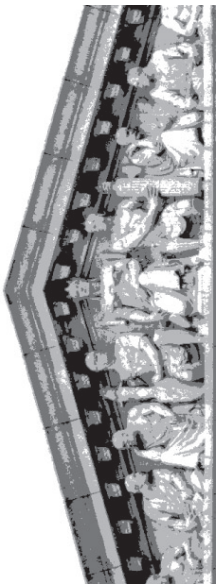

G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. V, No. 1, January 2003

For Hospitals, Laboratories and Physician Practices


# New Guidance Issued On HIPAA Privacy Rule

## *Business Ties Between Hospitals, Labs Clarified*

New guidance on the soon-to-be-implemented medical privacy rule should help clear up confusion over several key issues affecting healthcare providers, including workforce requirements and the relationship between reference laboratories and hospitals or other independent labs.

The guidance, issued Dec. 3 by the HHS Office for Civil Rights (OCR), states clearly that a hospital lab is not required to have a business associate contract with a reference lab in order to disclose protected health information to that lab for treatment of an individual. Nor is a physician required to have a business associate contract with a lab as a condition for disclosing protected health information for treatment.

Generally, entities covered by the privacy rule must have contracts in place with business associates to ensure that the associates will appropriately safeguard patients' health information. However, the relationships between hospital labs and reference labs and between physicians and reference labs fall under the permitted uses and disclosures for treatment, payment and healthcare operations, says OCR. ➔ *p. 10*

# Dianon To Pay $4.8M In False Claims Settlement

## *Reference Lab Allegedly Billed For Unnecessary Tests*

Dianon Systems Inc., a national pathology reference lab located in Stratford, CT, will pay the Federal Government $4.8 million to resolve allegations that it mischarged Medicare and other federal healthcare programs for certain tests it performed between 1995 and 2002.

The company, which specializes in cancer and genomic diagnostic services, also has agreed to enter into a compliance agreement with the U.S. Department of Health & Human Services. It requires Dianon to develop a compliance program to prevent future violations, according to Robert McCallum, assistant attorney general for the U.S. Department of Justice's Civil Division.

The settlement, announced Dec. 12, resolves a complaint against Dianon filed on behalf of the United States under the *qui tam* (whistleblower) provisions of the federal False Claims Act. The complaint, filed by Theresa Worner, MD, made a number of allegations about Dianon's billing practices, including charging for medically unnecessary tests and charging for investigational tests. She will receive $535,569 as her share of the proceeds of the settlement. ➔ *p. 4*

## Inside this issue

# HCA To Pay $631M More In Fraud Settlement

## *Deal Wraps Up Investigation Of The Company*

HCA Inc. (Nashville, TN), the nation's largest for-profit hospital chain, announced Dec. 18 that it had reached an understanding with the U.S. Department of Justice to pay $631 million more to resolve allegations that it defrauded Medicare and other federal healthcare programs. The settlement, still subject to approval by departmental officials, covers civil allegations that Justice made in 2001 about kickbacks to physicians and falsified Medicare cost reports.

*Attorneys representing the HCA whistleblowers say they may challenge the settlement*

The company will begin making the payment in February 2003 at an interest rate of 4.5%. The $631 million is in addition to the $250 million that HCA agreed to pay last March to settle "outstanding cost report issues" with the Centers for Medicare & Medicaid Services. HCA also said it would pay $17.5 million to settle similar claims by state Medicaid programs.

In all, the Justice Department's probe of HCA has resulted in recoveries totaling $1.7 billion, by far the largest ever in a federal healthcare fraud case. According to HCA, the latest settlement agreement ends the investigation by Justice, the department's longest-running healthcare fraud probe.

The alleged fraud at HCA began in the 1980s. In 1993 and 1996, separate whistleblowers in different parts of the country filed suits claiming HCA "cooked the books" on its Medicare cost reports. In 1997, the FBI raided HCA facilities across the country and seized thousands of documents. Years were spent poring over the cost reports and other materials to show that the company systematically defrauded the government and sought to cover up the scheme. Two years ago, the company pled guilty to 14 criminal counts.

At issue in the probe were a number of charges raised in eight civil lawsuits brought under the False Claims Act, including accusations that HCA intentionally overstated expenses in order to increase payment from federal healthcare programs and that the company paid kickbacks to some doctors to get them to refer patients to HCA facilities.

# OIG Offers Caveat To Gift Prohibition

## *Free Local Transportation May Be OK*

Free local transportation for Medicare beneficiaries and Medicaid recipients might not necessarily violate the prohibition against free goods and services issued last August, says the HHS Office of Inspector General.

In a letter released Dec. 10, the OIG noted that, in the context of some complimentary local transportation, it would not strictly enforce provisions that limit gifts and inducements to beneficiaries.

The letter was in response to a hospital's inquiry about an existing program that provides free transportation to patients and their families to the hospital and hospital-owned ambulatory surgical centers. The name of the hospital was redacted from the publicly released letter.

In an Aug. 30 special advisory bulletin, the OIG warned healthcare providers not to offer free goods and services that exceeded $10 per item and $50 in the aggregate per year. Gifts or services exceeding these limits could be considered illegal remuneration under the federal anti-kickback statute or the Stark self-referral law *(GCR, Oct. 02, p. 1)*.

The OIG noted in the bulletin that it was considering a regulatory exception to allow hospitals to provide some free local transportation that was valued higher than the $10/$50 limits.

In the Dec. 10 letter, the OIG said it would not impose administrative sanctions for violations related to free local transportation until an exception had been adopted or a decision had been made to restrict all ➔ *p. 3*

# IG Rehnquist Investigated For Questionable Activities

## *GAO Probe Includes Personnel Changes, Gun Possession*

*Janet Rehnquist*

HHS Inspector General Janet Rehnquist could be in jeopardy of losing her job, pending the outcome of a General Accounting Office investigation into questionable activities, including the ouster of career employees, unauthorized possession of a gun and shredding of documents.

GAO began its investigation of Rehnquist last November at the request of Sens. Charles Grassley (R-IA) and Max Baucus (D-MT), both concerned about widespread personnel changes at the OIG. Rehnquist, daughter of U.S. Chief Justice William Rehnquist, reportedly began replacing career employees with political appointees shortly after taking office in August 2001, in violation of federal personnel rules.

Among those replaced were four deputy inspectors general with extensive experience: Thomas Roslewicz, chief of audit services; George Grob, chief of program evaluation and inspections; Michael Mangano, the #2 official at the OIG; and D. McCarty Thornton, chief counsel since 1990. Altogether, there have been 19 senior staff changes, according to Grassley.

The GAO investigation has since broadened to include allegations that Rehnquist kept an unauthorized gun in her office. Several people who worked for Rehnquist have told investigators she kept an unloaded pistol in her office that she used for target practice. Rehnquist reportedly later replaced the handgun with a laser gun at the suggestion of another HHS official who gave her a poster of a "menacing man" to aim at.

GAO investigators are also looking into whether Rehnquist repeatedly delayed an audit of a Florida state government pension fund in the six months before Gov. Jeb Bush (R) was up for re-election.

In addition, they are investigating the alleged shredding of documents after the GAO inquiry began. In an early December letter to Grassley and Baucus, Rehnquist said she became aware of document destruction in her office in late November and ordered a halt to it.

**OIG Offers Caveat,** *from p. 2*

free services to the dollar limits in the advisory bulletin. The OIG did, however, specify that free local transportation may be provided only within the primary service area of the hospital or ambulatory surgical center. In addition, transportation costs may not be directly or indirectly submitted on federal healthcare program claims or cost reports, nor may the transportation include via ambulance.

**Resources**

- OIG Dec. 10 letter: *http://oig.hhs.gov/fraud/docs/alertsandbulletins/LocalTransportation.pdf*
- OIG special advisory bulletin, "Offering Gifts and Other Inducements to Beneficiaries": *http://oig.hhs.gov/fraud/docs/alertsandbulletins.SABGiftsandInducements.pdf*

### Final HIPAA Security Rule Delayed

A much-anticipated final rule designed to ensure the security of electronic healthcare transmissions subject to HIPAA (Health Insurance Portability & Accountability Act) has been delayed, and at press time no firm publication date has been set. Officials of the Centers for Medicare & Medicaid Services had promised to promulgate the rule by Dec. 27, 2002.

The Clinton Administration released a preliminary security rule on Aug. 12, 1998. Since then, CMS has set various target dates for publication of a final version, but has repeatedly failed to meet these deadlines.

Monetary constraints may be one reason CMS is reluctant to issue the final rule, says Ken Yale, vice president and director of consulting at EduNeering Inc., a consulting company active in HIPAA compliance. According to Yale, proposals for earmarking a portion of the CMS budget for fiscal 2004 to implement HIPAA electronic security requirements have been slashed from $20 million to $2 million, with $18 million diverted to homeland security.

# Dialysis Holdings Inc. Fined $4.1M For Unnecessary Blood Draws, Test Unbundling

Dialysis Holdings Inc., based in Lakewood, CO, has agreed to pay $4.1 million to settle charges that it defrauded Medicare through a joint venture laboratory arrangement involving unnecessary blood draws from terminally ill dialysis patients.

According to the U.S. attorney's office for the District of Massachusetts, Dialysis and its two predecessor companies (Vivra Inc. and Community Psychiatric Centers Inc.) entered into a deal with Damon Clinical Laboratories, formerly based in Needham, MA, to create a clinical laboratory in Smyrna, GA.

The companies defrauded Medicare by "regularly and unnecessarily drawing blood [from patients] with no medical justification whatsoever, and over the objections of their own medical staff, to create thousands of referrals of additional tests for which the dialysis companies expected profit," says U.S. attorney Michael Sullivan.

Damon and the dialysis companies split an automated chemistry panel of 19 blood tests into two separate tests run on blood draws taken on two separate days to avoid a Medicare reimbursement change designed to control laboratory costs for automated chemistry panel testing furnished to end-stage renal disease patients, the government alleges. "While all 19 tests had previously been performed on one blood draw and paid for as one test, the dialysis companies now split the panel in two, drawing blood a second time each month on these very sick patients for no purpose other than to increase the joint venture laboratory's profits," says Sullivan.

The government further alleges that the dialysis companies conspired with Damon to conduct medically unnecessary lab testing on dialysis patients by adding unnecessary lab tests to the weekly and monthly panels of tests offered to physicians.

Gambro Healthcare Inc. (Denver, CO) purchased the dialysis business of Vivra in July 1997 and renamed it Dialysis Holdings. Vivra's corporate predecessor, CPC, was purchased by Transitional Hospitals Corporation, which in March 2001 agreed to pay approximately $1.5 million as part of a bankruptcy settlement to resolve CPC's liabilities in connection with this misconduct. The recent $4.1 million settlement resolves the liability of the final corporate participant in the joint venture arrangement, according to Sullivan.

The former general manager of the joint venture lab, who filed suit on behalf of the government under whistleblower provisions of the federal False Claims Act, will receive $696,397 from the settlement.

**Dianon To Pay $4.8M,** *from p. 1*

Dianon's chief financial officer David Schreiber tells *GCR* that while company officials don't believe the company has done anything wrong, they believe a settlement is in its best interest and that of its shareholders. "We wanted to put this all behind us. The settlement amount represents a very small amount of our total Medicare billing." For the 12 months ended Sept. 30, 2002, Dianon had revenue of $182.1 million, about 44% of it from Medicare business.

The settlement is not expected to affect the sale of Dianon to Laboratory Corp. of America (Burlington, NC), Schreiber says. Dianon announced last November that it had reached a definitive agreement with LabCorp to sell for $47.50 per share in cash, or approximately $598 million. Dianon had already recorded a non-recurring charge of $5.5 million in the third quarter to cover the settlement. "LabCorp officials have known about this," Schreiber notes. "They were well aware of our discussions with the Justice Department."

McCallum says the settlement demonstrates the agency's continuing commitment to pursue vigorously allegations of fraud and abuse in Medicare and other federal healthcare programs. "Testing laboratories that charge for unnecessary tests will be held accountable for their billing practices," he cautions.

COMPLIANCE PERSPECTIVES

# FTC's Focus On Healthcare Providers: How *Not* To Become A Target

*David Marx Jr. is an antitrust attorney in the Chicago office of McDermott, Will & Emery*

The Federal Trade Commission (FTC) has a long history of investigating and challenging antitrust violations involving healthcare providers. In the mid-1970s, the FTC formed a division within its Bureau of Competition dedicated to ferreting out violations of federal antitrust laws involving healthcare; this unit—the Healthcare Services and Products Division—now has about 25 attorneys specializing in healthcare antitrust issues. It will be supplemented by the FTC's recently formed Merger Litigation Task Force, which is conducting a comprehensive review of several consummated hospital mergers to assess whether those transactions have been pro- or anti-competitive and also will be responsible for reviewing proposed mergers of hospitals or hospital systems in the future.

The FTC shares responsibility for enforcing federal antitrust laws with the Antitrust Division of the U.S. Department of Justice (*see box*). While only the FTC can enforce FTC Act Section 5, the Antitrust Division has exclusive responsibility for criminal enforcement (in rare cases, price-fixing by competing healthcare providers has been challenged as a criminal violation of Sherman Act Section 1). Over the past 25 years, the FTC and the Antitrust Division have instituted enforcement actions based on allegations that:

- Competing pharmaceutical companies have agreed not to compete to manufacture and sell the same products;
- Competing physicians, physician groups or hospitals have agreed on the fees they would charge, or other price-related terms on which they would contract with, payers;
- Competing healthcare providers have agreed to obstruct or boycott innovative forms of healthcare delivery or financing;
- Competing healthcare providers have agreed to restrain advertising or other forms of solicitation;
- Providers of healthcare products or services have engaged in illegal tying or exclusive dealing arrangements; and
- Members of a hospital's medical staff have conspired (sometimes with the hospital) to coerce the hospital to boycott competing providers.

The antitrust enforcement agencies also have successfully challenged mergers involving competing pharmaceutical companies, drug wholesalers, hospitals (general acute care as

## Federal Antitrust Laws

- Sherman Act Section 1 (15 U.S.C. § 1) prohibits agreements that *unreasonably* restrain competition, such as price-fixing, market allocations and boycotts by competitors.
- Sherman Act Section 2 (15 U.S.C. § 2) prohibits monopolization, attempts to monopolize, and conspiracies to monopolize.
- Clayton Act Section 2 (15 U.S.C. § 13) prohibits price discrimination in the sale of goods where the discrimination adversely affects competition.
- Clayton Act Section 3 (15 U.S.C. § 14) prohibits certain exclusive dealing arrangements, tying arrangements and requirements contracts in the sale of goods where the effect of those arrangements may be substantially to lessen competition.
- Clayton Act Section 7 (15 U.S.C. § 18) prohibits mergers or acquisitions whose effect may be substantially to lessen competition or tend to create a monopoly.
- Federal Trade Commission Act Section 5 (15 U.S.C. § 45) broadly prohibits unfair methods of competition in commerce. This provision has been held to embody the substantive provisions of the Sherman and Clayton Acts as well as practices that are contrary to the policy or spirit of those more-specific statutes.

well as psychiatric facilities), retail pharmacies, health insurers and outpatient surgery centers, where the transaction's effect would have been to lessen competition.

### Federal Guidance On Antitrust Compliance

The federal antitrust enforcement agencies appear to have singled out healthcare for special treatment. Besides having a dedicated "shop" within the Bureau of Competition (the Antitrust Division at Justice had its own Healthcare Task Force until last summer), in 1993 the FTC and the Antitrust Division jointly issued six statements of their antitrust enforcement policies regarding mergers and various joint activities in the healthcare arena. The agencies revised and expanded the original policy statements in 1994 and again in 1996. Today, the "Statements of Antitrust Enforcement Policy in Healthcare" address nine separate topics:

- Mergers Among Hospitals;
- Hospital Joint Ventures Involving High Technology or Other Expensive Healthcare Equipment;
- Hospital Joint Ventures Involving Specialized Clinical or Other Expensive Healthcare Services;
- Providers' Collective Provision of Non-Fee-Related Information to Purchasers of Healthcare Services;
- Providers' Collective Provision of Fee-Related Information to Purchasers of Healthcare Services;
- Provider Participation in Exchanges of Price and Cost Information;
- Joint Purchasing Arrangements Among Healthcare Providers;
- Physician Network Joint Ventures; and
- Multi-provider Networks.

Most of the policy enforcement statements include "antitrust safety zones," which describe conduct that the FTC and the Antitrust Division will not challenge under the antitrust laws, absent extraordinary circumstances. Additionally, the statements include many hypothetical examples illustrating their application to real-life situations and issues. Finally, both the FTC and the Antitrust Division have issued several staff advisory opinions and business review letters regarding specific proposed conduct by healthcare providers (*see box below*).

### Renewed Emphasis On Antitrust Enforcement

FTC chairman Tim Muris has repeatedly expressed his particular interest in ensuring that healthcare markets remain competitive because, in his view, "competitive markets systematically outperform all alternative forms of distribution." He believes that "[a]ggressive competition promotes lower prices, higher quality, greater innovation and enhanced access. More concretely, in healthcare, competition results in new and improved drugs, cheaper generic drugs, treatments with less pain and fewer side effects, and treatments offered in a manner and location consumers desire."

The FTC's focus on healthcare is based in part on a dramatic increase in healthcare insurance premiums, which suggest that managed care was not the panacea that many predicted it would be. Additionally, it appears that neither the FTC's prior enforcement initiatives nor the formal and informal guidance it has provided about its enforcement policies has deterred healthcare providers from continuing to engage in what Muris has characterized as "a wide variety of overt anti-competitive behavior, along with some new variants." Not surprisingly, the FTC's recent enforcement activity is intended to stop ongoing anti-competitive conduct and prevent it from occurring in the future.

### Physician Provider Network Cases

Within the past year, the FTC has settled cases with five different networks of competing physicians or physician groups accused of colluding to raise fees paid by healthcare insurers. Three of those cases involved physician provider networks located around Denver; one, a network of obstetricians/gynecologists in Napa Valley, CA; and one, a 1,200-

### Antitrust Reference Material Online

The Websites of the FTC and the Department of Justice's Antitrust Division are excellent sources of publicly available reference material.

- The FTC's Website, *http://www.ftc.gov/bc/healthindex.htm*, which is regularly updated, has a special section devoted to "Healthcare Antitrust Issues" with links to such documents as "Statements of Antitrust Enforcement Policy in Healthcare" and advisory opinions.
- The Antitrust Division's Website also has a special Healthcare Section, *http://www.usdoj.gov/atr/public/health_care/health_care.htm*, with links to healthcare case summaries, statements of policy and case filings.

### What Is "Financial Risk Sharing"?

The Statements of Antitrust Enforcement Policy in Healthcare discuss what it means for members of a provider network to share substantial financial risk and why it is important. According to the enforcement agencies, financial "[r]isk sharing provides incentives for the physicians to cooperate in controlling costs and improving quality by managing the provision of services by network physicians." Examples of arrangements through which participants in physician networks can *share substantial financial risk* are:

- An agreement by the network to provide services to a payer at a "capitated" rate;
- An agreement by the network to provide designated services or classes of services to a payer for a predetermined percentage of premium or revenue from the payer;
- Use by the network of significant financial incentives (such as fee withholds) for its physician participants, as a group, to achieve specified cost-containment goals; or
- An agreement by the network to provide a complex or extended course of treatment that requires substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the patient's condition; the choice, complexity or length of treatment; or other factors.

member network in the Dallas-Fort Worth area. The basic fact patterns in those cases were the same and, most troubling to the FTC, were remarkably similar to cases that had been resolved against other networks not more than a few years ago.

While certain facts are unique to each provider network case, the provider network or IPA that was the subject of the recent FTC complaints, whether single-specialty or a multi-specialty group:

- Included a majority, if not all, of the eligible providers in the affected market;
- Was formed mainly in response to the planned entry of managed care into the market;
- Entered into no payer contracts for which the network members shared "substantial financial risk" (*see box above*);
- Undertook no effort to "clinically integrate" the practices of its members (*see box, p. 8*);
- Purported to act as a messenger, but served instead as a facilitator for, and coordinator of, anti-competitive, collusive activities by network members;
- Became the *de facto* exclusive contracting network for its members; and
- Negotiated fees with payers.

In each case, the network's physician members refused to contract with payers independently of the network, thereby forcing payers to contract with the network at inflated reimbursement levels in order to develop a provider panel. In several of the cases, the network had retained and relied on a third-party consultant to assist with development and implementation of its payer-contracting strategy; that is, the consultant was an active participant in the network's anti-competitive conduct.

The relief typically sought by the FTC in cases involving provider networks is a "consent decree" that prohibits, on a prospective basis, the network and its member physicians and physician groups from entering into or facilitating any agreement:

- To negotiate physician services on behalf of any physicians with any payer or provider;
- To deal, refuse to deal, or threaten to refuse to deal with any payer or provider;
- Regarding any term on which any physicians deal, or are willing to deal, with any payer or provider;
- To restrict the ability, or facilitate the refusal, of any physician to deal with any payer or provider on an individual basis or through any other arrangement; or
- To convey to any payer or provider, through any competing physician or the network, any information concerning actual or potential dealings by any physician with any payer or provider.

Additionally, the FTC typically prohibits a provider network (and its members) that have engaged in anti-competitive conduct from exchanging, transferring or facilitating the exchange or transfer of information among member physicians concerning negotiation with any payer or provider regarding reimbursement terms or actual or contemplated intentions or decisions with respect to any terms, dealings or refusals to deal with any payer or provider. None of the FTC's enforcement actions have sought monetary relief or damages from the offending provider network or its members.

The FTC currently has several ongoing investigations of provider networks. Because physicians' fees represent a significant part of any payer's costs, the agency is likely to continue to pursue cases where competing providers are collectively negotiating fees

with payers through networks that are neither financially nor clinically integrated.

### Cases Involving Hospital Mergers

The FTC's Merger Litigation Task Force was developed, in part, to engage in a "retrospective study" to evaluate the competitive effects of consummated hospital mergers. The task force initiated investigations of mergers involving hospitals in several different geographic areas. Among the transactions presently known to be under review are: the merger of Doctors Regional Medical Center and Lucy Lee Hospital, in Poplar Bluff, MO; Evanston Hospital's acquisition of Highland Park Hospital, near Chicago, IL; and the combination of Victory Memorial Hospital and Provena St. Therese Medical Center into Vista Health, in Waukegan, IL. (These are not the only deals under re-review; they are the only ones that have been publicly acknowledged and confirmed by the FTC.) Ironically, the FTC challenged the Poplar Bluff transaction as a violation of Clayton Act Section 7 and succeeded in obtaining a preliminary injunction preventing consummation of the transaction, only to have the Eighth Circuit Court of Appeals reverse the district court's opinion and allow the transaction to proceed.

### What Is "Clinical Integration?"

The concept of *clinical integration* (which does *not* involve the sharing of substantial financial risk) is more subjective. The policy enforcement statements describe it as "sufficient integration to demonstrate that the network is likely to produce significant efficiencies. Such integration can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and to create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of healthcare services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies."

In February 2002, the FTC issued the only staff advisory opinion approving a physician network's proposal to clinically, but not financially, integrate its member physicians' practices and to enter into contracts with payers for the sale of the network's physicians' services to payers on a fee-for-service basis. The proposal by MedSouth Inc.—a 400-physician, multi-specialty independent practice association outside Denver—contained several features designed to result in lower costs, higher quality and more efficient delivery of physician care.

The FTC is conducting its hospital merger retrospective just like it would investigate any proposed merger of competing hospitals. It has issued comprehensive document and data requests to the merging hospitals and their competitors. The FTC has deposed current and former senior-level managers of the competing hospitals and interviewed executives of their competitors as well as representatives of the payers that might have been affected by the transaction. The agency is attempting to verify and quantify any pro-competitive cost-savings or efficiencies that the hospitals would have achieved from their merger. Finally, the FTC is closely scrutinizing how the hospitals' prices and pricing policies changed following consummation of the transaction.

The FTC hopes to complete and announce the results of its hospital merger retrospective by early 2003. At a minimum, the agency expects to obtain useful real-world information about the competitive effects of consummated hospital mergers in several different markets, each with its own set of competitive characteristics. This should enable the FTC to update its prior assumptions about the consequences of particular transactions and the nature of competitive forces in healthcare, and serve as a basis for future merger enforcement. If the FTC finds that a consummated hospital merger has had anti-competitive effects, it may pursue administrative litigation to address the issue.

### Conclusion

At its healthcare workshop in September 2002, the FTC stated its intent to focus on price-fixing among providers and hospital mergers. In conjunction with the Antitrust Division, it plans to conduct additional hearings on healthcare competition law and policy in February 2003. The topics are expected to include issues such as hospital mergers, the significance of a hospital's non-profit status, quality and efficiency, and the adequacy of existing remedies for anti-competitive conduct. That the federal antitrust enforcement agencies are holding a second set of hearings so soon after the September workshop signals their intent to vigorously scrutinize competition in the healthcare field.

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# Stark Compensation Delay May Indicate Second-Thoughts

A decision by the Centers for Medicare & Medicaid Services to delay the effective date of the Stark physician self-referral law's controversial "percentage compensation" provision could be a sign that the agency may ultimately rescind the provision altogether, according to Charles Oppenheim, a healthcare attorney with Foley & Lardner (Los Angeles, CA).

CMS announced Nov. 22, 2002, that it was delaying until July 7, 2003, the effective date of the provision stating that percentage compensation does not qualify as "set in advance" for purposes of the Stark statute.

This is important, Oppenheim notes, because a number of key Stark exceptions permit compensation arrangements only if, among other things, compensation is "set in advance." For example, the "personal services" exception (which allows certain personal services arrangements) and the "fair market value" exception (which allows certain arrangements for the provision of items or services at fair market value) both require that compensation be set in advance.

The Stark law prohibits physicians from referring Medicare patients for certain "designated health services" to entities with which the physician (or an immediate family member) has a financial relationship by either an ownership interest or a compensation arrangement, unless an exception applies. The "designated health services" include, among other things, clinical laboratory, radiology, physical and occupational therapy, home health and all inpatient/outpatient hospital services.

In the final Phase I Stark regulations issued Jan. 4, 2001, CMS concluded that percentage compensation arrangements did not qualify as compensation set in advance. This interpretation was widely criticized, Oppenheim says, especially because CMS considers per-unit and per-service payments to be set in advance if the amount per unit or service is established ahead of time.

"It seems incongruous to disallow percentage compensation, given that both percentage compensation and per-service compensation arrangements establish a method, in advance, that renders certain the calculations of actual compensation, even though the aggregate dollar amount is not known prospectively," he asserts.

> ***Given this rationale, and the fact that CMS has now twice delayed the effective date of this interpretation, it seems that CMS may recant its prior interpretation altogether when it publishes Phase II Stark regulations***
>
> ***— Charles Oppenheim***

This is the second time CMS has delayed the percentage compensation provision. In Dec. 2001, it postponed the effective date until Jan. 6, 2003 (*GCR, Jan. 02, p. 2*). Agency officials say they are extending the delay until at least July 7, 2003, to avoid disruptions since hospitals, physician group practices, academic medical centers and medical foundations commonly use percentage compensation arrangements with physicians.

"Given this rationale, and the fact that CMS has now twice delayed the effective date of this interpretation, it seems that CMS may well recant its prior interpretation altogether when it publishes Phase II Stark regulations, and clarify once and for all that percentage compensation can be considered set in advance under the Stark law," Oppenheim says. The agency is expected to issue final Phase II Stark regulations on or before July 7, 2003.

**Resources**

- Charles Oppenheim: 310-277-2223
- *Federal Register*, Nov. 22, 2002: *www.access.gpo.gov/su_docs*.

*Jeffrey Boothe*

**HIPAA Privacy Rule,** *from p. 1*

"Hopefully, this puts to rest efforts by hospitals and other independent labs to make reference labs business associates," attorney Jeffrey Boothe, a partner with Holland & Knight (Washington, DC), tells *G-2 Compliance Report (GCR)*. "This is a clear statement by HHS that the labs to which hospitals and independent labs refer are themselves covered entities."

The medical privacy rule, mandated by the Health Insurance Portability & Accountability Act of 1996, goes into effect on Apr. 14, 2003, for most healthcare providers, health plans and healthcare clearinghouses that conduct certain healthcare transactions electronically (small health plans have an additional year to comply). HHS published the final privacy rule on Dec. 28, 2000, and adopted modifications to it on Aug. 14, 2002 (*GCR, Sept. 02, p. 1*).

### Workforce Issues

The guidance from OCR addresses a number of workforce issues, including public health and workmen's compensation and the relationship between covered entities and workers under direct control of the entity, such as janitors, plumbers, etc.

According to OCR, permission is not required for entities to notify public health officials of the occurrence of a reportable disease. Such notification is, in some degree, required by all states. "This provision is intended to allow covered entities to continue current voluntary reporting practices that are critically important to public health and safety," the guidance says. In addition, workers do not have the right to request that covered entities restrict a disclosure of personal health information when the law requires disclosure, such as under workmen's compensation laws.

The new guidance also makes clear that a business associate contract is not required with people or organizations whose functions, activities or services do not involve use or disclosure of protected health information, such as janitors, plumbers, electricians and photocopy repair technicians. Organizations that merely transport protected health information, such the Postal Service, UPS or other delivery or courier services, also would not be considered business associates under the privacy rule.

If a service is hired to do work for a covered entity where disclosure of protected health information is not limited in nature—such as routine handling of records or shredding of documents containing protected health information—that service likely would be a business associate. However, when such work is performed under the direct control of the covered entity (on its premises, for example), the privacy rule permits the covered entity to treat the service as part of the workforce, so a business associate contract would not be required, OCR declares.

"This is something that had caused a lot of confusion," Boothe says. "[The guidance] makes clear that the function of an outside entity in performing a service is important in determining whether it's a business associate or not."

### Resources

- Jeffrey Boothe: 202-828-1896
- Privacy rule guidance from OCR: *www.hhs.gov/ocr/hipaa* (under "What's New")

## CMS Extends Pathology TC Billing Protection

The Centers for Medicare & Medicaid Services has extended—for the time being—the "grandfather" provision that allows an independent laboratory to bill Medicare directly for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients if the hospital used an independent lab for these services as of July 22, 1999. The provision was set to expire Dec. 31, 2002. The extension was announced in a Dec. 10, 2002 CMS transmittal (AB-01-47).

In 1999, CMS had proposed to end such arrangements and instead require these labs to seek TC reimbursement from the hospital. Congress intervened in 2000 to stop CMS from going ahead, enacted the "grandfather" provision and called for a study on whether to make the reprieve permanent and whether to expand it to other hospitals.

To qualify for the "grandfather" protection, CMS has stipulated that the lab must forward to its carrier(s) a copy of the hospital/lab agreement in effect as of July 22, 1999, or other documentation. The agency also has clarified that the "grandfather" provision applies to the hospital, not the independent lab; that is, a covered hospital may switch inpatient/outpatient referrals to another lab, but not vice versa.

The latest extension will give the General Accounting Office time to complete the study and will give Congress time to consider making the provision permanent.

Transmittal AB-02-177 is online at *http://cms.hhs.gov/manuals/pm_trans/a02177.pdf*.

# CMS Cracks Down On Hospital Billing Practices

*"We will carefully scrutinize any billing trends or other indications of inappropriate reimbursement," CMS administrator Thomas Scully said in a statement*

Concerned that some hospitals may have unusually high numbers of Medicare outlier payments, the Centers for Medicare & Medicaid Services has directed fiscal intermediaries (FIs) to carefully scrutinize hospital billing practices.

In a Dec. 3 program memo (Transmittal A-02-122), CMS said that analysis of hospital charges since 1999 reveals that some have increased at a much higher rate than the national average, which could indicate that "some hospitals may be attempting to 'game' current payment systems." The agency instructed FIs to begin data analysis to identify high outlier payments and find hospitals that will be subject to further compliance review.

The action is being taken, in part, in response to allegations that hospitals—notably 24 Tenet Healthcare Corp. facilities—have received higher than usual outlier payments from Medicare over the past several years. Tenet has disclosed that the Department of Health & Human Services has requested an audit of the company's outlier payments. Tenet received $763 million in outlier payments in fiscal 2002 and expects to receive $750 million in 2003, according to company officials.

Outlier payments are made for patients with higher-than-average costs. CMS sets the threshold each year at an amount that is projected to generate outlier payments equal to 5.1% of total inpatient prospective payment. The outlier threshold was set at $33,560 per case in 2003, up from $21,025 the previous year.

CMS plans to revise outlier policy to limit inappropriate billing by hospitals and expects to announce further action against hospitals that may be abusing the outlier system. These actions may include on-site visits, reviews of hospital charging data, audits of cost-reimbursed expenses and reviews of inpatient/outpatient outlier stays and services and non-outlier stays and services, according to the program memo.

### Resource

- Transmittal A-02-122: *http://cms.hhs.gov/manuals/pm_trans/a02122.pdf*

## Standardized ABNs Mandatory, Starting Jan. 1


Starting Jan. 1, 2003, Medicare will accept as valid Advance Beneficiary Notices (ABNs) only the single-page, standardized formats that cleared government channels last year. The start date for mandatory use had been last Oct. 1, but the Centers for Medicare & Medicaid Services bumped it up three months. Formal notice of the date change is made in CMS Program Memo AB-02-168 (Nov. 22, 2002). "The memo applies to Part B physicians, practitioners and suppliers and to Part A providers, so the mandatory date for using the new ABN forms is the same for all," according to a CMS official.

For laboratory services, you may use either the general ABN form (CMS-131-G) or the lab-specific ABN (CMS-131-L).

Meantime, CMS says Medicare fiscal intermediaries should be able to process billings involving ABNs beginning in January 2003. Unexpected systems problems have plagued ABN-related billings over the past few months, with many providers complaining about rejections. CMS recently asked FIs to tell providers to hold billings involving ABNs until system changes involving occurrence code 32 go into effect Jan. 1. These changes are detailed in CMS Transmittal A-02-177 (Nov. 1, 2002). Use of occurrence code 32 on a claim indicates that an ABN was given to a beneficiary.

The transmittal reminds providers to submit separate claims for services requiring an ABN and services not requiring one. "If the time periods cannot be separated (*i.e.,* a service requiring an ABN is given on the same day as a service not requiring an ABN), a single claim must be submitted, just for the overlapping period, using occurrence code 32, showing all services as covered and placing modifier GA on the HCPCS code to identify the service (revenue code) line for which the ABN was given. Since this is an exception process, providers are reminded to use this mechanism only when it is impossible to separate the billing periods."

To access the above transmittals, go to *http://cms.hhs.gov/manuals/memos* . The ABN forms are found at *http://cms.hhs.gov/medicare/bni.*

*As expected, Medicare payment for physician services will be reduced an average 4.4% in 2003. The effective date is Mar. 1, the Centers for Medicare & Medicaid Services has announced. Services provided on or after Jan. 1 and before Mar. 1 will be paid under the 2002 physician fee schedule. The final physician fee schedule rule is to be published in the Dec. 31 Federal Register. Pathology and other physician groups are looking to the new 108th Congress for relief from the fee cut.*

**CARDIAC DEVICE COMPLAINTS:** The Justice Department has filed complaints against 27 hospitals accused of submitting false claims to Medicare. The lawsuits, which stem from a whistleblower suit filed by former medical device salesman Kevin Cousins, allege that the hospitals falsely charged for millions of dollars worth of procedures involving experimental cardiac devices that were not properly reimbursable. The most recent interventions bring to 40 the number of hospitals being actively pursued in these related cases. Justice previously settled with 31 hospitals for a total of about $42 million and is finalizing settlements with two other hospitals.

**OIG SEEKS INPUT:** The HHS Office of Inspector General is seeking recommendations on development of proposed or modified safe harbors and new special fraud alerts under the anti-kickback statute. The OIG also is soliciting input on development of guidance addressing hospital credentialing practices. In a separate Dec. 9 notice, the OIG asked for comments on developing exceptions to the civil money penalty prohibition on inducements offered to Medicare and Medicaid beneficiaries to influence their selection of a provider. The notices, published in the *Federal Register*, are posted at *www.access.gpo.gov/su_docs.*

**LAB SELECT AGENTS PROGRAM EXPANDED:** The Centers for Disease Control & Prevention issued a rule on Dec. 13 that widens the reach of its "select agents" program, in accord with recently enacted anti-bioterrorism legislation. The interim final rule requires facilities to register with CDC if they possess an agent or toxin that appears on a CDC list of agents and toxins deemed dangerous to public health. The rule, which will affect clinical and diagnostic laboratories, academic institutions, biomedical centers, pharmaceutical companies and research facilities, is online at *www.cdc.gov/od/sap*.

**OIG SAVES $21 BILLION:** The HHS Office of Inspector General "saved" federal healthcare programs a record $21 billion through its healthcare fraud program in fiscal 2002, the agency claimed in its semi-annual report to Congress, issued Dec. 11. The $21 billion is $3 billion more than was saved in FY 2001 and $13.5 billion more than was saved in FY 1997 when Congress significantly expanded the authority and financial resources of federal agencies to combat healthcare fraud. The savings in FY 2002 included $19.9 billion from recommendations made to improve efficiencies and reduced costs, $1.49 billion in investigative receivables and $426 million in audit disallowances. To access the OIG report, go to *www.oig.hhs.gov/publications/semiannual. html.*





G-2 Compliance Report (ISSN 1524-0304). © 2002 Washington G-2 Reports, 1111 14th St, NW, Suite 500, Washington DC 20005-5663.
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