS WITH MEDICAL PRACTICE COMPLIANCE SOLUTIONS

## Quality Assessment: What Is a Group Owner's Liability?

**A**re the owners of a medical group legally responsible for the quality of care provided by one of its physician-employees? Does a group have a duty to review the clinical performance of its providers, even if those providers are independent contractors? Before initiating a quality improvement or credentialing program for your medical group, it's crucial to know the facts. While peer review and other clinical quality improvement programs offer obvious benefits when it comes to sharing expertise and improving patient care, the resulting documentation might expose you to legal risk in the event of a medical mishap. At the same time, the absence of a quality assurance (QA) program could surely work against you if you're sued for an error or other bad result.

### Damned if you do...

Consider a hypothetical case in which several independent physicians share a practice site and a shingle and implement a clinical quality review program to assess and improve the care they provide. If a malpractice suit is filed against one of them, the documentation from QA activities could be used as evidence against that doctor. The records could even be used to make a case for negligence against the group if they indicate that a problem was identified, and no remedial steps were taken.

With a negligence claim, liability caps would not apply, according to Stephen M. Pizzo, an attorney for Blue, Williams, in New Orleans. The potential exists for much larger judgments than those seen in malpractice suits. "If you find something bad, you had better act on it because it could be discoverable," says Pizzo. Discovery is the process by which the parties in a lawsuit exchange information on the facts of the case.

Or think about a scenario in which the employees of a large practice decide that they will sit down together on the first Friday afternoon of every month to review charts and any accumulated patient feedback. Notes are made during these regular meetings and retained so that important findings are available for later use—

perhaps in the development of office standards. If the group draws a negative conclusion about the way some aspect of care has been handled and chronicles the details of the discussion, then depending on state laws, information could ostensibly work its way into a courtroom.

### ... Or damned if you don't

But what happens when a lawsuit is filed against a group that has no checks on competency or quality in place? "It could be argued that the group is negligent if it does not perform some type of quality review process, just like any other entity would be," Pizzo notes. It would probably not be a slam-dunk case for plaintiffs, though. "I think such a suit would involve a case within a case," observes Pizzo. "The plaintiff would have to show that the group had a duty to do the QA, and it would also have to show that quality assessment efforts would have caught and fixed the problem leading to the particular adverse event." That is a large burden of proof, especially considering that benchmarks of standards of care are not precise . . . or perfect for that matter.

"Take a situation in which a physician fails to give a patient an antibiotic for an infection, and the patient dies soon after being seen," says Rhonda Lynn Picou, RN, MSN, CPC, vice president of physician com-

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## The Next Big Thing in Liability

In an August 2004 report, the Office of the Inspector General for the US Department of Health and Human Services describes a credentialing and privileging failure at Northern Navajo Medical Center, also known as Shiprock Hospital, in Shiprock, NM. This slip-up in quality assurance (QA) could well imperil the hospital's accreditation from the Joint Commission on Accreditation of Healthcare Organizations, and ultimately, its participation in Medicare and Medicaid (*Credentialing and Privileging Practices at Northern Navajo Medical Center* is available at: [www.oig.hhs.gov/oas/reports/region6/60400023.pdf](http://www.oig.hhs.gov/oas/reports/region6/60400023.pdf)). The Indian Health Service requested an audit after media reports in 2002 generated questions about the quality of medical practitioners at its facilities. After evaluating the records of 84 practitioners, the OIG found that the hospital had not:

- Completely verified the credentials—for example, education, training, licensure, or references—of 32 practitioners.
- Made certain that 67 practitioners had current privileges. These individuals cared for patients during intervals in which they had no privileges, with gaps ranging from three days to three years.
- No proof of background investigations existed for 41 of the practitioners.

Perhaps this anecdote seems irrelevant to your medical practice, but it's not. Long an issue for hospitals, QA is becoming increasingly important in private practices. Many do not have formal QA or risk management programs to regularly monitor the patient care provided by employees in addition to such activities as chart documentation, treatment protocols, or outpatient follow-up. Attorneys are beginning to point out the absence of these programs when bringing medical malpractice claims against physicians. In addition, practices must investigate the past professional performance of hired practitioners to avoid liability associated with so-called negligent credentialing, the problem that surfaced at Shiprock Hospital. Keep in mind that many professional insurers recommend the adoption of some type of QA program. We address this subject, including the worries it might inspire, in this month's cover article.

We also explore the Centers for Medicare and Medicaid Services' recent change in language pertaining to obesity. Find out what it means for your patients. And we answer questions you've posed to us in recent months.



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# Medicare Alters Obesity Language But What Has Actually Changed?

When Medicare was created on July 30, 1965, only an estimated 13.4% of Americans aged 20 to 74 years were obese.<sup>1</sup> The prevalence of obesity among men and women aged 60 to 74 years was 8.4% and 26.2%, respectively. Reaching Medicare eligibility was probably something of a feat in itself, what with average life expectancy for infants born in 1900 being 46.3 years for males and 48.3 years for females.<sup>2</sup> However, men who managed to reach 65 years of age in 1960 could expect to live an average of 12.8 more years and women, another 15.8 years.

In an era when the US Surgeon General's first report on smoking and health, just 18 months old, declared tobacco use a habituation rather than an addiction, it's not startling that the new agency, which promised to cover treatments for illness or injury, did not consider obesity an illness. In fact, obesity had not yet been linked to increased risk of heart disease, an association uncovered by the Framingham Heart Study in 1967.<sup>3</sup>

Obesity is clearly dangerous, regardless of how it's categorized. And it's more prevalent than ever: 30.9% of the nation's population aged 20 and older is obese.<sup>1</sup> Among those aged 60 to 69 years, 38.1% of men and 42.5% of women are obese. Some 28.9% of men and 31.9% of women aged 70 to 79 years are obese, as are 9.6% of men and 19.5% of women aged 80 years and older.

But until recently, a significant passage in section 35-26 of the Coverage Issues Manual (CIM) prohibited coverage of treatment for obesity unless it was the result of an illness or exacerbated an illness. Attributing the condition to a persistent imbalance in caloric intake and output, the manual stated that "obesity itself could not be considered an illness." Thus, obesity-related therapy could not be viewed as "reasonable and necessary

for the diagnosis or treatment of an illness or injury."

## Opportunity knocks

On July 15, 2004, Tommy G. Thompson, Secretary of the US Department of Health and Human Services, which oversees the Centers for Medicare and Medicaid Services (CMS), announced that the troublesome phrase would be stricken from the manual, making it possible for Medicare to cover therapies when used solely for the treatment of obesity. Although the new text no longer stipulates that obesity is not an illness, it also states that treatment for obesity alone "has not been determined to be reasonable and necessary" (see "A look at the new language," page 4).

"This is not a new coverage," explains a CMS spokesman. "It opens the way for us to consider coverage requests, which is something we couldn't do before." The agency had not received any such requests as of late August 2004. "We expect to get some, but they're not flooding in," he adds. Anybody—a physician, a patient, a manufacturer, a hospital, or a medical specialty society, for example—can ask Medicare to cover an intervention for obesity by submitting a formal request for a National Coverage Determination (NCD), a

process that is described in detail in the September 26, 2003, issue of the *Federal Register*. In short, the CMS scrutinizes the document along with all available data supporting the merit of the application. "These are evidence-based decisions," the spokesman points out. "Normally, that means clinical trial evidence."

The new language in the CIM came about in a similar fashion. On September 6, 2001, a division of the Centers for Disease Control and Prevention asked the CMS to contemplate removal of the prohibitive statement citing increasing evidence that obesity might qualify as a disease. A tracking sheet was opened on the CMS Web site that documented the agency's progress toward a decision. The public is also invited to provide relevant evidence or comments. "The Agency for Healthcare Research and Quality did a technology assessment, which is essentially a survey of the literature, and sifted down whatever evidence is out there," the CMS spokesman notes. Although the CMS found "no general agreement" on whether obesity is actually an illness, it concluded that "the critical issue is not the classification of obesity but whether particular items or services are reasonable and necessary."

Early this November, a Medicare

*(Continued on page 4)*

Coverage Advisory Committee will discuss whether bariatric surgery improves the health of obese patients. "A panel of private sector experts gives us advice about the amount and quality of evidence on surgery for obesity without comorbidities, but they won't make recommendations about coverage," the CMS spokesman says. "We're not waiting to get a request. It's part of an effort to anticipate what might be of interest."

The CMS official says that surgery for morbid obesity is already provided to beneficiaries if the procedure will improve maladies such as arthritis, congestive heart failure, diabetes mellitus, or hypertension. Similarly, dietary counseling would be paid for when the diagnosis is diabetes mellitus. "That's another reason you probably shouldn't look for any great change right away," he notes. "Most of what's likely to be covered for obesity is already being covered. The bridge we haven't crossed yet is what to do if an obese patient with no comorbidities wants treatment to avoid these problems."

Don't expect coverage of anti-obesity medications any time soon. "In passing the Medicare Modernization Act in 2003, the US Congress expressly precluded weight-loss drugs from coverage," the spokesman says. "Even if a great new drug comes out, Congress would have to change the law before we could pay for it."

### A welcome change

It appears that some private insurers are ahead of the curve when it comes to provision of obesity services. Preliminary data from a 2004 survey of insurers by America's Health Insurance Plans (AHIP) indicate that roughly 40% provide coverage for some types of anti-obesity drugs, according to Mohit M. Ghose, Director of Public Affairs for AHIP, an organization formed when the Health Insurance Association of America and the American Association of Health Plans merged in October 2003. More than 75% of member companies offer access to discounted membership to fitness centers, and more than 75% cover some

type of nutritional counseling as part of a basic benefit package.

Some of AHIP's member companies are also working with local school systems to provide nutritional guidance to parents of overweight children in an effort to turn the situation around early, Ghose says. "While a number of our members do provide coverage for bariatric surgical interventions, some of them have stepped away from coverage because of the risks involved," he added.

Ghose believes the CMS's change in position is significant. "The government has made a bold move," he emphasizes. "This has started an important conversation about how to tackle obesity and related issues in America. This will now permit a discussion of all available interventions.

"We have a responsibility to provide as many options as possible so that people can start living healthier lifestyles," Ghose concludes. "When it comes to health insurance, one of the tenets over the last decade has been prevention, and if something cannot be prevented, the next step is early intervention. In the case of obesity, even without calling it a disease, one can clearly see that early intervention is a good thing."

*Reported and written by Cynthia Starr, editor. For more information on Medicare coverage, visit our Web site (see page 8).*

1. Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and trends in obesity among US adults. *JAMA*. 2002;288:1723-1727.

2. National Center for Health Statistics. Life expectancy at birth, at 65 years of age, and at 75 years of age, according to race and sex: United States, selected years 1900-2001. Available at: [www.cdc.gov/nchs/data/hus/tables/2003/03hus027.pdf](http://www.cdc.gov/nchs/data/hus/tables/2003/03hus027.pdf). Accessed August 29, 2004.

3. Framingham Heart Study. A timeline of milestones from the Framingham Heart Study. Available at: [www.framingham.com/heart/timeline.htm](http://www.framingham.com/heart/timeline.htm). Accessed August 29, 2004.

## A Look At the New Language

Now that the statement "obesity in itself is not considered an illness" is to be eliminated from Medicare's Coverage Issues Manual, the Centers for Medicare and Medicaid Services can explore coverage for obesity therapies. The following paragraph is to be inserted in section 35-26:

*Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these medical conditions. However, program payment may not be made for treatment of obesity unrelated to such a medical condition since treatment in this context has not been determined to be reasonable and necessary.*

Source: Centers for Medicare and Medicaid Services: National coverage analysis tracking sheet for obesity as an illness (CAG-00108N). Available at: [www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=57](http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=57). Accessed August 22, 2004.

# Are Restrictive Covenants Really Prohibited Under the Stark II Regs?

**Q:** *I am a partner in a 250-physician multispecialty group in Florida. Our contracts have a two-year 30-mile restrictive covenant. Is this still valid under the new Stark rules?*

**A:** Restrictive covenants or non-compete clauses can't be inserted into a new physician's contract if the group hiring that physician has received financial assistance in its recruitment efforts from a hospital, according to John W. McDaniel, president and CEO of Peak Performance Physicians, LLC, which is based in New Orleans. This also holds true for contracts that were in place before the Stark II regulations went into effect on July 26, 2004. Let's say several physicians were hired two years ago through a joint recruitment arrangement between your group and a local hospital and their contracts contain a noncompete clause. These documents should have been revised in order to comply with Stark II. However, medical groups that directly recruit new physicians into the practice without any financial help from a hospital can require the employee to sign an employment agreement with a restrictive covenant. Otherwise, the practice would be at financial risk if the new physician decides to leave and compete against his or her former colleagues once the employment agreement is terminated.

**Q:** *Our family practice group has one physician who is a real draw. However, he is too busy to accommodate all the patients who want to see him. We are thinking about having a physician assistant (PA) see our hospital patients to give the physicians more time*

*to see outpatients; we already have a PA who works in the office. I've heard that incident-to billing can't be applied to services rendered in the hospital by mid-level providers. Also, I'm not sure patients want to see a PA while they're hospitalized. And if the PA and physicians are both visiting inpatients, what have we gained aside from a scribe?*

**A:** You are correct that incident-to billing would not apply to care provided by the PA in the hospital setting, says Rhonda Lynn Picou, RN, MSN, CPC, vice president of physician compliance for Peak Performance Physicians, LLC. However, you can bill Medicare under the PA's provider number, and the practice will be reimbursed at 85% of the physician's fee schedule. First you need to make sure that your state regulations allow PAs to provide hospital services and that the hospital will extend PAs the right to perform rounds without a physician. (Generally, though, Medicare does not reimburse hospital services as well as it does office services because the expense relative value units are lower.) You should also look into how other third-party payers would reimburse in-hospital care provided by PAs. Some do not recognize PAs as separate providers but do allow you to bill their work under the physician's name, and they will reimburse you at the physician's rate.

You also need to check with your malpractice carrier to see if coverage is affected if the PA replaces the physician for hospital visits. And of course, recognize that some inpatients will require a physician's attention. On these occasions, the PA could act as a scribe, and this might save the

physician some time and relieve some pressure, factors that may well contribute to increased productivity in the office. If you find that a PA can pick up some of the inpatient workload so that the physicians—particularly the one who is so popular with patients—can perform more office services and meet the demand for care, the increased productivity could easily make up for the 15% loss in reimbursement for hospital care provided by the PA. Otherwise, if the physicians continue to see all hospitalized patients and are not able to see significantly more outpatients, the additional PA may shave time off hospital visits and augment the quality of care given to patients, but he or she will not add to the financial productivity of the practice.

**Q:** *I am the new owner of two urgent care clinics, both with x-ray equipment. When billing for the x-rays, should I be using modifiers and if so, which one: “-TC” or “-26”? I want to make sure that it is being done correctly.*

**A:** If a physician is providing both the professional and technical components, no modifier should be used, says Thomas Loughrey, MBA, CCS-P, chairman and CEO of Economedix, LLC, which is based in Orange, Calif. Otherwise, the physician providing the technical component should use modifier “-TC”, and the radiologist would bill the same code with modifier “-26”.

*Editor's note: Readers of The Physician's Compliance Alert are invited to visit our Web site (see page 8) and submit their questions. Members of our Advisory Board will offer their expert opinions in response.*

pliance for Peak Performance Physicians, LLC, also in New Orleans. Even if the group routinely monitors how many patients with a similar infection are prescribed antibiotics, the physician could argue that the assessment data in this particular case indicated that the infection was viral and therefore unlikely to respond to antibiotics. In other words, almost nothing in medicine is carved in stone, even in these days of practice protocols.

Unlike hospitals, medical groups are not required by any certifying agency to perform quality assessment or credentialing. “The question is, do they have an obligation as employers to do this?” asks Picou. For years, hospitals let physicians come in and do their work without worrying about quality management, she says. “Then, there was a successful suit against a hospital regarding the quality of physician care, and peer review became common practice. Will it take a similar lawsuit to change medical practices?” she inquires.

Such lawsuits may be rare at present, but they certainly exist. Peak Performance Physicians has been asked to help design a clinical QA and risk-management protocol for a practice that is being sued for failure to monitor the care its physicians provided to patients, says company president, John W. McDaniel. “Failure to structure a meaningful clinical QA program will render a medical practice defenseless in the case of an unfavorable outcome,” he counsels. Discovery could also work in your favor in the event of a liability case, agrees Pizzo, who adds, “If quality assessment is done and you can show that problems were caught and remedied, it indicates that your group makes an effort to improve quality.”

Landmark lawsuit or not, McDaniel also believes that third-party payers

may one day require physicians to meet quality benchmarks before they can be reimbursed for care. The Doctor’s Office Quality Project, sponsored by the Centers for Medicare and Medicaid Services, supports that point of view. Currently under way in California, Iowa, and New York, it is examining the quality of care that physicians provide to patients with common chronic illnesses and the quality of preventive services offered. According to the agency, “it is anticipated that findings from this project will become the framework for standardizing measures in doctors’ offices.” (Look for more information at [cms.hhs.gov/quality/doq](http://cms.hhs.gov/quality/doq).)

### A reasonable course

“You’ve got consequences on either side,” McDaniel comments. “But somewhere in all this, we have to do the right thing. We can’t have an ostrich mentality when it comes to mistakes.” He recommends adapting the seven elements of a coding compliance program to a QA plan (see “Seven Essential Elements,” page 7). If errors are uncovered, they should be disclosed and corrected. Then, a preventive mechanism should be devised to ensure similar mistakes don’t occur in the future. “I think to not do that is negligent,” he adds.

McDaniel also tells clients to run an ICD-9-CM frequency report to determine the most common complaints treated in your practice. “The top 20 diagnoses will likely represent 80% of the total cases you see,” he says. “Make sure you have treatment protocols in place for the top 10 diagnoses. When you’re finished, go on to the next 10.” Segregate high-risk treatments, too, and ensure that your usual treatment plan is consistent with whatever national guidelines exist. Pay extra attention to patients whose health is more precarious—

those who have several concomitant ailments, for example.

Before developing a clinical quality management program, however, consult with an attorney to determine the best way to go about it. Know the laws in your own state for discovery and disclosure of self-critical information. “Each state has a different variation on discoverability,” says Burke Giblin, an attorney at Giblin & Combs in Morristown, NJ. “Some states are very liberal concerning what can be discovered, and some are very restricted,” he adds. Like hospitals, which constantly confront the legal landmines of discoverability, medical groups should know what could become of their documents in the case of a lawsuit.

“In our state, peer review activities are protected from discovery for medical entities with 20 or more providers,” says Ron Kennedy, vice president of risk management for the malpractice insurance company Lammico, also located in New Orleans. “The whole idea of providing protection from discovery for peer review activities is to ensure that physicians feel open about discussing cases with their peers without fear of the information being used against them in the event of a lawsuit,” he explains.

Client-attorney privilege can provide some protection from discovery and disclosure laws, but it does not apply in all cases. Hospitals may routinely have an outside law firm request an evaluation and analysis when an adverse clinical event occurs. This is done so that attorney-client privilege can be invoked in the event of a lawsuit. The hospital may then be at least partly protected from discovery. The laws on attorney-client privilege vary by state, as does the protection they provide.

If you do not have an attorney, con-

## Seven Essential Elements

When creating a program to monitor some aspect of your practice, turn to the format for a coding compliance program suggested by the Office of the Inspector General of the US Department of Health and Human Services. These components could also form the basis of a solid QA program. These are:

- Conducting internal monitoring and auditing;
- Implementing compliance and practice standards;
- Designating a compliance officer or contact;
- Conducting appropriate training and education;
- Responding appropriately to detected offenses and developing corrective action;
- Developing open lines of communication;
- Enforcing disciplinary standards through well-publicized guidelines.

*Source: US Dept of Health and Human Services, Office of the Inspector General: OIG compliance program for individual and small group physician practices. Federal Register. 2000;65:59434-59452.*

tact your malpractice insurance company. Experts there can provide an attorney and give you general guidance on the liability risks of clinical assessment programs. Some insurance companies may also provide help with quality management or risk management. "Our company conducts surveys of the groups we cover in order to help with their policies and practices and to prevent potential problems," says Kennedy.

Specific clauses in contracts and written agreements can help group owners reduce the practice's repercussions from an employee's misstep. One is an indemnification clause, which requires a physician to provide a defense and pay any judgments against him or her. "Indemnification clauses are common, but they only apply if the physician who signed the indemnity agreement to the group is a named defendant in the suit," notes Pizzo. "It does not go beyond the doctor's own personal negligence, and it would not protect the owners if the issue was that there was no quality control," he adds. Certainly, the doctor would not be

responsible for the group's lack of quality improvement efforts.

The group that hires independent contractors could also post signs stating that these physicians are not employed by the group and include that information on patient bills and other forms, as many hospital emergency rooms do. "These steps might also help to provide some protection for the owning entity," says Giblin. Finally, many groups require physicians to have their own insurance so they would be covered in most malpractice cases.

Front-office quality improvement steps are helpful, relatively easy to undertake, and generally carried out by the office manager. This includes, for example, evaluating general patient satisfaction, patient waiting time once in the office, record-keeping, waiting times for an appointment, how efficient follow-ups are for referred patients, and the process for ensuring that laboratory results and other reports are seen by doctors. Findings should be documented and available for future comparisons.

## Negligent credentialing risks

It is also advisable for a group to evaluate the credentials of its physicians. Most physicians have hospital privileges, and they have already met the credential requirements for the hospital. "If a physician has hospital privileges, I would say that the group does not have to establish that physician's credentials," advises Pizzo.

On the other hand, some physicians do not have hospital privileges for a variety of reasons, and in these situations the group has a duty to do what a credentialing committee in a hospital would do, warns Pizzo. "The group should review the provider's credentials by checking the individual's DEA license, medical board license, and employment background," he urges.

Even though a group's insurance company evaluates the credentials of its doctors, the process is generally not ongoing. "Our company does a considerable amount of credentialing before underwriting a group for malpractice insurance, but as new doctors come on board, it is up to the group to credential them," emphasizes Kennedy.

"It just makes good business sense to look into a hired doctor's background and credentials," says Giblin. "And there should be no real risk of exposure or discoverability in doing so in the event of a malpractice suit."

Of course, nothing is certain when it comes to liability. "The group's credentialing activities may not be risky in the event of a malpractice case, but it could lead to the threat of a lawsuit for libel if a physician is discharged by the group," warns Giblin. As with all potential programs, therefore, groups should first discuss any credentialing efforts they make with an attorney.

—Reported and written by Deborah Epstein, contributing editor in West Milford, NJ. More information on quality assurance programs is on our Web site (see page 8).

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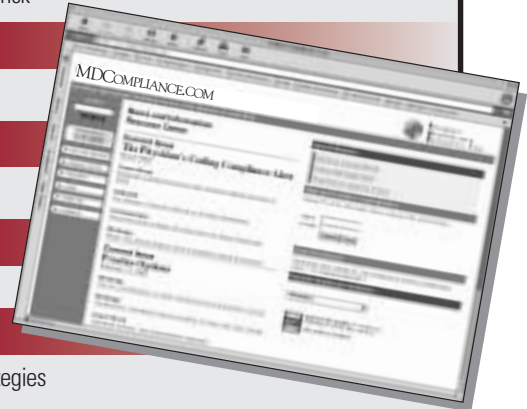
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