



Compliance Report



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For Hospitals, Laboratories and Physician Practices

Pathologists May Seek Arbitration Over Professional Reimbursement

Several pathology practices around the country are considering seeking class-action arbitration against United Healthcare (UHC) over denial of reimbursement for the professional component of clinical pathology services, according to Jane Pine Wood, an attorney with McDonald Hopkins Co. (Cleveland), whose firm represents the pathology practices and is undertaking the class representation.

UHC, like Medicare, maintains that compensation for pathology professional component (PC) services in the clinical laboratory is included in payments to hospitals and other facilities and that pathologists should turn to those sources for PC pay-

ments. As such, UHC in October 2004 began denying clinical pathology claims that use the “-26” modifier to indicate professional component services.

According to Wood, United not only ceased paying pathologists for these services, but also sent overpayment demand letters to some pathologists, demanding repayment for the professional component of clinical pathology services dating to the beginning of 2004. “I filed appeals, and several of those have received letters just recently that United is dropping the repayment request based upon the appeal letters,” she tells *G-2 Compliance Report*.

➔ p. 2

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Gambro Agrees To Lab Overbilling Settlement

Gambro Healthcare Inc. (Lakewood, CO), one of the country’s largest providers of kidney dialysis services, will pay the federal government more than \$328,000 to resolve Medicare overbilling allegations stemming from the company’s contracts with local laboratories to perform expedited lab tests, according to the U.S. Attorney’s Office for the Eastern District of Pennsylvania.

The government alleged that Gambro, which owns or operates outpatient dialysis clinics throughout the country, entered into indi-

vidual contracts with local laboratories to perform expedited or “stat” lab tests on an as-needed basis. Many of these contracts provided that the local labs bill all payers, including the Medicare program, for stat lab tests, even though Medicare already had reimbursed Gambro for some of those tests as part of the composite rate it pays for dialysis treatment, the government alleged.

Because some of the stat lab tests performed by local labs included tests that were covered by the composite rate, it was improper to bill for them, the government argued. ➔ p. 9



Jane Pine Wood, Esq.

Pathologists May Seek Arbitration, from p. 1

It appears that other insurers are following United's lead. "Other payers are ceasing to pay, including Blue Cross and Aetna," notes Wood. "I heard that Aetna just released a new policy manual explaining that it has adopted Medicare's reimbursement methodology on a national basis, which presumably would include paying the hospital for the professional component services." McDonald Hopkins is

in negotiation with these and other payers on behalf of certain pathology associations and organizations.

CAP In Discussions

The College of American Pathologists (CAP) has been in discussions with UHC officials over this issue. CAP President Mary Kass, M.D., and Jack Bierig, general counsel, met recently with Reed Tuckson, M.D., UHC's senior vice president of consumer health and medical care advancement.

Dr. Kass and Bierig pointed out that hospitals often fail to pass on PC payments to pathologists. They buttressed their position on the correctness of PC billings with a letter of support from the American Medical Association (AMA) on correct CPT coding for clinical pathology PC services and use of the -26 modifier.

"We have recently become aware that United Health Care has recently implemented a policy change regarding payments for professional component services for clinical pathology," says the letter, written by Michael Beebe, director of AMA's CPT editorial and information services. "Your policy indicates that [United] will not pay a professional component (modifier -26) for laboratory oversight services since it is your belief that this service is part of the facility payment. We believe this policy change is contrary to CPT guidelines with respect to the use of modifier -26."

According to CAP, Dr. Tuckson expressed a willingness to study the problem of passthrough payments from hospitals to pathologists and to consider earmarking dollars in UHC contracts with hospitals for pathologists' clinical pathology PC services.

"They're reviewing the policy in good faith and said they'll get back to us soon with an answer," explains Bierig, an attorney with Sidley Austin (Chicago).

Resources

- ❖ Jane Pine Wood: 508-385-5227
- ❖ Jack Bierig: 312-853-7614
- ❖ College of American Pathologists: 800-323-4040 🏠

Don't miss this upcoming audioconference ...

Putting "Pod" Labs Under The Microscope: Which Way Are The Feds Heading?

Thursday, February 10, 2005
2:00-3:30 p.m. (Eastern time)

Featured Faculty:

Jane Pine Wood, Esq.
McDonald Hopkins Co. LPA

W. Bradley Tully, Esq.
Hooper, Lundy & Bookman Inc.

Host and Moderator:

Kimberly Scott, Managing Editor,
G-2 Compliance Report & Diagnostic Imaging Intelligence Report,
Washington G-2 Reports

The proliferation of "pod" labs, a fast-spreading business arrangement in which specialty physicians take advantage of relaxed benefits reassignments rules to boost Medicare revenue from pathology referrals, has attracted the attention of federal agencies. Both the Health and Human Services Office of Inspector General and the Centers for Medicare and Medicaid Services have expressed concern about these arrangements and their potential legal and economic implications.

But what exactly has Uncle Sam done about the growth of pod labs and what are the ongoing considerations for pathologists? During this special 90-minute audio conference, you'll:

- Learn what CMS has to say about pod labs and Medicare's reassignment rules and whether the agency's stance puts the issue to rest.
- Hear the steps the OIG is taking to address the pod lab controversy.
- Discover how the pod lab model is evolving in response to the government's concerns.
- Find out what issues remain to be resolved in this area, from questions regarding malpractice insurance to federal and state licensure and certification.

You'll also have a chance to ask questions—and hear expert advice—in our interactive Q&A portion of the program. Join your colleagues and take the hassle-free approach to discovering what the government intends to do about the pod lab controversy. And you can invite your entire staff—for one low fee! Continuing education credit is available through AACC/ACCENT and ASCLT/PACE. For program information, call (800) 522-7347 or visit www.g2reports.com.

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MedPAC Recommends That Labs Provide Values On Claims

MedPAC's report is due to Congress in March.

The Medicare Payment Advisory Commission (MedPAC) plans to recommend to Congress that providers performing laboratory tests submit values on either Medicare claims or separately, using common vocabulary standards.

MedPAC members and staff believe that having this information will allow the Centers for Medicare & Medicaid Services (CMS) to begin identifying and rewarding physicians who provide efficient, quality care to beneficiaries.

However, in meetings and calls with MedPAC staff, the American Clinical Laboratory Association (ACLA) has expressed a number of concerns about the recommendation. Among the concerns:

- ❖ There will be a considerable cost to laboratories in retooling their billing and results reporting systems to comply with the terms of the recommendations.
- ❖ Laboratory values must not be viewed independent of a medical record. Other data influential to the laboratory results provides a complete picture for the test requisition, the subsequent outcomes, and the implications of the result.

- ❖ While some standardization currently exists for the coding and electronic transmission of laboratory data, a tremendous amount of work remains. Efforts are underway. However, issues such as mapping LOINC codes and developing implementation guides for interoperability standards take time to provide for the effective and efficient standardization of laboratory values. Standardization of these systems would need to be the precursor to the commission's recommendation.
- ❖ The recommendation presents potential problems with respect to the minimum necessary standard under the HIPAA privacy rule's "minimum necessary standard." In addition, many state laws limit who can receive results; in many instances, this information may only be provided to the ordering physician.
- ❖ Not all laboratory tests report reference values. For example, services such as cytopathology, flow cytometry, and microbiology provide narrative results.
- ❖ Many laboratories actually contract out the submission of claims information, further complicating the transmission of this information, either on a claim or separately.

During the commission's January 12 meeting, MedPAC staff acknowledged that there would be "some increase in burden for those who conduct lab tests" and proposed including language in the commission report that implementation be accomplished over a two- to three-year period, according to ACLA.

While most commissioners emphasized the great potential they saw in improving quality and efficiency through pay-for-performance, several commissioners raised concerns similar to those expressed by ACLA and voted against the recommendation. ACLA now plans to turn its attention to briefing key congressional staff about the problems in going forward with this requirement.

Resources

- ❖ ACLA: 202-637-9466 🏠

Scrushy Trial Underway

The trial of former HealthSouth CEO Richard Scrushy, one of the most-watched corporate fraud cases in the country, is now underway in Birmingham, Alabama.

Scrushy, founder of the Birmingham-based health system, is charged with creating phony profits to boost the stock price of the publicly traded company. He has pleaded not guilty. The case is the first brought under the Sarbanes-Oxley Act, a 2002 federal law passed to increase penalties on dishonest corporate leaders. The law was passed after legislators and regulators acted to stop corporate fraud that cost investors billions of dollars at Enron Corp. and other companies.

Prosecutors in Scrushy's trial are seeking \$278 million in personal assets, including waterfront homes, luxury cars, and a yacht, as well as a prison sentence that could amount to life if he is convicted. The trial is expected to last for several months.

Florida Lab Bidding Plan Mired In New Dispute State Halts Procurements

The Florida Medicaid program has halted, for the third time, a controversial procurement for independent laboratory services for all recipients statewide, this time in response to a petition for an administration hearing by the American Clinical Laboratory Association (ACLA).

The stoppage comes just two weeks after the state's Agency for Health Care Administration reissued the solicitation, following a seven-month hiatus triggered by a previous protest. Last December 13, the agency had reissued an Invitation to Negotiate (AHCA ITN 0508) a winner-take-all contract to provide independent lab services to Florida Medicaid for three to four years. The ITN had an ambitious schedule, with a contract to be awarded by April 4 of this year.

As required by the state legislature, AHCA invited bids based on monthly capitated payments. But the agency also wanted to negotiate a percentage reduction of at least 9% from the Medicaid fee schedule to adjudicate fee-for-service claims

for beneficiaries not included in monthly capitation rates.

If there is no contract by April 1, the state must cut lab reimbursement by 10% below the Medicaid fee schedule, as per the state legislature (HB 1835). Bid protests don't alter this statutory deadline.

ACLA Protest

ACLA challenged Florida Medicaid's ITN on behalf of its 24 members, saying they provide more than 45,000 tests per week to the

state's Medicaid recipients. The association said its two largest members, Quest Diagnostics and LabCorp, provided nearly \$25 million of the \$37 million of lab services Florida Medicaid paid for in fiscal 2003.

In its petition, ACLA claims the ITN would

"The ITN [issued by Florida Medicaid] treats the acquisition of complex clinical laboratory services as though they were comparable to unsophisticated medical equipment, such as a bedpan," says ACLA.

deprive Medicaid recipients of their right under federal law to obtain tests from any lab qualified to perform the service. The association said the state had obtained from the federal Health and Human Services Department neither an exception nor a waiver from this freedom-of-choice requirement.

Further, ACLA said, the solicitation would violate state Medicaid requirements for "delivery of quality healthcare." Also, lab test prices would skyrocket as soon as the winning bidder's contract ends, because there would no longer be any competitors in Florida, the trade group asserted.

In another petition, ACLA challenged the solicitation as an "unpromulgated rule," saying there is no regulatory basis for the performance standards, monitoring and reporting requirements, and capitated payment system set forth in the solicitation. ▲

In Other Competitive Bidding News ...

On the Medicare front, RTI International Inc. (Research Triangle Park, NC), the contractor for the Part B lab bidding demo required under the Medicare Modernization Act of 2003, is developing a set of design options, which its Technical Expert Panel is expected to review in the spring.

In California, the state's Medicaid program—MediCal—is reviewing applications from independent laboratories for two-year contracts allowing them to continue providing moderate or high-complexity testing services. Other types of labs will be asked to apply later.

California intends to contract only with labs that provide quality services and agree to reduced Medi-Cal reimbursement. The state plans to announce contract awards in February.

COMPLIANCE PERSPECTIVES



Brian S. Chilton, Esq.



Tom Carlucci, Esq.

Brian S. Chilton and Tom Carlucci are attorneys with Foley & Lardner LLP. Chilton is senior counsel in the Washington, DC, office, and Carlucci is a partner in the San Francisco office.

Despite Ruling, Federal Sentencing Guidelines Remain “Gold Standard” For Healthcare Compliance Programs

Two weeks ago in *United States v. Booker* and *United States v. Fanfan* (Nos. 04-104 and 04-105, 543 U. S. ____ Jan. 12, 2005), the U.S. Supreme Court struck down the 17-year-old federal sentencing guidelines, reducing them to advisory rather than mandatory status.

Although perhaps not apparent to the casual observer, the court’s opinion is extremely important to healthcare compliance officials. Healthcare entities face a daunting array of regulations, including the False Claims Act; Food and Drug Administration regulations; federal and state anti-kickback and fraud and abuse laws; federal and state self-referral laws, including the federal Stark law; and federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). In order to comply with these many laws, most healthcare entities have adopted compliance programs designed according to the standards for an “effective” compliance program under the federal sentencing guidelines since that standard was first promulgated in 1991, and recently amended effective Nov. 1, 2004.

Ever since the court issued *Blakely v. Washington* (542 U.S. ____, 124 S. Ct. 2531, June 24, 2004), striking down a similar state sentencing guidelines system as violative of the Sixth Amendment, the healthcare legal compliance community has been anxiously waiting for the Supreme Court to rule on the constitutionality of the federal sentencing guidelines to assess the impact of the court’s Sixth Amendment analysis on the federal sentencing guidelines’ requirement that business en-

ties maintain an “effective” compliance program. That wait is now over, and for the reasons discussed below, even though the guidelines are now “advisory,” for purposes of corporate compliance, healthcare companies should continue to presume that the guidelines’ criteria for an “effective” compliance program remain in force.

The Road To Booker/Fanfan

Congress created the U.S. Sentencing Commission in 1984 to establish “guidelines” defining offense behaviors and characteristics for federal judges to follow during sentencing. The term “guidelines” was a euphemism, though, because it was a reversible error to ignore them. State legislatures soon passed similar guidelines.

In *Blakely*, the Supreme Court reviewed Washington state’s sentencing guidelines to determine whether that scheme offended the Sixth Amendment’s guarantee of criminal trial by jury. The Sixth Amendment problem condemned in *Blakely* occurred because under the guidelines, certain offense characteristics can result in additional sentencing “points” that increase the sentencing range. These characteristics need not have been elements of the crime charged or proven to the jury at trial. For example, routinely in federal drug cases the defendant receives an enhancement for “using” a firearm, even though the indictment and trial required evidence only of drug possession. Only at post-conviction sentencing does the judge review evidence that the defendant had a firearm. The *Blakely* majority held that this scheme violated the principle in *Apprendi v. New Jersey* (530 U.S. 466, 490

(2000)), where the court said, “Other than the fact of a prior conviction, any fact that increases the penalty for a crime beyond the prescribed statutory maximum must be submitted to a jury, and proved beyond a reasonable doubt.”

The court’s holding in *Blakely* cast an obvious shadow over the federal sentencing guidelines, given that Washington state’s guidelines were modeled after the federal ones. At the request of the U.S. Department of Justice and the Solicitor General, the Supreme Court agreed to hear the *Booker/Fanfan* cases on an expedited basis to determine the fate of the federal guidelines.

The Ruling In *Booker/Fanfan*

By a 5-4 vote (Justice Stevens, joined by Justices Scalia, Thomas, Souter and Ginsburg) the court applied the Sixth Amendment analysis advanced in *Blakely* to the federal sentencing guidelines. As most analysts had predicted, the Court’s ruling in *Booker/Fanfan* held that because the federal sentencing guidelines scheme was mandatory and included enhancement procedures indistinguishable from those declared unconstitutional in *Blakely*, the federal guidelines were equally unconstitutional.

The surprise of the decision lies in the court’s determination of remedy.

Justice Breyer wrote for the Court (joined by Chief Justice Rehnquist and Justices O’Connor, Kennedy, and Ginsburg), and said that the correct remedy was to declare unconstitutional the provisions making the guidelines mandatory, leaving the rest of the system intact. As a consequence, the federal sentencing guidelines are now “advisory.”

The Fallout

Time will tell as to what “advisory” means in practice once the lower federal courts resume sentencing. According to Justice Breyer’s majority opinion on remedy, a sentencing court is still required to consider the “advisory” sentence yielded by the guidelines, even if the judge ultimately chooses not to apply that sentence. Presumably it would be an er-

ror, then, for a lower court to refuse even to calculate the sentence otherwise called for under the guidelines. Justice Breyer also emphasized that on appeal, the reviewing court must review the “reasonableness” of the sentence by reference to various statutory criteria, including the criteria established by the Sentencing Commission under the sentencing guidelines for a given offense.

As a practical matter the sentencing guidelines will still serve as the starting point for determining a criminal sentence, and although judges no longer are required to follow the guidelines, they are still required to calculate a sentence under the guidelines and offer some reasoned basis for refusing to apply the sentence otherwise called for by the guidelines.

The Sentencing Guidelines & Corporate Compliance Programs

When the guidelines first defined an “effective” compliance program in 1991, that standard quickly became the “gold standard” within the corporate compliance community for uses well beyond criminal sentencing.

One of the best examples of how the guidelines’ definition of an “effective” compliance program has become the “gold standard” for compliance purposes far beyond corporate criminal sentencing comes from the healthcare industry’s own compliance experience. In its Compliance Program Guidance for Hospitals (63 *Fed. Reg.* 8987, Feb. 23, 1998), the Office of the Inspector General of the U.S. Department of Health and Human Services reviewed its history of promulgating voluntary compliance programs over the prior years and predicted that, “Future compliance program guidances to be developed will be similarly structured and based on substantive policy recommendations, the elements of the federal sentencing guidelines, and applicable statutes, regulations, and federal healthcare program requirements.”

Over the succeeding years, the OIG developed a series of compliance program guidances (CPGs) directed at substantial segments of the healthcare industry: Hospitals; clinical laboratories; home health agencies; third-party bill-

ing companies; the durable medical equipment, prosthetics, orthotics, and supply industry; hospices; Medicare+Choice organizations; nursing facilities; physicians; ambulance suppliers; and pharmaceutical manufacturers. Each of these CPG's continued to track the essential elements of an effective compliance program under the federal sentencing guidelines.

Maintaining an "effective" compliance program has additional potential benefits for healthcare organizations beyond interactions with the OIG. Many compliance experts in the healthcare field believe that an aggressive, state-of-the-art compliance program can inoculate a healthcare company from one of the more onerous forms of litigation – *qui tam* false claims cases. Disgruntled employees and competitors are less likely to file a *qui tam* suit if they know the company has an effective compliance program. Even if one is filed, in order to succeed, a *qui tam* relator must be the first source to disclose the wrongdoing to the government, something less likely to occur when an effective compliance program is in place to prevent and report company violations. Again, nothing about the Supreme Court's rendering of the guidelines' standard as "advisory" changes anything about this potential benefit from a compliance program that satisfies the guidelines' standards.

Maintaining an "effective" compliance program is important to other enforcement agencies within the federal government beyond the OIG. On Jan. 23, 2003, the U.S. Department of Justice, through then-Deputy Attorney General Larry D. Thompson, issued a memorandum entitled "Principles of Federal Prosecution of Business Organizations." These principles counsel federal prosecutors to examine nine criteria when deciding whether charges should be sought against a business entity. One of these criteria directs prosecutors to decide "[w]hether the corporation has a compliance program in place that is adequately designed to prevent wrongdoing by employees and is enforced by management." In the past, the Department of Justice has looked to the guidelines' standard of "effective" as authoritative criteria for compliance programs, and as with OIG, nothing about the

Court's holding in *Booker/Fanfan* prevents DOJ from continuing to do so.

Compliance practice and theory are also relevant to companies subject to the Sarbanes-Oxley Act. Section 404 of that Act requires a company's management to present an internal control report in the company's annual report containing: (1) a statement of the responsibility of management for establishing and maintaining an adequate internal control structure and procedures for financial reporting; and (2) an assessment, as of the end of the company's most recent fiscal year, of the effectiveness of the company's internal control structure and procedures for financial reporting. In addition, in order to harmonize Sarbanes-Oxley's section 404 requirements with section 302's quarterly certification requirements, the Securities and Exchange Commission adopted regulations requiring companies to perform quarterly evaluations of changes that have materially affected or are reasonably likely to materially affect the company's internal controls over financial reporting. Compliance with these aspects of Sarbanes Oxley has, in practice, been a part of companies' overall compliance efforts under their compliance programs designed under the federal guidelines.

Even those companies not subject to Sarbanes-Oxley must review their compliance efforts in light of the proposed guideline for purposes of ensuring that their compliance program satisfies the fiduciary duty of good care. *In re Caremark International Inc. Derivative Litigation* (698 A.2d 959, 967, Del. Ch. 1996) and *McCall v. Scott* (250 F.3d 997, 6th Cir. 2001) are the two most prominent cases prescribing officer and director fiduciary responsibility to ensure a corporation has an effective compliance program. Indeed, the *Caremark* holding is well known in the healthcare compliance community, having resulted from a shareholder suit against the Caremark board of directors for breach of the fiduciary duty of care after the company entered into a multi-million dollar civil settlement and criminal plea relating to the payment of kickbacks to physicians and improper billing to federal healthcare programs.

The Guidelines' Definition of "Effective" Will Continue To Be The Standard

The *Blakely/Booker/Fanfan* review of sentencing guidelines could not have come at a more awkward time from a corporate compliance perspective. For the last three years, the sentencing commission has been in the process of revising the standards for compliance programs, and the revisions went into effect on Nov. 1, 2004.

After the court's holding in *Booker/Fanfan*, corporate compliance officials were understandably left to wonder whether the court's ruling rendering the guidelines "advisory" means they no longer need to have a corporate compliance program, or if they have one, need to ensure that it meets the new standard that became effective November 1. The better judgment is that companies still need compliance programs, and that those programs should meet the November 1 standard, because the federal sentencing guidelines definition of "effective" will likely remain the "gold standard" for years to come.

In *Booker/Fanfan*, Justice Breyer emphasized that even though the guidelines are now "advisory," a sentencing judge is still required to sentence according to the factors defined in 18 U.S.C. § 3553(a), the portion of the legislation creating the guidelines that was not struck down. § 3553(a) refers to the sentencing criteria in the guidelines, and additionally states that a judge "shall consider the need for the sentence imposed to protect the public from further crimes of the defendant." Thus, any judge sentencing a business entity will still be required to examine the adequacy of the entity's compliance program according to the guidelines, as amended on November 1. Moreover, if the judge finds that the program is deficient under the guidelines' standard, as part of the sentence, the judge can order the company to implement a compliance program that meets the standard "to protect the public from further crimes of the defendant." Thus, the now "advisory" nature of the guidelines does not change the fact that companies' programs will still be reviewed according to the standard defined in the guidelines, or that they could have a program that

meets the standard imposed on them as part of the terms of a sentence. Stated another way, it is highly unlikely that federal district courts will discard the guidelines' definition of an "effective" compliance program in favor of a standard created by the lower courts on an ad hoc basis. Many district court judges have expressed dissatisfaction with the guidelines' calculations for street crimes. No district court judge has ever publicly expressed dissatisfaction with the guidelines' definition of an "effective" compliance program.

Just as it is expected that federal criminal courts will continue to look to the guidelines' definition of "effective" as the governing standard for compliance programs, it can also be predicted that the other enforcement entities relevant to the healthcare community – OIG and other federal law enforcement officials, the common law courts, and for Sarbanes-Oxley purposes – will continue to look to that standard. Nothing about the Supreme Court's *Booker/Fanfan* holding prevents or discourages any of these bodies from continuing to rely upon the guidelines' compliance program standards. Indeed, it seems unlikely that federal enforcers like the OIG would suddenly determine that those standards, which the OIG has looked to for years, were suddenly inoperative merely because the Supreme Court has now called the guidelines "advisory."

Conclusion

The court's decision in *Booker/Fanfan* to make the federal sentencing guidelines "advisory" is less dramatic than might appear at first glance. Businesses generally – but particularly those in the heavily regulated area of healthcare – should continue assessing their compliance programs to make sure that they are "effective" for purposes of the federal sentencing guidelines, as amended Nov. 1, 2004, because this remains the "gold standard" within the healthcare compliance community specifically, and the corporate compliance community generally.

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Lab Overbilling Settlement, *from p. 1*

The settlement provides for the payment of \$328,286 to the government and a comprehensive Corporate Integrity Agreement that will be monitored by the Department of Health and Human Services.

“Not only does this settlement hold Gambro accountable for past conduct, but the Corporate Integrity Agreement will ensure that it doesn’t happen again,” said U.S. Attorney Patrick Meehan in announcing the agreement.

Gambro spokesman Kevin Smith says the company is “always glad to get these kinds

of things behind us” and will implement procedures to ensure clarity with regard to which party is responsible for billing. The company made no admission of liability under the settlement.

Gambro recently agreed to a much larger settlement of \$350 million to resolve civil liabilities stemming from alleged kickbacks paid to physicians, false statements made to procure payment for unnecessary tests and services, and payments made to Gambro Supply, which federal investigators called “a sham durable medical equipment company” (*GCR*, January 2005). 🏠

OIG Approves Hospice-Hospital Scheme

A proposed arrangement under which a healthcare foundation would make donations each year to a hospice would be unlikely to result in fraud or abuse under the anti-kickback statute, the Health and Human Services Office of Inspector General concluded in a recent advisory opinion.

While the arrangement could potentially generate prohibited remuneration, sanctions would not be imposed because the “requisite intent” on the part of the requestor to induce or reward referrals of healthcare business is not present, the OIG said in opinion No. 04-18, published December 29.

The health system requesting the opinion operates the only hospital in its community. The health system formed a healthcare foundation to raise money and provide financial healthcare services in the region. The foundation, the health system, and the hospital are nonprofit corporations exempt from federal taxation. Many of the foundation’s directors are also directors of the health system and the hospital.

The hospice, also a nonprofit entity, was formed to provide Medicare-certified inpatient hospice care for beneficiaries nearing death. No patient would be denied care, regardless of ability to pay for that care.

Under the proposed arrangement, the foundation would make unrestricted donations to the hospice each year for five years. Neither the foundation nor the health system would exert any control over the hospice. The hos-

pice may, but is not required to, purchase healthcare supplies and services from the health system.

“Although the crux of the proposed donations is an unrestricted donation from a charitable foundation to a nonprofit hospice, the proposed donations warrant closer scrutiny because of the donor-foundation’s affiliation with the health system through its origins and common officers and directors, in combination with the prospect that the hospice may generate federal healthcare program business for the health system,” says the opinion.

“In most arrangements between hospices and other healthcare providers, such as nursing homes or hospitals, we are concerned about remuneration flowing from the hospice to the other healthcare providers in exchange for the other providers’ referrals of hospice business payable by a federal healthcare program. However, in the instant case, the remuneration (i.e., the donation) will flow *to* the hospice. Therefore, to assess the risk of fraud and abuse, we must consider whether there is any nexus between the proposed donations and the generation of federal healthcare program business by the hospice for the health system.

The OIG concluded that the proposed donations were unlikely to result in fraud or abuse under the anti-kickback statute for three reasons:

1 Referrals of patients from the hospice to the health system would be limited because dying patients choosing hospice care

also relinquish their rights to curative care for their illnesses;

2 Donations to the hospice will be unrestricted as to their use; and

3 Donations would be subject to an annual cap and to a fixed duration of five years.

Further, the OIG noted that the foundation is a charitable entity formed to assist healthcare

providers and that the uses to which the donations would be put—establishing the hospice center for dying patients without regard to ability to pay—would further that mission.

Resource

❖ Advisory Opinion 04-18: www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0418.pdf. 🏠

HCA To Provide Discounts To Uninsured Patients

HCA's new policy is effective as of January 1.

HCA (Nashville, TN) said January 6 that it has modified its policies to provide a discount to uninsured patients who do not qualify for Medicaid or charity care. These discounts are similar to those provided to many local managed care plans.

HCA says it is able to make this based on guidance issued December 29 by the Centers for Medicare & Medicaid Services (CMS), which says such discounts will not put hospital Medicare payments at risk. According to the CMS guidance, when a hospital discounts charges to non-Medicare patients, such as uninsured patients, “there is no effect on outlier payments under either Medicare’s Hospital Inpatient Prospective Payment System or Medicare’s Hospital Outpatient Prospective Payment System.”

The agency explained that only Medicare reimbursable cost and the undiscounted Medicare-covered charges from Medicare claims are used to calculate the cost-to-charge ratio. “The cost-to-charge ratio is applied to the undiscounted Medicare covered charged from each Medicare claim to calculate the outlier threshold and the outlier payment,” CMS said.

“Similarly, to the extent that other payments, including new technology add-on payments, under the Medicare program are derived by use of a cost-to-charge ratio, the cost-to-charge ratio is applied to the undiscounted Medicare covered charge to calculate the Medicare payment amount,” CMS continued.

“We have modified our policies based on CMS guidance and in response to the growing problem of uninsured patients,” noted Jack Bovender Jr., HCA chairman and CEO. “There are now more than 45 million Americans without health insurance—providing them some form of discount is a step toward addressing this problem.”

HCA’s announcement comes as both for-profit and nonprofit hospitals remain under fire for their billing and collection practices. The issue is being highlighted in lawsuits and in Congress and state legislatures.

In implementing the discount policy, hospitals will first attempt to qualify uninsured patients for Medicaid, other federal or state assistance, or charity care. If an uninsured patient does not qualify for these programs, the uninsured discount will be applied.

Resources

❖ Jack Bovender: 615-344-2688
❖ CMS guidance on discounts to uninsured patients: www.cms.hhs.gov/providers/FAQ_Uninsured_Additional.pdf 🏠

Seattle Doctor Gets Prison Term For Fraud

A Seattle doctor in January was sentenced to a year in prison and ordered to pay \$1 million to the government for falsely billing Medicare, Medicaid, and a state insurance program, according to a report in the *Seattle Times*.

Federal prosecutors charged Vimlesh Ahmad, 58, with filing false claims with both the government and private insurance programs. Dr. Ahmad in October pleaded guilty to one count of healthcare fraud.

Dr. Ahmad reportedly regularly submitted claims at a higher level of service than she provided, sometimes billing for tests that weren’t performed or office visits that never occurred. For example, she once billed Medicaid for three visits with a patient who was out of state at the time.

Healthcare regulators started looking at Dr. Ahmad’s medical practice 12 years ago, noting the amount of highly addictive drugs she prescribed and the fact that she did not allow pharmacy refills, meaning patients had to return for more office visits to get new prescriptions, according to the *Times*. She was told to change the practice.

Dr. Ahmad will pay \$1 million in fines, restitution, repayment, and civil damages, including double damages to Medicare and Medicaid. She also will give up her medical license and is prohibited from practicing medicine in the United States.

OIG OKs Plans For Malpractice Insurance Subsidy

A hospital and two neurosurgeons are not at risk for administrative sanctions and penalties because of an arrangement in which the hospital provided malpractice premium subsidies to the doctors for a two-year term, the Department of Health and Human Services Office of Inspector General said in an advisory opinion released January 6 (No. 04-19).

In May 2003, the physicians were alerted by their malpractice insurance carrier that it would not renew coverage on their claims policies that expired two weeks later, according to the opinion. In addition, the carrier told the doctors that unless they retired from practice they would be responsible for “tail coverage,” which pays claims made for actions while the policy was in effect but filed after the policy expired.

The doctors told the hospital that they intended to retire unless it provided a malpractice subsidy, according to the advisory opinion. They cited the increased cost of malpractice insurance through a new carrier in addition to the cost of tail coverage through the old carrier as being too burdensome.

According to the hospital, several factors rendered the physicians’ expressed intent to retire immediately especially credible and potentially harmful for the local patient population. First, the availability of free tail coverage from the original carrier created a powerful financial incentive for the physicians to accelerate their retirement. In addition, the hospital functions as a hub for neurosurgical services for the county in which it is located, as well as several neighboring counties.

What’s more, the physicians provide a substantial amount of care to Medicaid and indigent patients. In the two years prior to entering the arrangement, the hospital had attempted to recruit new neurosurgeons to the area without success.

Subsidy Plan

Under the arrangement worked out with the physicians, the hospital agreed to pay the entire cost of the tail coverage from the old carrier, a portion of the increased premiums from

the new malpractice insurance carrier, and all or part of the cost of tail coverage from the new carrier. The hospital certified that the physicians continued to incur out-of-pocket expenses for malpractice insurance premiums, and that even with the subsidies, they paid higher overall costs.

The hospital also certified to the OIG that the subsidies were not tied to volume or value of referrals, and that the physicians were not required to refer patients to or otherwise generate business for the hospital. The doctors also were permitted under the arrangement to furnish services at other facilities, and the subsidized malpractice insurance extended to services provided at other facilities, including competing hospitals.

In return for the insurance premium support, the hospital required that the physicians maintain full-service practice in the community, assume neurosurgical call duty for the hospital’s emergency department, participate in assigned hospital committees, continue providing care for Medicare beneficiaries, provide at least the same level of Medicaid and indigent care as before the arrangement, and cooperate with the hospital’s efforts to recruit additional neurosurgeons.

OIG Analysis

The OIG notes that it has long been concerned that hospitals providing malpractice insurance premium subsidies could induce inappropriate referrals, especially in cases where “subsidies are offered in a conditional or selective manner that reflects referrals from the subsidized practitioners,” according to the advisory opinion.

However, the OIG determined that the hospital had incorporated sufficient safeguards into the subsidy arrangement to prevent the risk of fraud and abuse. The OIG also said it recognized the need to ensure access to care and had issued an anti-kickback safe harbor for providing malpractice insurance premium subsidies to obstetricians at the hospital.

Resource

Advisory opinion 04-19: www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0419.pdf 

The OIG concluded the structure of the arrangement prevented the doctors from benefiting from a “significant financial windfall.”

❖ Medicare paid too much or too little for 9.3% of all fee-for-service claims in fiscal 2004, according to a recent report by Centers for Medicare & Medicaid Services (CMS). The error rate report indicates that Medicare overpaid \$20.8 billion and underpaid \$900 million in Medicare claims. The agency is taking a number of steps to improve the error-rate-testing program, as well as the claims errors resulting in over and under payments, the report said.

❖ A complaint filed January 14 against the Department of Health and Human Services and the Centers for Medicare & Medicaid Services alleges that a provision in the Stark II interim final rule dealing with fair market value compensation for medical directors would unfairly and inappropriately result in drastically reduced compensation for nephrologists who act as medical directors at dialysis centers. The complaint, brought by Renal Physicians Association, involves a safe harbor in the interim final rule that CMS said could be used in determining fair market value for medical directorships.

❖ The Medicare Payment Advisory Commission (MedPAC) is expected to recommend broad changes to the way Medicare reim-

burses for hospital services under the diagnosis-related group payment system as a way to level the playing field among physician-owned specialty hospitals and larger community hospitals. MedPAC also will recommend that Congress extend until Jan. 1, 2007, the specialty hospital moratorium mandated in the Medicare Modernization Act of 2003. In addition, commissioners called for allowing hospitals and doctors to enter into gainsharing arrangements as an alternative to specialty hospital ventures.

❖ An enhanced and formalized advisory opinion process for Medicare providers would be costly to implement, would not provide timely answers to inquiries, and would have limited applicability beyond those requesting the guidance, the Department of Health and Human Services told the Government Accountability Office (GAO) in a recent report on Medicare advisory opinions. "We believe that an enhanced and more formal process of developing advisory opinions would not be a successful pursuit at this time," HHS said. The Medicare Modernization Act of 2003 (MMA) required GAO to determine the appropriateness and feasibility of establishing within HHS the authority to provide legally binding advisory opinions on the appropriate interpretations and application of Medicare regulations. The report is available at www.gao.gov/new.items/d05129.pdf. 🏛️

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