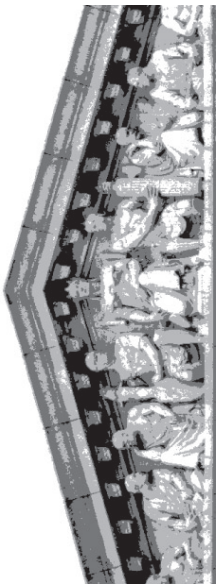
G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. VIII, No. 2, February 2006

For Hospitals, Laboratories and Physician Practices



Groups Oppose New CCI Edits

Lab and pathology groups are calling on the Centers for Medicare and Medicaid Services (CMS) to nix a proposal that would restrict the number of services that would be paid by Medicare to a set number of services per patient per day.

The proposal is part of a National Correct Coding Initiative (CCI) called "Medically Unbelievable Edits" (MUEs). The edits, which have not been formally issued but are under internal review at CMS, are similar to those contained in a transmittal issued in February 2005 (Change Request Number 2987) but later rescinded. CMS has said that the edits are intended to catch "typographical and unbelievable cases" submitted to Medicare for payment. Use of the MUEs, which have been circulated to some physician groups for comment, is proposed to start in July 2006.

In a Jan. 6, 2006, letter to CMS Administrator Mark McClellan, the American Clinical Laboratory Association (ACLA) says the current MUE initiative goes well beyond its intended purpose and should not have been proposed without benefit of a CMS reissued program notice and the opportunity for stakeholders to comment on the program notice. ➥ *p. 2*

OIG Proposes Guidance For Research Awards Recipients

New proposed compliance guidance for recipients of research awards from the National Institutes of Health and other components of the U.S. Public Health Service (PHS) highlights important risk areas that could trigger administrative, civil, or criminal liability and offers suggestions for developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and other requirements of PHS programs.

The draft guidance, issued Nov. 28, 2005, marks the first time the Health and Human Services Office of Inspector General (OIG) has published compliance guidance for entities that are not involved in furnishing items or services covered under the Medicare or Medicaid program. The draft follows several cases brought under the False Claims Act against universities, research institutions, and researchers involving improper use of grant funds.

The guidance document contains seven elements that have been widely recognized as fundamental to an effective compliance program, and an additional element (number 8) that the OIG believes is especially important for research institutions. ➥ *p. 9*

Inside this issue

Groups Oppose New CCI Edits, *from p. 1*

After review of the draft MUE list, ACLA concludes that it was developed 1) without appropriate CMS guidance as to its purpose, 2) without a process to appeal the edits, 3) without disclosure of the methodology employed to develop the edits, and 4) without appropriate stakeholder involvement, writes ACLA President Alan Mertz in the letter.

"ACLA further believes that, in many instances, the proposed unit of service edits fly in the face of accepted medical practice, are contrary to the conventions established when the laboratory CPT codes were developed, and, if implemented, will have negative healthcare consequences for Medicare recipients," says Mertz.

For example, CPT code 82784 (Gamma Globulin, IgA, IgD, IgG, IgM each) is ordered 77% of the time more frequently than the proposed unit of service edit of one, he writes. In the vast majority of instances, appropriate patient care dictates that a physician considering a diagnosis of multiple myeloma simultaneously orders more than one immunoglobulin class to establish the nature of the specific immunoglobulin involved in the disease. Once the diagnosis is made, the patient would then be followed by serial orders of only the specific immunoglobulin.

As another example, says ACLA, the series of CPT codes for molecular diagnostic testing (2005 CPT codes 83896 through 83906) are routinely and appropriately ordered more frequently than the proposed unit of service edit of one. These CPT codes were developed to recognize a series of steps of analyses required to amplify nucleic material, and thus these codes are intended to be ordered more than one unit of service for appropriate patient specimen evaluation.

Yet another example is the investigation of why a patient is bleeding, says ACLA. A physician might order a series of bleeding or clotting tests that might utilize the same CPT/HCPCS code to identify the cause and to avoid multiple patient visits and delay in diagnosis. The same process of ordering multiple tests would apply when a physician is trying to diagnose the cause of apparent autoimmune disease in a woman with generalized symptoms.

"While the examples cited above relate to clinical laboratory tests reimbursed under the Medicare clinical laboratory fee schedule, ACLA also wishes to express our deep concern regarding the severe impact of the proposed MUEs on certain pathology services reimbursed under the Medicare physician fee schedule, some of which are performed by clinical laboratories," writes Mertz.

Pathology Codes Also Affected

The new edits would also affect pathology codes, notes the College of American Pathologists (CAP). "The edits, whose use will result in automatic denials of all claimed units in excess of the criteria units of service ceiling, are far reaching," CAP says in an alert. Of particular concern to pathologists is the proposed limit of two units for CPT 88305 (Level IV – Surgical Pathology, Gross, and Microscopic Exam) on claims for the same beneficiary on the same date of service for a given provider.

"We are actively reviewing the proposed edits to identify necessary modifications to the MUE list and are working now on a firm response," says Mark Synovec, MD, chair of the CAP Economic Affairs Committee. "We will develop clinical evidence of why these unit limitations are clearly inappropriate for pathology and pursue other measures, as appropriate, to fight this process, which appears to be seriously flawed."

Resource

- Letter from Alan Mertz to CMS: *www.clinical-labs.org*
- College of American Pathologists: *www.cap.org*

CMS May Suspend Cytology PT Penalties In 2006

The Centers for Medicare and Medicaid Services (CMS) is considering suspending cytology proficiency testing (PT) sanctions in 2006, effectively maintaining the program as it was conducted in 2005, according to the College of American Pathologists (CAP).

CAP leaders spoke with CMS officials in late December during a conference call. Thomas Hamilton, director of CMS's Surveys and Certification Program, said he would recommend suspension of sanctions to the administrator, Mark McClellan.

CMS convened the conference call in direct response to a December 22 letter from CAP President Thomas Sodeman, MD, who urged the agency to suspend penalties under the PT program for an additional year to give Congress time to fully consider College-advocated legislation that would suspend and revise the program. That bill, the Proficiency Testing Improvement Act of 2005 (H.R. 4568), won House approval December 17 and now awaits Senate action.

In 2005, CMS launched the cytology PT testing program, but stipulated that sanctions would not be imposed on laboratories, pathologists, and cytotechnologists for testing failures during the initial year of testing.

According to CAP, Dr. Hamilton also made a commitment to work with the profession to more quickly resolve scientific concerns and other issues. The Clinical Laboratory Improvement Advisory Committee (CLIAC), which advises the agency on the Clinical Laboratory Improvement Amendments (CLIA) of 1988, unanimously recommended that CMS revise the grading criteria and other elements of the PT program.

CMS previously indicated that it could take three to four years to revise the regulations, but in the December 29 call with CAP leaders, agency officials said they are exploring various rule making options for expediting changes and would consult further with the CLIAC and professional societies on necessary revisions.

Bill Would Suspend Program For One Year

H.R. 4568 would suspend the cytology PT program for one year and require revisions along the lines advocated by CAP and other national and state pathology societies. The legislation was introduced by Rep. Nathan Deal (R-GA), chairman of the House Energy & Commerce health subcommittee, which has jurisdiction over the program.

CMS began nationwide enforcement of the CLIA cytology PT requirements in January 2005, more than a dozen years after the requirements became final. Despite criticism that the rules had become badly outdated, CMS officials said they had no choice but to begin enforcing them on a national scale when an applicant came forth with an acceptable cytology PT program. That applicant was the Midwest Institute for Medical Education (Indianapolis, IN).

CAP has since been approved as a national cytology PT provider, beginning this year, but the College remains committed to an overhaul of current requirements.

Resource

❖ College of American Pathologists: *www.cap.org*

GAO To Investigate Reprocessing Of Single-Use Devices

The Government Accountability Office (GAO) has agreed to open a probe into the safety of using reconditioned medical devices designed for one-time use, according to a report in *The Washington Post*.

The GAO agreed to begin an investigation at the request of Reps. Thomas Davis III (R-VA) and Henry Waxman (D-CA), the chair and ranking minority member of the House Committee on Government Reform. The *Post* recently ran a series of

articles about problems with single-use devices, known as SUDs that are reprocessed and reused.

Device manufacturers say they cannot vouch for the safety of their reconditioned single-use devices, but reprocessors say there is no credible evidence that their refurbished devices are riskier than new ones, according to the *Post*.

The GAO examined reuse of SUDs in 2000, when the practice was still relatively new, but found little available evidence of harm from reuse. However, reprocessing has increased since then, and the practice is believed to be used by many of the nation's hospitals.

OIG Urges Tighter Controls On Modifier 59

Modifier 59, which is used to bypass software edits under Medicare's Correct Coding Initiative (CCI), was used incorrectly 40% of the time in fiscal 2003, according to a recent report by the Health and Human Services Office of Inspector General (OIG), which is urging tighter controls on the modifier's use.

CCI edits contain pairs of HCPCS/CPT codes that generally should not be billed together by a provider for a beneficiary on the same date of service. Under certain circumstances, however, a provider may bill for two services in a CCI code pair and include a modifier on the claim that would bypass the edit and allow both services to be paid. Modifier 59 is used to indicate that a provider performed a distinct procedure or service for a beneficiary on the same day as another procedure or service. When modifier 59 is used, a provider's documentation must demonstrate that the service was distinct from other services performed that day.

The OIG examined 350 code pairs for services that bypassed CCI edits using modifier 59 in fiscal year 2003. It found that 40% of code pairs billed with modifier 59 did not meet program requirements, resulting in $59 million in improper payments. Specifically, the modifier was used inappropriately with 15% of the code pairs because the services were not distinct from each other.

Five code pairs represented 53% of the services that were not distinct, and 25% of the code pairs billed with modifier 59 were not adequately documented, the OIG concluded. While most carriers did not conduct reviews of modifier 59, those that did found providers who were using the modifier incorrectly. In fact, one-third of 32 reviews completed found error rates of 40% or more for services billed with modifier 59.

The OIG recommends that CMS encourage carriers to conduct prepayment and postpayment reviews of the use of modifier 59. Because the agency found that a small number of code pairs made up more than half of the services that were not distinct in its sample, carriers may want to focus their initial analysis on these code pairs, says the report.

In the study sample, modifier 59 was used inappropriately most often with the CCI code pair for bone marrow biopsy (83221) and bone marrow aspiration (38220). A cytopathology code pair (88108/88104) represented six of the services billed inappropriately with the modifier. In most of the cases, the documentation showed that the services were performed on the same specimen and only one code should have been billed.

The OIG also found a potential high error rate and low frequency code pairs for any combination of the following pathology codes: 88104-88112 (excluding 88108/88104), 88160-88162, 88173, 88174, 88180, 88271-88275, and 88300-88365.

Resource

- "Use Of Modifier 59 To Bypass Medicare's National Correct Coding Initiative Edits": *www.oig.hhs.gov/oei/reports/oei-03-02-00771.pdf*.

COMPLIANCE PERSPECTIVES

Tax-Exempt Health Systems: More Uncertainty And New Challenges

Dale C. Van Demark and Taylor Lea Jones are attorneys in the Health Care & Life Sciences Practice of Epstein Becker & Green, P.C., Washington, D.C.

Tax-exempt health systems have always operated within a complicated tax-exempt and health regulatory environment. The challenges posed by these distinct bodies of regulatory authority are significant. Now, tax-exempt health systems face new scrutiny from the Internal Revenue Service (IRS), private citizens in class-action lawsuits, Congress, the capital markets, and state and local taxing authorities. Change, and the rumor of change, in the tax-exempt community has created significant uncertainty and is producing new challenges.

IRS Focus

Recently, the IRS has increased its oversight of tax-exempt health systems, with an emphasis on financial arrangements with insiders, conflicts of interest, and, significantly, assessing how hospitals meet the "community benefit standard," the standard for exemption to which hospitals have been held for over 30 years.

Over the past two years, the IRS has changed the IRS Form 1023, Application for Recognition of Exemption, and Form 990, Return of Organization Exempt from Income Tax, to require greater disclosure of compensation arrangements and conflicts of interest. Specifically, Form 1023 now requires detailed information regarding the applying entity's compensation structure, payments to related parties and vendors, and the role of insiders. Form 990 now requires organizations to disclose the five most highly compensated independent contractors for professional services and the five most highly compensated independent contractors for all other services.

In addition, the IRS has proposed further changes to Form 990 which would require the disclosure of key employees or officers related by business or family to the tax-exempt entity or compensated by organizations under common supervision and control with the filing entity, and disclosure of deferred compensation or benefits to former officers, directors, trustees, or key employees. According to the IRS, the purposes of these changes are the prevention of private inurement and the assurance of the independence and loyalty of the tax-exempt organization's insiders.

More recently, the IRS's Tax Exempt and Government Entities Division issued its Fiscal Year 2006 *Implementing Guidelines*, in which the IRS outlines goals and initiatives for the coming year. One of the 2006 IRS priorities is to pursue abusive tax avoidance through targeted examinations. The IRS plans to target tax-exempt hospitals as part of this initiative. The IRS will focus on the method by which hospitals determine and pay executive compensation and how hospitals meet the community benefit standard.

Executive compensation has been a topic of repeated focus by the IRS in recent years. Last year, the IRS executed a letter-writing campaign in which 1,250 compliance check letters were sent to a wide range of tax-exempt organizations. The purpose of this campaign was to study how tax-exempt organizations determine and report compensation, how often the organizations loan money to their employees, the incidence of business relationships between these organizations and their employees, the proportion of compensation as compared to the organizations' assets, and whether the organizations reported any "excess benefits"

on their annual tax returns. The IRS has analyzed the results of this initiative and has stated that it will now be "better able to target more productive cases involving compensation." The IRS compensation compliance program is now being focused on hospitals.

The second part of the initiative of the 2006 IRS initiative addresses the fundamental standard of tax-exemption for hospitals—the community benefit standard. The fundamental purpose of most hospitals is the promotion of health. The IRS recognizes that the promotion of health qualifies as an appropriate tax-exempt purpose as long as the community as a whole benefits. To determine whether a hospital benefits its community, the IRS utilizes a number of factors that indicate the hospital is meeting the community's needs. These factors are:

The IRS review of compliance with the community benefit standard potentially reflects greater scrutiny of the basis for health system tax exemption.

1 Whether the hospital operates a full-time emergency room open to all people, regardless of their ability to pay;
2 Whether the hospital provides nonemergency services for all people who are able to pay for these services by themselves or through insurance or public programs;
3 Whether the hospital participates in the Medicare and Medicaid programs;
4 Whether the hospital has a board of directors that is representative of the community;
5 Whether the hospital has an open medical staff; and
6 Whether the hospital applies any sur plus funds toward improving facilities, equipment, patient care, medical training, research, and education.

This increased scrutiny of compensation and conflicts of interest policies is forcing tax-exempt health systems to expend resources and energy to comply with new legal and "best practices" standards. This may result in an increased interest in the economics underlying any business relationship, but particularly one involving insiders.

Additionally, the IRS focus on compliance with the community benefit standard will force tax-exempt health systems to review and modify their operations to assure compliance. Many health systems are responding to this scrutiny and the threat of civil lawsuits and state or local taxing authority challenges (discussed below) by publicizing their compliance with the community benefit standard through "Community Benefit Reports," and by more carefully assessing business relationships to better understand, and perhaps enhance, the community benefit provided.

Class Actions

During the past few years, a steady stream of class-action suits have been filed against tax-exempt hospitals. The primary claim of most of these cases is a challenge to the hospitals' tax-exempt status. Specifically, plaintiffs allege that certain practices of these hospitals violate an implied contract between the hospitals and the public under which the hospitals are expected to provide a certain amount of health services to the poor and uninsured in exchange for the hospitals' tax-exempt status. Specific hospital practices that have been targeted by these lawsuits include the failure to provide adequate charity care, charging uninsured patients higher rates than those charged to insurance companies and federally administered health insurance programs, and aggressive collection practices.

These lawsuits have been largely unsuccessful in federal courts. Courts have held that tax exemption under the Internal Revenue Code does not create a valid contract under which plaintiffs may assert a claim. Further, some courts have noted that even if an implied contract existed, the uninsured would not necessarily be the intended beneficiaries of that contract. Hospitals do not receive tax-exemption by providing charity care services. Instead, the provision of health services, in conformity with the community benefit standard, is the basis for their exemption.

Accordingly, the courts have held that the uninsured are, at most, incidental beneficiaries of the hospitals' tax-exempt status. Although few of these suits have been successful, several have resulted in settlements in which the defendant hospitals agreed to modify billing and charity care

policies. More recently, class action suits in state courts have been instituted. In light of the different standards for state tax exemption, the disposition of state lawsuits cannot be predicted with any certainty.

In light of the scrutiny and negative publicity associated with these lawsuits, many tax-exempt hospitals are updating their charity care policies and collection practices to ensure compliance with state laws and to buttress their adherence to the community benefit standard.

State Tax Exemption Scrutiny

Hospital tax exemption has been recently scrutinized by state and local tax authorities. Unlike private litigants, state and local taxing authorities have been successful in challenging the tax-exempt status of hospitals. For example, in October 2005, Ohio Tax Commissioner William Wilkins ruled that the Cleveland Clinic's family health and surgery center in Beachwood, Ohio, must pay property taxes because the clinic provides insufficient charity care to qualify for state tax exemption. The Cleveland Clinic argued that the larger health system should be the focus of the charity care scrutiny. The Commissioner disagreed and ruled that "[p]roperty used as physicians' offices is not a charitable use of property, and such property is not entitled to exemption." If the ruling is upheld, the Cleveland Clinic will likely have to pay more than $17 million in property taxes for its property located in Cleveland alone.

In Illinois, the Champaign County Board of Review has twice recommended denial of tax exemption of certain hospitals. One of these cases is still pending, but the Illinois Department of Revenue agreed with the Champaign County Board of Review in the case against Provena Covenant Medical Center and denied the Center's tax-exempt status. Additionally, in May 2005 Stan Jenkins, the chairman of Champaign County Board of Review testified about these actions before the House Ways and Means Committee. Jenkins testified that the Champaign County Board of Review focused on three main issues when deciding whether to grant tax-exempt status: pricing to the uninsured, billing and collection practices, and the availability of charity care.

While these actions can be viewed in isolation, it is not beyond reason to anticipate similar actions in the future. In addition, state legislative bodies are also reviewing the justification for exempting health systems from state taxes.

Sarbanes-Oxley

The Sarbanes-Oxley Act of 2002 (SOX) was enacted on July 30, 2002, to strengthen regulatory

Congress Focuses On Tax-Exempt Issues

Congress, and particularly the Senate Finance Committee, has also become more focused on tax-exempt issues and, in some cases, the tax-exempt status of health systems. During the past two years, a number of events have occurred that many view as harbingers for legislative change:

- In June 2004, the Senate Finance Committee Staff prepared a draft report regarding tax exemption that suggested a variety of changes to enhance compliance and accountability;
- In September 2004, the chairman and ranking member of the Senate Finance Committee solicited Independent Sector, a nonprofit coalition of approximately 500 national charities, foundations, and philanthropic programs, to assemble a group to consider and recommend ways to strengthen governance, ethical conduct, and accountability within the nonprofit sector. The group issued an Interim Report in March 2005 and a Final Report in June 2005, which offered a broad range of recommendations;
- In April 2005, the staff of the Joint Committee on Taxation published a report on the historical development and current law of tax exemption, which highlighted changing standards and areas that have been considered for action, such as proposals increasing the importance of charity care for tax exemption;
- Throughout 2005, both the Senate Finance Committee and House Ways and Means Committee held hearings regarding tax exemption and tax exemption for health systems specifically; and
- Senate Finance Committee Chairman Chuck Grassley has made public statements suggesting that legislation addressing abuses in the tax-exempt sector were on his agenda.

Despite all the signals, the Senate approved only limited changes to the Internal Revenue Code in the Tax Relief Act of 2005. These changes have not yet been considered by the House of Representatives as of this writing. Provisions in the Act would require large systems to more fully disclose and be accountable for the income they derive from business not related to their charitable activities and could make it more difficult for health systems to own for-profit enterprises.

Given all of the activity and interest expressed by Congress, it is likely that more legislative proposals will be forthcoming in 2006.

oversight and curb abuses by management of publicly traded companies. SOX accomplishes these goals by: 1) requiring that companies create audit committees having broad authority over financial matters, 2) narrowly defining the permissible relationships between a company and its auditors, 3) requiring that companies adopt rigorous internal controls over financial information gathering and reporting, and 4) requiring that management operate in an environment that fosters accountability, including the adoption of an enforceable code of ethics and the certification of financial reports.

As tax-exempt health systems are not publicly traded companies, most of the provisions of SOX do not apply to these organizations. Despite its nonapplicability, however, tax-exempt health systems have struggled with the implications of SOX–with some commentators suggesting that tax-exempt health systems adopt SOX wholesale and others suggesting that not-for-profits "wait and see" whether SOX will be imposed on them by the government. In fact, some states have adopted legislation that imposes some SOX-like requirements on not-for-profits, and other states are considering similar legislation.

In its Aug. 9, 2005, report entitled, "Sarbanes-Oxley and Not-For-Profit Hospitals: Increased Transparency and Improved Accountability," Fitch Ratings, a credit rating agency, concluded that the voluntary adoption of certain provisions of SOX and greater financial disclosures to the capital markets will lend significant credibility to a health system's financial reporting and enhance the organization's credit rating. The Fitch report acknowledges the costs associated with adoption of the provisions of SOX and notes that strict adherence to SOX requirements is not necessary. Nonetheless, the clear implication of the report is that Fitch Ratings will rate tax-exempt health systems that adopt the SOX provisions recommended by Fitch more highly than those that do not.

Conclusion

Tax-exempt health systems are contending with a changing regulatory and business environment. Health systems are under increasing pressure to provide and demonstrate community benefits, to carefully regulate compensation practices, to institute greater internal controls and financial reporting, and to open to public scrutiny certain internal operations.

The effects of the changing environment ripple through the many components of tax-exempt health systems and the relationships with their community and business partners. The extent of issues that tax-exempt health systems face in light of this changing environment is well beyond the scope of this article. Generally, however, tax-exempt health systems should consider the following:

- Boards of directors should adopt and periodically review and update their conflicts-of-interest policies and procedures for determining executive compensation;
- Adoption of SOX provisions should be carefully considered in light of the potential impact on the credit rating of the health system and the cost of implementing SOX provisions;
- Compliance programs should accommodate better internal controls and policies that rigorously avoid conflicts of interest and ensure the integrity of financial information;
- Tax-exempt health systems should understand, document, and be prepared to defend the community benefits they provide;
- Charity care, uninsured patient care policies, and collection practices should be designed and applied in a manner consistent with the emerging standards applied by state and local governments, to the extent such standards are knowable; and
- Joint venture and other business relationships should be examined to ensure compliance with the community benefit standard and to ensure appropriate accounting for unrelated business income tax purposes.

The challenges and uncertainty facing tax-exempt health systems emanate from a variety of places and potentially impact nearly every aspect of an organization's operations. Proactively addressing the issues described above can help health systems avoid significant problems in the future.

Dale Van Demark and Taylor Lea Jones can be reached at Epstein Becker & Green, 1227 25th St., NW, 7th Floor, Washington, DC 20037. Phone: 202-861-4187. E-mail: dvandemark@ebglaw.com *and* tjones@ebglaw.com.

OIG Proposes Guidance, *from p. 1*

1. Implementing written policies and procedures;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines;
7. Responding promptly to detected problems and undertaking corrective action; and
8. Defining roles and responsibilities and assigning oversight responsibility.

Although many research institutions have developed their own compliance policies for handling federal grants and contracts to ensure that claimed costs are allowable, this is the first time that one of the key enforcement agencies has published compliance advice on this topic.

As with previously issued guidance, the document represents OIG's suggestions regarding how institutions can establish internal controls to ensure adherence to applicable rules and program requirements. The OIG stresses that the guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program.

"Moreover, the guidance does not establish a set of program rules or standards by which to evaluate the compliance of an institution,' says the OIG. "Rather, it is merely a set of suggestions regarding how institutions may establish internal controls to allow the institution to better comply with rules and standards that apply to PHS extramural research awards."

Recipients of research awards are required to comply with a wide range of terms and conditions that include financial reports to the granting agency, according to Robert Wanerman, an attorney with the law firm of Epstein Becker & Green (Washington, D.C.). Without appropriate compliance procedures in place, the award recipient may have costs disallowed; in more serious cases, the recipient may be exposed to liability under the federal False Claims Act (FCA).

The FCA imposes monetary penalties and damages on any entity for a range of conduct involving government funds including, but not limited to, submitting a false or fraudulent claim for payment by the federal government, or knowingly making a false record or statement to avoid or conceal an obligation to repay monies to the federal government. As the process for obtaining research grant awards and administering those awards involves numerous certifications of compliance with a broad range of laws and policies, any one material misrepresentation could result in liability under the act, notes the law firm.

Risk Areas

The draft guidance identifies three risk areas for recipients of PHS research awards that have come to the OIG's attention:

1 Time and effort reporting. Because the compensation for the personal services of researchers—both direct salary and fringe benefits—is typically a major cost of a project, it is critical that the portion of the researcher's compensation for particular research projects be accurately reported, says the OIG. A failure to account properly for the time spent by researchers on a project can result in overcharges to the government and potential liability under the False Claim Act.

2 Properly allocating charges to award projects. Research institutions commonly receive multiple awards for a single research area. It is essential that accounting systems properly separate the amount of funding from each funding source, says the OIG. The failure to account accurately for charges to various award projects can result in significant disallowances or, in certain circumstances, could subject an institution to criminal or civil fraud investigations.

3 Reporting financial support from other sources. For PHS awards, the reporting of other financial support is a required element of award applications, and the failure to provide this information could, in certain instances, subject an institution to a criminal or civil fraud investigation. Any knowing misrepresentation could result in an investigation or liability under the False Claims Act.

Resources

- Draft Compliance Program Guidance for Recipients of PHS Research Awards: *www.oig.hhs.gov/authorities/docs/05/fr120805.pdf*
- Robert Wanerman, Esq.: 202-861-1885

Severance Agreement Prevents Pursuit Of *Qui Tam* Case

A former hospital employee who signed a severance agreement barring him from filing suit under the *qui tam* provisions of the False Claims Act had no right to bring a lawsuit against his former employer, ruled the U.S. District Court for the Southern District of Georgia in a recent case.

Between 1980 and 2001, Ted Whitten worked for the Glynn Brunswick Memorial Hospital Authority in a number of positions, including compliance officer. In 1989, Quorum Health Resources began providing the authority with management services. On Sept. 29, 2000, the authority terminated its relationship with Quorum, and a few months later, Whitten left.

On Jan. 3, 2001, Whitten accepted a severance agreement. As part of the agreement, Whitten was paid $124,000 and agreed to release the authority, along with its officers and agents, from "any and all claims, demands, actions, and causes of action of any kind or nature, known or unknown, arising or existing until the date of this instrument."

The agreement also acknowledged that Whitten was contemplating an action against Quorum "regarding matters arising out of his employment" and said that nothing in the agreement was "intended to or shall be construed to release Quorum, et al, from any such claims or liabilities."

Whitten later brought a complaint against Quorum, alleging that it engaged in healthcare billing fraud. The district court, however, dismissed the complaint, saying he did not have the right to file a *qui tam* case because the severance agreement only protected his right to file a complaint about matters arising out of his employment, not matters related to the False Claims Act.

Make Provision Standard

Leon Rodriguez, an attorney with Ober/Kaler (Baltimore, MD), believes this case is significant because it upholds the right of healthcare providers to include in severance agreements provisions protecting themselves from whistleblower cases.

"Given the climate that healthcare providers live in, this [type of provision] should become a standard part of all severance agreements or severance agreements where one has reason to be concerned that someone might become a whistleblower," he tells *GCR*. "But this would apply only in a situation where the government has not intervened."

However, a court is unlikely to uphold a provision that "tries to completely gag" employees and attempt to stop them from going to law enforcement to report possible fraud, Rodriguez adds. "The key here is that if the employee is aware of wrongdoing, the employee has a place to go, but not necessarily the right to get a windfall through a *qui tam* lawsuit," he explains.

FTC Orders Physicians To Stop Price-Fixing

The Federal Trade Commission (FTC) has ruled that North Texas Specialty Physicians (NTSP), an association of independent physicians in the Forth Worth, Texas, area illegally fixed prices in its negotiations with payers, including insurance companies and health plans.

The ruling, which upholds a November 2004 opinion by an administrative law judge, requires the group to stop the illegal conduct and to terminate pre-existing contracts with payers for physician services.

NTSP had approximately 480 physician members at the time of its trial in April 2004, including more than 100 primary care physicians and others in 26 medical specialties. These physicians have distinct

economic interests, and many compete with one another, notes the FTC in its opinion, issued December 1.

NTSP's main functions are to negotiate and review contract proposals for the services of its members, to review payment issues, and to act as a lobbyist for the interests of its members. The group has negotiated both risk-sharing contracts (where doctors are typically reimbursed on a dollar-per-patient basis) and nonrisk sharing contracts (which provide fee-for-service payments). The challenged conduct involved only the negotiation of nonrisk sharing contracts, which were more common for NTSP.

In negotiation of its contracts, NTSP engaged in conduct designed to enhance the collective bargaining power of its members, says the FTC. This conduct included the use of member polls on prospective fees and communication of the results to members in a way that affected payment levels in nonrisk sharing contracts.

"In addition, NTSP's agreement with its members granted NTSP the right of first negotiation with payers and inhibited independent negotiations by individual physicians," the commission wrote in the ruling. "NTSP's illegal conduct also included refusals to deal and refusals to forward payer offers to member physicians that NTSP itself deemed unacceptable."

The administrative complaint against NTSP was filed in September 2003, and the initial decision in favor of the complaint counsel was issued in November 2004. Both NTSP and the complaint counsel subsequently appealed to the commission.

Unlawful Price Fixing

The FTC concluded that NTSP's contracting activities with payers "amount[s] to unlawful horizontal price fixing." The opinion states that, through a variety of mechanisms, NTSP was able to orchestrate price agreements among its physicians.

The evidence in the case, the commission found, "shows not only negotiation activity in aid of a collective agreement on a minimum fee schedule, but also specific enforcement mechanisms—such as the powers of attorney and collective withdrawal from payer networks—in order to coerce agreement from payers."

These actions, when viewed as a whole, "leave no doubt that the overriding purpose behind NTSP's conduct was to fix prices." The FTC order requires NTSP to cease and desist from engaging in anticompetitive price-fixing conduct alleged in the complaint.

To avoid interference with potential efficiencies, the order does not prohibit any agreement involving conduct that is reasonably necessary to further a qualified risk-sharing joint arrangement or a qualified clinically integrated arrangement among physicians. The order also allows NTSP to act as a messenger or an agent on behalf of physicians for contracts with payers, but for three years NTSP is required to notify the commission in advance before doing so.

Resource

- FTC opinion "In the Matter of North Texas Specialty Physicians": *www.ftc.gov/os/adjpro/d9312/051201opinion.pdf*

For the Record

Archived Specimens Date of Service

Effective April 3, 2006, the date of service (DOS) for archived laboratory specimens will be the date the specimen was collected, according to a transmittal issued December 30 by the Centers for Medicare and Medicaid Services. This policy was announced in 2005, but the new transmittal (Change Request 4156) includes the effective date.

If a specimen is collected over a period that spans two calendar days, then the DOS shall be the date the collection ended. If a specimen was stored for more than 30 calendar days before testing, the DOS is the date the specimen was obtained from storage.

The transmittal is available online at *http://new.cms.hhs.gov/Transmittals/*.

Compliance Officer Survey: The majority of compliance officers (89%) who responded to a survey by the Health Care Compliance Association (HCCA) say they do not have an employment contract, with just 11% reporting they do have such a contract. On the question of whether or not they have assurance that their organization will cover their legal expenses if they are sued professionally as a result of their job, the responses are almost equally divided, with 51% responding yes, and 49% responding no. And just 23% of the 209 survey respondents say they have professional liability insurance.

OIG Seeks Safe Harbor Input: The Department of Health and Human Services Office of Inspector General (OIG) is seeking recommendations for developing new safe harbor provisions under the federal anti-kickback statute. To date, the OIG has developed a total of 22 safe harbors that describe practices sheltered from liability. The OIG is also seeking suggestions on special fraud alerts, which give healthcare providers guidance about potentially abusive practices. Proposals are due by February 7. For more information, go to the OIG's Web site at *www.oig.hhs.gov*.

Are You Happy With Your Contractor?: The Centers for Medicare & Medicaid Services (CMS) plans to measure how satisfied providers in the fee-for-service program are with the services of the contractors responsible for processing their claims, educating them about changes in Medicare policies, and responding to provider inquiries. The Medicare Contractor Provider Satisfaction Survey (MCPPS) will be administered on an annual basis and will query 25,000 randomly selected providers. CMS will use the results for Medicare contractor oversight.

Drug Company Excluded From Medicare: Serono Laboratories Inc., the U.S. subsidiary of a Swiss drug company, will be excluded from federal health care programs for at least three years as a result of a plea in a drug marketing case. The Boston-based company pleaded guilty in Massachusetts federal court and was sentenced in relation to schemes to promote and sell its Serostim drug, used to treat weight loss in AIDS patients. The plea follows an October 2005 agreement by the Swiss parent firm and its U.S. affiliates to plead guilty to two counts of criminal conspiracy and pay $704 million to settle criminal charges and civil liabilities.

G-2 Compliance Report Subscription Order or Renewal Form

❑ ***YES***, enter my one-year subscription to the ***G-2 Compliance Report (GCR)*** at the rate of $419/yr. Subscription includes the ***GCR*** newsletter, The G-2 Compliance Resource Guide, the Quarterly Compliance Tips on Disk, and electronic access to the current and all back issues at www.ioma.com/g2reports/issues/GCR. Subscribers outside the U.S. add $50 postal.*

❑ I would like to save $174 with a 2-year subscription to ***GCR*** for $646.*

Please Choose One:

❑ Check Enclosed (payable to Washington G-2 Reports)

❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Ordered by:

Name _____

Title _____

Company/Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

e-mail address: _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

Mail to: Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Or call 212-629-3679 and order via credit card or fax order to 212-564-0465 GCR 2/06

 G-2 Compliance Report (ISSN 1524-0304) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Web site: www.g2reports.com.

Kimberly Scott, Managing Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Group Publisher; Joe Bremner, President.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 2.