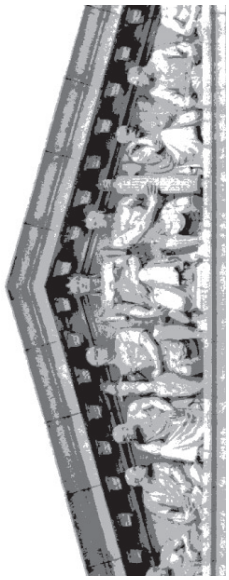

G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

Switching To Medicare's New ABN
Challenges Ahead For Compliance Officers

Medicare's new, uniform Advance Beneficiary Notice (ABN) for use by physician offices and laboratories won't become official till later this year, but industry experts say healthcare provider compliance programs should start preparing now for the transition.

The ABN alerts beneficiaries, prior to a Part B service being furnished, that they may be financially liable for the service in the event Medicare denies payment.

Two standard, single-page ABNs were recently approved by the Office of Management & Budget. One ABN is for general use, the other for laboratory services. However, providers will not be required to begin using them until the Centers for Medicare & Medicaid Services (CMS) has finalized instructions for local carriers and fiscal intermediaries. This is expected by year's end.

CMS Gives Go-Ahead

Providers may adopt the new formats even without the final instructions, according to CMS. Failure to execute a valid ABN can expose a provider or supplier to potential financial liability for denied items or services, the agency notes in its draft ABN instructions.

Some providers have introduced ABNs that are similar to the OMB-approved forms, says Larry Small, director of compliance and billing services for PCS Laboratory Services Group in Ann Arbor, MI. "I think quite a few labs have already begun moving toward the new format at least in terms of going to a separate

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Medical Practice Nailed Under Stark II
Group Charged With Improper Lab Referrals

A Boston-area group medical practice has agreed to pay nearly a quarter of a million dollars to settle allegations that it billed Medicare for laboratory services in violation of physician self-referral prohibitions (popularly dubbed the Stark II ban).

B.J. Carlen Inc., formerly known as Pastor Medical Associates (Brookline, MA), will pay $230,000 to settle federal civil charges that it improperly submitted claims for blood chemistry tests and other laboratory services performed at Pastor's on-site lab during 1995 and 1996, according to prosecutors.

The government alleged that physicians who referred their patients to the Pastor lab had a financial relationship with Pastor "pursuant to which they received annual compensation in an amount that was linked directly to the monetary value of the referrals they made to the lab."

This "direct financial link between compensation and referrals violates" the Stark II statute, said the

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Inside this issue

Compliance Hotlines: An Inside Look At How They Work
Providers Take Varied Approaches

Just how effective are reporting hotlines in helping healthcare compliance officers root out potential problems before they turn into compliance nightmares?

While reporting hotlines are not required by law, the HHS Office of Inspector General encourages their use to help detect violations of a provider's compliance policies or federal and state healthcare program requirements.

In its compliance guidance for healthcare sectors—including clinical laboratories, hospitals, and physician practices—the OIG urges providers to establish a means of allowing employees to report problems or concerns anonymously. Matters so reported should be documented and investigated. Providers should maintain a hotline log and brief their compliance committees, CEOs, and governing bodies on the types of calls received, the follow-up, and the ultimate resolution.

It's not known how many labs, hospitals, and physician groups use reporting lines for compliance issues, but Andrew Quinn, a principal with Compliance Concepts Inc. (CCI), estimates that at least 60% of healthcare providers have some type of employee reporting mechanism in place. CCI, based in Pittsburgh, PA, operates hotlines for hundreds of organizations.

In-House vs. Third-Party

Of those organizations that use reporting lines, about half operate the systems themselves, while the rest contract with an outside vendor, says Quinn. The advantage of an outside service, he believes, is that callers concerned about anonymity may be more likely to report problems to a third party than to a hotline run by their employer.

> *"If we get a call from someone who says a scrub nurse came to work under the influence of a drug, that's the kind of call we would get someone out of bed for."*
>
> *— Andrew Quinn*

Whether run in-house or by an outside service, reporting systems manned by live operators tend to be more effective than those relying on some type of recorded messaging system, he maintains.

"If people know they're being taped, it can be a hindrance to being completely open." Live operators also are trained to elicit more information from callers, which can help in investigating allegations, particularly when callers wish to remain anonymous.

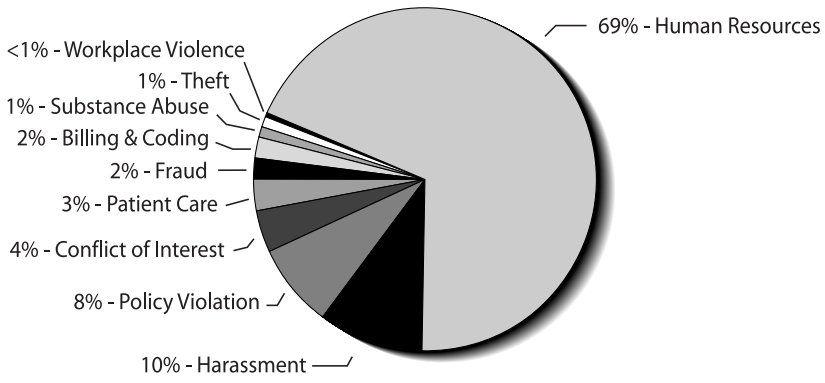
CCI assigns callers a number they can use to identify themselves and gives callers a date to call back to see what has happened with their allegations or complaints, explains Quinn. Hotline operators type up summaries of calls and e-mail or fax them to the contracting organization's compliance officer, who then is charged with investigating the issues. Call records are kept for as long as the employer requests, and CCI can give clients custom reports showing the number and types of calls received (*see chart*).

Hotline calls are prioritized by urgency, with a deadline for resolution. Immediate attention is given to calls related to patient safety, quality of care, or fraud and abuse, notes Quinn. Human resource issues, which account for the bulk of all calls, get lower priority.

Call volume varies widely by provider, depending on the organization's size and how extensively the reporting system has been marketed, according to Quinn. Some provider hotlines might receive one or two calls a month while others get dozens, he says.

The cost of the hotline service also runs the gamut, from $500 per year for a small organization to up to $10,000 per year for a large employer; fees are based primarily on the number of employees. On average, reporting lines for mid-size healthcare systems run about $1,500-$2,000 per year, Quinn estimates. The expense of operating or

Compliance Call Categories *(sample)*



Source: Compliance Concepts Inc.

contracting for a hotline system, however, can sometimes be offset by reductions in insurance premiums, he adds.

Last Resort

At Ohio's Cleveland Clinic Health System, the four-year-old reporting line—which the system operates in-house—serves as a sort of "last resort" for employees who want to report a problem, according to John Steiner, chief compliance officer.

> *"We've been able to intercept some real problems. What generally happens is that a subordinate reports a matter after trying to get a supervisor to understand and react but gets nowhere. We pay attention to each call."*
>
> *— John Steiner*

Workers are encouraged to first go through normal channels with concerns and to use the reporting line if they feel their concerns have not been addressed. Employees learn about the reporting system through a variety of methods, including new employee orientation, internal bulletins, and Cleveland Clinic's intranet site.

"We don't get a lot of calls, maybe about 24 in a given year," Steiner says. "That's mainly because we have made it clear to employees that issues should percolate up through the compliance committee within their own business unit, such as the division of lab medicine."

Cleveland Clinic's reporting system consists of two dedicated telephone lines—one with a toll-free number, the other with a local number. When employees call, they hear a recording asking them to describe their concern and furnish as much information as possible, says Steiner. Callers may choose to remain anonymous or may give their name. Callers who don't want to leave a message but want to talk to a person may call Steiner's office instead.

A member of Steiner's staff listens to the recorded messages and uses an intake form to document key information. Steiner then reviews the intake forms and decides how to handle the issues. Typically he will first discuss a reported problem with the head of the facility or department in question, such as the hospital or laboratory. Human resource issues are usually referred to the HR department.

Steiner reports the hotline results periodically to the organization's compliance committee. Because the reporting system is relatively simple and does not require a full-time employee, the cost is fairly low, notes Steiner, who says he considered contracting out for the service but saw no real need to do so.

Tapping The Trustline

Emory Healthcare Inc., in Atlanta, GA, began its hotline reporting system, which it calls "Trustline," in 1999, says Nilda Johnson, office manager for the compliance office. Emory Healthcare contracts with Pinkerton Services Group (Westlake Village, CA) for the toll-free service, but because the compliance office staff has built trust with employees, the majority of compliance concerns are reported directly to the compliance office, notes Johnson.

> *"There are other benefits than finding out you might have billing and coding problems. The reduced liability exposure can be significant."*
>
> *— Andrew Quinn*

Like the service provided by CCI, calls are prioritized. Calls rated "A" require an immediate response; "B," five business days; and "C," 21 business days. These response times are set by the compliance office. All calls are logged by the compliance office and investigated by the organization's chief compliance officer, Anne Adams, who works closely with the risk management and legal departments.

"Most of the calls we receive are Category C, and about 80% are human resource-related," says Johnson. "An example of [the latter] would be an employee calling about favoritism in the office."

Trustline call reports are kept confidential and in a secured location. The chief compliance officer briefs Emory Healthcare's Audit and Compliance Committee periodically on the number of calls received and the concerns that are addressed.

Added Protection

While hotlines or other reporting lines can help organizations identify and resolve problem areas, they also can serve as an added layer of protection against lawsuits, notes CCI's Quinn. He urges labs, hospitals, and physician offices that don't already have a reporting system to begin now to implement one.

When properly handled, hotline reports can protect organizations against lawsuits, he says. For example, a lab that can prove it received an allegation of a quality problem and took steps to fix it would likely fare better in the event that the employee later sued the company. Documentation of calls and follow-up action, he stresses, is crucial.

Resources

- Andrew Quinn: 724-940-0077
- John Steiner: 216-444-1708
- Nilda Johnson: 404-778-2757

Stark II, *from page 1*

U.S. attorney's office in Boston. Stark II generally bars doctors from making referrals to entities with which they (or an immediate family member) have a financial relationship, either by ownership interest or by compensation arrangements. Physicians who submit and receive payment for Medicare claims that result from prohibited referrals are strictly liable to refund the entire amount received. In addition, they may be assessed penalties of up to $15,000 per claim.

Through the civil settlement announced Aug. 15, the U.S. attorney's office said it has recovered 100% of the Medicare funds paid to Pastor for clinical lab services during the relevant time period, along with civil penalties and costs.

The whistleblower who brought the case to the government's attention, Randy Averback, will receive $41,400 of the settlement amount. Averback is a doctor who practices in the Boston area.

Don't Assume You're Safe

This case and the subsequent settlement should serve as a warning to physicians who believe their compensation arrangements meet legal requirements, says attorney Robert Mazer with Ober/Kaler in Baltimore, MD.

"The basis for the Stark violation was apparently not a relationship between the physicians and another entity, such as an outside lab, but the compensation arrangements among the physicians themselves. According to the government, those arrangements unlawfully tied compensation to orders for lab tests to be performed in the in-office lab.

"The settlement shows that the government differs in opinion from physicians who believe that their compensation arrangements are none of the government's business—or that these types of arrangements appropriately reflect relative productivity."

The Pastor case also indicates that the government is investigating compensation arrangements in place before there was any Stark II regulatory guidance in effect. Accordingly, Mazer recommends that physicians have their compensation arrangements reviewed for Stark II compliance, no matter how long these arrangements have been in place.

The Stark II final rulemaking is being handled by the Centers for Medicare & Medicaid Services in two phases. The Phase I rule was published Jan. 4, 2001 and takes effect Jan. 4, 2002. It does address physicians who operate in-house labs; however, the exceptions frequently relied on by labs—such as payment to physicians for services or for rental of office space—are not fully discussed, Mazer notes. CMS says it will address these concerns in a yet-to-surface Phase II rule.

Healthcare providers should not wait for the Phase II rule before taking a closer look at their existing referral arrangements, Mazer advises. "Physicians who believe they are safe from Stark law violations until final regulations are effective may be seriously mistaken."

Resources

- U.S attorney's office, Boston: 617-748-3139
- Robert Mazer: 410-547-0699
- Our previous coverage: "Perspectives: Stark II Final Rule," Feb. '01, pp. 5-8

Labs Offering "Unestablished" Tests May Face Increased Oversight

Laboratories that provide non-traditional lab tests may soon find themselves facing beefed-up government regulation and oversight.

Worried over the number of labs that offer "unestablished" tests, such as Live Blood Cell Analysis, the HHS Office of Inspector General is urging the Centers for Medicare & Medicaid Services (CMS) to do a better job of regulating these non-traditional tests.

An increasing number of laboratory sites are offering patients what the OIG in a recent inspection report calls "unestablished tests"—tests that are not generally accepted by many of the people involved in traditional laboratory practice and oversight. Besides Live Blood Cell Analysis, these tests include Biological Terrain Assessment, hair analysis to assess nutritional deficiencies, and food allergy testing.

To improve oversight of unestablished tests, the OIG recommends that CMS:

- Conduct a study to determine whether Live Blood Cell Analysis has diagnostic value.
- Establish procedures for evaluating the usefulness of other unestablished tests.
- Seek new administrative authority to allow the agency to take specific actions when a laboratory fails to enroll in CLIA.
- Require labs to disclose on their CLIA application whether they are conducting unestablished tests.
- Improve test verification reviews by improving surveyor training and standardizing reviews.
- Use the CMS Internet site and other means to inform the public about unestablished laboratory tests.

Resource

- OIG Report, *CLIA Regulation of Unestablished Laboratory Tests* (OEI-05-00-00250), *www.hhs.gov/progorg/oei.*

COMPLIANCE PERSPECTIVES

Think Twice Before Heeding Advice

Practical Tips On Proper Use Of Consultants

John T. Brennan, Jr., and Christina Mireles are attorneys with Crowell & Moring (Washington, DC). Brennan is a partner and head of the Health Care Group; Mireles is an associate.

Arguably, no other industry presents as daunting and complex a regulatory environment as does the healthcare industry.

No wonder then that providers have increasingly turned to an ever-growing cadre of accountants, coding and reimbursement specialists, and other business advisers for help with the intricacies of appropriate coding and billing, most notably in pursuit of Medicare and Medicaid reimbursement.

While most consultants properly advise their healthcare clients on ways of maximizing legitimately earned reimbursement, a recent flurry of federal government initiatives has sensitized the industry to consultant practices that may exceed the bounds of proper counsel. In addition, part of the focus of the sweeping Columbia/HCA investigation is on the role that that entity's accountant-advisers played in facility recordkeeping practices.

The examples of improper consulting advice ferreted out by government investigations in recent months appear rather radical indeed (no legitimate provider would, for instance, heed a consultant's advice to "create" paperwork to support a particular billing code).

Nonetheless, the Federal Government's current focus on aberrant consultant activity does present a useful platform for providers to recognize the legal implications of obtaining and heeding the advice of consultants regarding clinical recordkeeping, coding, and billing activities.

The simple fact is that despite the Federal Government's avowed concern over the activities of unscrupulous consultants, it most often will be those providers who *rely* on such inappropriate advice—not the consultants—who will find themselves the most tempting targets of government prosecutors for improper billing activities.

Consumer Beware!

In June of this year, in a well-choreographed effort, the HHS Office of Inspector General and the Senate Finance Committee widely publicized their concerns over unethical and inappropriate healthcare consultant practices. In so doing, both the executive and legislative branches proffered a form of "consumer protection" advice to providers in their dealings with consultants.

❖ **OIG Advisory:** In a Special Advisory Bulletin, the OIG warned providers of certain specific practices employed by unscrupulous consultants. The bulletin advised that reliance on these practices could expose both the provider and the consultant to legal liability. Among the "questionable" consultant practices identified:

— ***Making illegal or misleading representations.***[1] Providers should be concerned if consultants make illegal or misleading statements about their relationship with the Medicare or Medicaid programs, the U.S. Department of Health and Human Services, etc., including the use of the names or acronyms of federal agencies in their marketing or labeling materials.

— ***Providing promises or guarantees*** *of specific results that are either unreasonable or unlikely*.

— ***Encouraging abusive practices***. Providers should avoid using consultants who encourage them to abuse the Medicare or Medicaid programs by engaging in aggressive billing schemes.

— ***Discouraging compliance efforts***. Providers should avoid consultants who advise them not to un-

[1] It is a federal offense to employ federal healthcare program terminology to suggest that one's services or products are approved, certified, endorsed, or recommended by the federal healthcare program. 42 U.S.C. §1320b-10 provides for civil money penalties for using terms such as "Medicare," "Medicaid," "Department of Health and Human Services," Social Security Administration," etc., along with related acronyms, in marketing materials.

dertake certain compliance efforts or cooperate with payer audits.

❖ **GAO Report/Senate Hearing:** At the request of Sen. Charles Grassley (R-IA), the General Accounting Office undertook a year-long investigation into healthcare consultants who conduct seminars on ways for providers to enhance Medicare revenue and avoid audits or investigations. Armed with concealed recorders, GAO investigators infiltrated a number of provider seminars directed at these topics.

The consultant advice collected by GAO was presented this year at a June 27 Senate Finance Committee hearing. Among the questionable forms of advice described by GAO:

—***Non-disclosure of overpayments.*** Providers should be leery of consultant workshops that focus on how to make their operations "audit proof" and how to avoid sending up red flags to the government by not reporting or refunding overpayments.[2]

—***Creating documentation to support higher-than-warranted billing codes.*** Providers should be concerned when consultants suggest, for example, that documentation of evaluation & management (E/M) services may be used to create the appearance that medical issues confronted at the time of the E/M service were more complex than they actually were.

—***Limiting services to Medicaid patients.*** Providers should question consultants who advise them to limit services to patients with low-paying insurance plans, such as Medicaid, and to discourage such patients from using the provider's services by offering inconvenient appointment times.

[2] Whether providers are legally obligated to report *and refund* overpayments presents complex legal issues beyond the scope of this article.

Legal Risks

While both the OIG's special bulletin and the GAO report/Congressional hearing focused primarily on aberrant consultant activity, a federal cause of action against a consultant who suggests undertaking improper billing activities to a roomful of providers in a public forum would be difficult to establish. Instead, from a practical, legal, and financial perspective, it is the *provider* who heeds such advice—not the consultant—who would be far more likely to face federal prosecution and the potential for significant penalties. Indeed, adherence to the sort of advice described above could lead to a provider's prosecution under several federal statutes.

❖ **The False Claims Act:** When a provider submits a claim to the government for payment, the provider certifies—among other things—that the claim submitted is not "false," or at least that the provider has not submitted it with "deliberate ignorance" or "reckless disregard" as to its truth or falsity. A false claim violation could lead to repayment to the government of triple the original amount of the claim, fines of $6,500-$11,000 per claim, potential program exclusion, and other penalties.[3] Among the more common bases for a false claim prosecution in the healthcare industry are instances of upcoding, billing for services not rendered, and the lack of "medical necessity" for the service.

While the Act includes within its ambit not only individuals or entities who actually "present" the false claim, but also those who "cause" it to be presented, it is important to recognize that the two actions—"filing a claim" and "causing" a false claim to be filed—are prosecutable as separate and distinct acts. Further, while under limited circumstances, reliance on a consultant's advice may serve as evidence that a provider had no intent to file a "false claim," reliance on obviously inappropriate advice will universally fail to protect the false claimant from prosecution.

While the false claimant could not turn to the unscrupulous consultant's advice under a "the devil made me do it" defense, the consultant could well succeed in arguing that merely "advising" its client to perform in a certain way did not "cause" the false claim to occur. In fact, a "causal" violation of the Act is more traditionally applied against other individuals or entities acting *within* the flow of activities and recordkeeping of the claiming entity itself. For example, creation of a false document to support a claim or upcoding a patient's medical condition on an E/M claim, are each likely to be "causal" elements to a false claim, involving liability to the "causing" parties.[4]

In contrast, absent (a) some overt agreement between the consultant and the provider to conspire to defraud the government, (b) some ongoing involvement by the consultant in the provider's clinical service/billing flow, or (c) some other sinister activity, the mere provision

[3] The False Claims Act is set forth at 31 U.S.C. §3729 *et seq*. Similar language—and additional penalties—are set forth under the Civil Money Penalties statute (42 U.S.C. §1320a-7a).

[4] See *United States v. Bornstein*, 423 U.S. 303 (1976) (held subcontractor liable for three acts that caused prime contractor to submit false claims to the government); *United States v. Peter Mackby*, 243 F.3d 1159 (9th Cir. 2001) (found that defendant knowingly caused false claims to be submitted to Medicare by instructing clinic's billing company and office manager to use defendant's physician father's Provider ID Number on claim forms to bill for physical therapy services provided at clinic); *United States v. George Krizek, MD*, 111 F.3d 934 (D.C. Cir. 1997) (held doctor liable for false claims prepared by his wife where he delegated to her the authority to submit claims on his behalf and failed to review the false submissions).

of improper advice by a consultant leading to a false claim by its client would be difficult to prosecute.[5]

❖ **Title VI, Civil Rights Act:** As GAO and the OIG noted, some consultants have been known, at least on occasion, to encourage providers to limit services to Medicaid patients because of that program's "low and slow" pay reputation. Among the improper encouragements:

— Stop accepting Medicaid patients.
— Offer better follow-up services to better-paying patients.
— Schedule Medicaid patients for services on inconvenient dates and times.

Following any of these practices could result in liability under Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d). Title VI prohibits discrimination based on race, color, or national origin in programs that receive federal financial assistance. Providers participating in Medicaid—including physicians in private offices—are obligated to adhere to Title VI requirements.

While a provider who follows a consultant's advice to limit services to Medicaid patients may argue that this activity does not involve *overt* discrimination (the actions are not directly focused on persons or a particular race, color, or national origin), the GAO report quite reasonably asserts that a provider's discrimination against Medicaid recipients is virtually certain to disproportionately harm a protected class.

Once again, under Title VI, a more difficult case arises with regard to the consultant offering the discriminatory advice. However, if the government could prove that the consultant has supplied the "tools" with which to discriminate (a term whose meaning is unclear), the potential for such a case may exist.

❖ **Anti-Kickback Statute:** This federal statute, while not a primary focus of the Federal Government's recent admonitions about unethical consultants, remains an important weapon for prosecutors in dealing with healthcare consultants whose compensation is tied to their success in growing provider revenue. The statute (42 U.S.C. §1320a-7b(b)), simply stated, prohibits the "offer or payment" or "solicitation or receipt" of any remuneration in exchange for referring, recommending, or arranging for the referral of an individual for the provision of an item or service covered by a federal healthcare program. Violation of this statute can lead to both criminal and civil penalties, civil money penalties, and program exclusion.

To be sure, neither a consultant who simply assists a provider to "enhance Medicare revenue" nor a provider who heeds that advice has done anything impermissible, even if that consultant's compensation is based on the success of its recommendations (through a "percentage" arrangement, for example).

However, when a consultant's compensation is tied to its involvement in marketing activities, referral growth, etc.—or if the consultant has provided software equipment or other methods for improperly enhancing revenue—an anti-kickback violation is far more likely to arise. It must be stressed that in such situations *both* parties to the kickback relationship would be prosecutable under the statute.

Practical Tips

1 Defining The Consultant's Role: The OIG/GAO's advice as to "what to avoid" in the use of consultants is truly of no groundbreaking import. Most of the admonitions are more in the nature of "consumer beware" propositions than anything else. Certainly, as with any purveyor of goods and services, consultants who misrepresent their credentials or promise or guarantee improbable results ought to be avoided. Providers should obviously screen and select consultants based on their reputation for honesty and integrity.

More practically, however, providers should recognize that healthcare consultants cannot enhance program revenue (or reduce expenses) beyond Medicare program parameters. Within these legal boundaries, as can be fairly and reasonable interpreted, consultants can provide valuable services, and providers can and ought to take advantage of these services.

Providers are entitled to every last penny legitimately earned for services rendered to federal healthcare program participants. If a provider is *under*coding, improperly documenting diagnoses or services rendered, or otherwise failing to record or code a service—to its own detriment—the provider is being underpaid and the Federal Government is experiencing a windfall. No government prosecution based on the premise that a provider gained advice from a consultant which merely *maximized* its Medicare reimbursement is likely to be brought—much less succeed.

Similarly, to the extent that a consultant's focus is on reducing costs by eliminating expenses not essential to providing medical care of appropriate standards, such initiatives are quite appropriate. Care should be taken, however, that cost reductions not be made in a way that diminishes the quality of medical care below reasonable levels. Such a result could present additional legal risks to the provider (see 42 U.S.C. §1320a-7a(b)).

With these general parameters in mind, it is wise to make certain that the relationship entered into be-

[5] See *e.g., United States v. Metzinger* No. CIV.A. 94-7520, E.D. Pa. 1995, where the defendant consultant not only provided advice on filing "false claims," but was also involved in a kickback relationship and participated in illegal billing and coding activities, etc.

tween a provider and a healthcare consultant be well articulated in writing, either via a service contract or a "scope of work" agreement. If the consultant's assignment is to "assist in enhancing revenue" or "reduce costs," the written agreement should state that such initiatives are to proceed "within regulatory parameters," "consistent with all government payer requirements," etc. If a consultant is to be paid for services on a "percentage basis," the scope of the consultant's work should explicitly *not* include marketing or referral building activities.

Likewise, when a consultant's work is concluded and its "deliverables" are presented, similar precautions ought to be taken. Providers should assure themselves through careful discussions with the consultant that the recommendations provided are legitimate, legal, and within the scope of reimbursement rules (or based on a reasonable interpretation). Consultants' recommendations should be explained and supported with reference to appropriate regulations, policy pronouncements, carrier or intermediary instructions, case law, etc.

2 Fighting False Claim Charges: Adherence to the suggestions above will help maximize the value of a consultant's recommendations. In utilizing a consultant's advice, however, providers ought to be cognizant that only in narrow circumstances may reliance on that advice actually protect the provider from a successful prosecution under the False Claims Act.

For example, a provider may confront a situation where Medicare payment policy for a particular clinical procedure is unclear or inconsistent. After efforts to seek official clarification from a fiscal intermediary or carrier have been to no avail, the provider may seek the advice and counsel of a reputable healthcare consultant. Assuming the consultant addresses the matter with due diligence and expertise and provides a reasonable opinion on which the provider thereafter relies, such good-faith efforts by the provider to *properly* bill could serve as a strong defense against a false claims allegation, even if the government ultimately concluded that the billing was in fact improper.

In such circumstances, the government would be hard-pressed to prove that the provider "knowingly and willfully" filed a "false claim." Indeed, rather than acting with "deliberate ignorance" or "reckless disregard" of the truth or falsity of the claim, the provider here undertook extra effort, at its own expense, to "do the right thing." Such a provider's defense would obviously be greatly enhanced if the practical recommendations described above had been followed.

3 Protecting Consultant Work Under Privilege: Finally, providers need to consider whether or not the consultant product it seeks to obtain will be discoverable in the event of a dispute with the Federal Government—or any other litigant—over matters concerning which the consultant's advice was obtained. As a general rule, a consultant's work product will *not* be protected from discovery under normal circumstances. Thus, in seeking a consultant's advice, the provider must recognize the potential that damaging materials may find their way into the hands of adversaries.

Depending on the situation, the work product of the consultant could be properly brought within the "attorney work product privilege." Generally speaking, in order to do so, the relationship must be initiated and directed by counsel, the work must be requested in contemplation of litigation (the contemplation must be real, not contrived), and the work product must be maintained, protected, and separated from non-privileged materials. By invoking the work product privilege when appropriate, the provider may be able to obtain important advice and counsel on billing/coding deficiencies with the security that otherwise harmful criticisms will not be generally discoverable by its adversaries.

Conclusion

Congress, the OIG, and the GAO have all recently singled out healthcare consultants for special criticism. In truth, the real targets of their admonishments are the *consumers* of these services; that is, the healthcare provider community. These concerns should be well-heeded: care should be taken to hire well-qualified consultants with a reputation for high integrity.

Healthcare providers should also be realistic about the parameters of a consultant's abilities to improve their business. While consultants can and should be expected to "maximize revenue" within regulatory parameters (or reasonable interpretations thereof), no consultant should be expected to exceed the proper bounds of advice and advocacy. A written agreement between provider and consultant should clearly reflect these expectations.

Because, in most cases, it will be providers—not consultants—who will be answerable for the results of improper advice rendered and applied, providers should clearly understand not only the benefits—but also the risks—inherent in relying on the recommendations of healthcare consultants. If this summer's flurry of governmental consultant-bashing serves this purpose alone, it will have achieved its true goal.

❖ *John Brennan and Christina Mireles may be reached at Crowell & Moring, 1001 Pennsylvania Ave., NW, Washington DC 20004-2595. Tel: 202-223-5000. E-mail:* jbrennan@crowell.com.

Problem Lab Tests Could Lead To False Claims Allegations

Billing For Worthless Tests May Constitute Fraud

Laboratories that knowingly submit claims for faulty tests could potentially be charged with fraud, says a government prosecutor known for advocating use of the federal False Claims Act (FCA) to enforce quality of care in healthcare settings.

James Sheehan, the Philadelphia-based assistant U.S. attorney for the Eastern District of Pennsylvania, believes a recent case involving a former SmithKline Beecham lab facility sets some precedent for bringing false claim charges against labs that seek payment from federal healthcare programs for tests that may be inaccurate.

In that case, *United States et rel. Lee v. SmithKline Beecham Inc.*, the former supervisor of a SmithKline Beecham-owned lab in Van Nuys, CA, in 1997 accused the lab of falsifying controls on an experimental drug in order to obtain payment for the testing.

Whistleblower Insoon Lee alleged that when test results for control samples fell outside the acceptable standard of error, SmithKline falsified the results and made no attempt to investigate the source of the error, fix the problem, or retest the affected patient specimens.

Because SmithKline billed Medicare for these allegedly worthless tests and falsely certified the payment requests it sent to the government, it violated the FCA, Lee asserted.

Court Rulings Clash

The District Court for the Central District of California in 1998 dismissed the case "with prejudice," saying Lee failed to satisfy the heightened pleading requirements of the Federal Rule of Civil Procedure. By dismissing the case "with prejudice," the court in effect said Lee could not amend his claim and file it again.

Lee asked the court to reconsider; it declined to do so. In April 2001, the Ninth Circuit Court of Appeals reversed the lower court's decision," saying he should have been allowed to amend his claim and refile his case. The appeals court remanded the case to the lower court for reconsideration.

SmithKline, which denies any wrongdoing, ultimately settled the case in May, paying Lee $50,000 to resolve the false claim allegations and $350,000 to settle other employment-related claims, according to SmithKline's attorney, Thomas Lee of Dechert Price & Rhoads (Philadelphia).

What is significant about the case, Sheehan tells *G-2 Compliance Report*, is that the appeals court acknowledged that inaccurate or falsified tests could be covered by the False Claims Act.

While the appeals court did not rule on the merits of Insoon Lee's allegations, it did acknowledge the possibility that healthcare providers that render a "worthless service" could be guilty of fraud.

In its ruling, the court wrote: "If, for the sake of analysis, we assume that a party to a government contract knowingly or with deliberate ignorance charged the government for worthless services, then there would be fraud on the government that may be pursued under the FCA."

> *"Essentially what the court said was that worthless lab tests constitute fraudulent claims. If a lab knows that a test is not accurate, but reports it out and bills for it anyway, that's a false claim."*
>
> *— James Sheehan*

Substantial Hurdles

While Lee, the SmithKline attorney, agrees that billing for worthless tests could constitute a false claim, he notes that a claimant would have to overcome "substantial hurdles" by proving that a test was inaccurate, that the lab knew it, and that the lab knowingly submitted a claim for the faulty test. The prosecutor in the above case, Lee is careful to note, could not prove any wrongdoing on the part of SmithKline.

"There is some truth to [Sheehan's theory] because the court did say that if someone can properly allege and prove that [a lab] performed a worthless test, knew it was worthless, and billed the government, then there could be an FCA claim," attorney Lee acknowledges. "But that's a long way from saying that just because a test turns out to be inaccurate or it's discovered later that there's a problem with the equipment, that that's a false claim."

In fact, prosecutors are not interested in going after labs that may have made one or two mistakes on lab tests, says Sheehan. Instead, they are more interested in systemic problems that are not addressed or a pattern of duplicity.

"If you hold yourself out as a lab that provides reliable results, which you have to in order to meet CLIA standards, and you know you're not, that's fraud," maintains Sheehan.

Resources

- James Sheehan: 215-861-8200
- Thomas Lee: 215-994-2994

New ABN, *from page 1*

sheet and making it easier to read." Those that haven't should start now, he advises.

The transition will be challenging for those that have not been using ABNs or are using an old format, believes Twila Henning, a compliance specialist with CareMedic Systems Inc., based in St. Petersburg, FL. Some labs and physician offices still have little experience with the ABN, she notes.

"The large national labs have been using ABNs. But hospital and physician office labs as well, as small regional independent labs, may not be as informed or have not yet put the ABN process into operation. The hard part will be going from what they have now to what will be required," she says.

For example, Henning explains, many labs and physicians offices have been placing ABNs on the back of lab request slips, using small (8-point) type. The new ABNs each consist of an entire page, and any modifications must be set in at least 12-point type according to CMS draft instructions. In addition, providers will likely have to give the beneficiary a copy and keep a duplicate on file.

"The education process for the people getting signatures will be much greater," says Henning. "According to the guidelines, there are many stipulations with regard to formatting and what's required to process a valid ABN. It will not be enough to list [lab] tests with check-off boxes; the person completing the ABN will actually have to cross off the tests that aren't being performed."

Whether providers begin using the new forms now or wait until final instructions are released, it's important to give some type of advance notice to patients, says Small.

"Every organization needs to have a front-end medical necessity checking program and an ABN-signing policy. The longer you go without one, the greater your liability."

ABN Requirements

According to CMS draft instructions on the new ABNs, a physician office or lab should give an ABN to a Medicare beneficiary if there is genuine doubt that Medicare will pay for some or all of the items or services to be provided.

If a physician or lab fails to provide a proper ABN in situations where one is required, it may be liable for payment unless the provider can show that it did not know, or could not have been expected to know, that Medicare would deny payment.

Among the key requirements in the draft instructions:

❖ *Allowed customization*. Physicians and labs must use the approved ABN forms. The forms may not be modified except for the user-customizable section (where the description of items or services and the reasons for denial are inserted) and the area at the top of the form for provider identification. Use of any other ABNs or ones modified beyond the allowed customization may expose providers to liability.

❖ *Reasons for predicting denial*. The ABN must give the beneficiary a reasonable idea why the provider is predicting the likelihood of Medicare denial. Simply stating "medically unnecessary" is not acceptable. On the general ABN, providers may list reasons for denial with check off-boxes, but must indicate which reason applies. Listing several reasons that apply in different situations without indicating the reason that applies is not acceptable. When checklists are used, non-selected items should be indicated by drawing a line through them.

❖ *Generic and blanket notices*. ABNs should not be given to beneficiaries unless there is some genuine doubt that Medicare will make payment. Generic or blanket notices stating that denial of payment is possible or that the physician or lab never knows whether Medicare will deny payment are not acceptable.

❖ *Services denied on medical necessity grounds*. In any case where a national coverage decision stipulates that a particular item/service is never covered, the provider may state in the "Because" box: "In accordance with a national coverage decision, Medicare never pays for this (item/service)."

❖ *Estimated cost*. The physician or lab may provide the patient with the estimated cost of the item or service to be provided. The patient may ask about the cost and jot down an amount in the designated space. The provider must respond to such inquiries to the best of its ability, but the lack of an amount on this line, or an amount that is different from the final actual cost, does not invalidate the ABN.

❖ *Emergency situations*. To address what is perceived as a conflict between treatment requirements under the Emergency Medical Treatment & Labor Act and Medicare's policy on ABNs, CMS has drafted a series of "frequently asked questions" to make its policy clear. According to the FAQs, an ABN should not be given to a beneficiary who is seeking emergency services until after he or she has been stabilized.

The approved Medicare ABNs may be downloaded from the CMS Website at www.hcfa.gov/medlearn/refabn.htm. *The general use form (CMS-R-131-G) may be used for all situations, including laboratory tests. The lab ABN (CMS-R-131-L) may be used for physician-ordered lab tests.*

Resources

❖ Twila Henning: 507-376-6096
❖ Larry Small: 727-866-1311
❖ Our previous coverage: "Standard Medicare ABNs Approved, CMS Working on Instructions," Aug. '01, p. 8

Are You Next On OSHA's Latest Inspection List?

You may well be if you work in a hospital or nursing home that has an injury and illness rate above the national average.

Over the next several months, the Occupational Safety & Health Administration plans to inspect 1,000 workplaces that it has deemed "high hazard," including nursing homes and general medical, surgical, and psychiatric hospitals with Lost Workday Injury and Illness (LWDII) rates at or above 14.0.

Once it completes these inspections, OSHA is likely to inspect, beginning in 2002, approximately 3,000 more worksites with rates at or above 14.0.

The workplaces due for inspection will be culled from a list of 14,000 that OSHA has pinpointed as having LWDII rates above the national average. The agency identified the sites with the highest rates, based on data reported by 80,000 employers surveyed last year.

Those in the inspection pool of 14,000 had eight or more injuries and illnesses resulting in lost workdays for every 100 full-time workers, according to OSHA. Nationwide, the average workplace had three instances for every 100 workers.

OSHA has sent letters to the 14,000 sites notifying them that their injury and illness rates exceed those of most workplaces and encouraging them to take steps to reduce hazards and protect their workers.

The 14,000 sites are listed, on OSHA's Website, *www.osha. gov* (under Freedom of Information).

Get Ready Now

Hospitals and nursing homes with high rates of worker injury and illness should begin to address the problems now, whether or not they are on the list of 14,000, advises Melissa Bailey, an attorney with Arent Fox's OSHA Practice Group (Washington, DC).

"Even if you're not on the list, you could still be inspected for a complaint or an injury. It's always important to be ready for an inspection," she says.

To get ready, Bailey suggests:

- Review such items as OSHA 200 logs and worker's compensation claims in order to determine the reason(s) for high injury and illness rates. Once a particular hazard has been identified, initiate remedies prior to an inspection.
- Identify key management personnel who will work with the OSHA inspectors. Such personnel should be knowledgeable about the inspection process and strategies to minimize liability.
- Examine written policies and training programs to determine whether they fully comply with OSHA requirements.

"By understanding their rights, using certain strategies, and preparing in advance for inspections, employers are often able to minimize OSHA liability, while making sure they can run their business during an inspection," Bailey explains.

"Another key during an inspection is to keep lines of communication open," she adds. Bailey recommends that employers ask inspectors to share during the inspection any problems they identify. This will give facility operators the opportunity to provide additional information showing that problems are already being addressed.

"The goal is to prevent citations before they are issued," Bailey says.

Resources

- OSHA Site-Specific Targeting 2001 Compliance Directive, No. 01-01: *www.osha.gov* (under Regulations and Compliance).
- Melissa Bailey: 202-857-6102; *baileym@arentfox.com*

In last month's column, we discussed the "grandfather" provision that allows independent laboratories to continue billing Medicare directly for the technical component (TC) of pathology services to hospital inpatients and outpatients through 2002 if the hospital had such an arrangement with an independent lab in effect as of July 22, 1999. This raises the question of what proof is required to show that a lab is eligible to continue direct TC billing.

According to a new transmittal from the Centers for Medicare & Medicaid Services (Transmittal B-01-50), attestation will be enough (if no written agreement is available) that a hospital had an agreement as of July 22, 1999, with an independent lab under which the lab bills Medicare for the TC of pathology services.

The attestation should contain the following:

- *Legal and business names and addresses of the laboratory.*
- *Medicare billing and CLIA number(s).*
- *Statement to the effect that on July 22, 1999, this arrangement existed between this lab (or its predecessor) and the hospital.*
- *Statement of any limitation to the agreement; for example, only certain tests are covered or certain time restrictions were imposed.*
- *Date of the attestation.*
- *Original signature of the lab's representative (if the lab had the arrangement with the hospital as of July 22, 1999) or a representative of the hospital (if the hospital had an arrangement with a different lab as of July 22, 1999).*
- *Statement that the signer is authorized to sign on behalf of the entity making the attestation.*

Transmittal B-01-50 is posted online at *www.hcfa.gov/pubforms/transmit/B0150.pdf*.

Have a question you'd like answered? E-mail it to Kimberly Scott, managing editor, at *kimscott@yahoo.com*. We'll select one to address in this column.

The Back Page

News-At-A-Glance

Bad Advice: A hospital and its cost-report consulting firm have agreed to pay $756,302 to settle allegations under the False Claims Act that they fraudulently claimed costs for the hospital's employee post-retirement health benefits when these were not reimbursable by Medicare, according to the U.S. attorney's office for the District of Delaware. Nanticoke Memorial Hospital (Seaford, DE) and McBee Associates of Maryland (doing business in Wayne, PA) allegedly claimed the unallowable costs in the hospital's 1995 Medicare cost report. Nanticoke will pay $567,227; McBee, $189,075.

Lab Overpayment: The Connecticut Medicaid program overpaid for lab and pathology services between 1996 and 1999 to the tune of more than $2.8 million, according to a recent audit report released by the HHS Office of Inspector General. According to the report, the state's Medicaid payments for lab services exceeded Medicare fee schedule limits. The OIG noted that the state had not updated its clinical laboratory fee schedule since 1994, and that Medicare fee schedules for many of the services had decreased since that time.

The OIG recommends that the state Medicaid program implement procedures to update clinical lab fee schedules on a regular basis to ensure that amounts for paid for clinical services do not exceed what Medicare pays for the same services. The report, "Review of Fee Schedules Used for Reimbursement of Clinical Laboratory Services-Connecticut Medicaid Program, is available online at *www.hhs.gov/progorg/oas/reports/region1/10100003.pdf.*

Pneumonia Upcoding: Newton-Wellesley Hospital (Boston, MA) will pay $2,789,682 for false and fraudulent claims to Medicare in bacterial pneumonia billings and $562,201 for upcoding in other billings. The agreement settles government allegations that between Oct. 1, 1992 and Sept. 30, 1997, Newton-Wellesley submitted claims with the principal diagnosis code of 482.89 for complex pneumonia due to "other specified bacteria," but the corresponding medical records did not support this. As a result, Newton-Wellesley allegedly received reimbursement to which it was not entitled because Medicare reimburses treatment of a simpler form of pneumonia at a lower rate.

Inaccurate Doctor Bills: The U.S. attorney's office for the District of Massachusetts announced Aug. 21 that Caritas Medical Group (Boston) will pay $196,521 to resolve Medicare false claim allegations for evaluation & management services rendered by a particular physician.

During a review of billings in 1999, the group discovered certain inaccurate bills submitted from 1997 through early 1999, using higher reimbursing codes not appropriate for the actual service furnished or for services either not performed or not documented in the medical records.

The group voluntarily reported the problem to the government and immediately took corrective action, the government said. As part of the settlement, Caritas will maintain its compliance measures and review medical claims by all physicians periodically.

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