



# G-2

# Compliance Report



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For Hospitals, Laboratories and Physician Practices

## Ready For HIPAA Privacy “Prime Time”? Final Compliance Readiness Review Advised

**W**ith the HIPAA medical privacy rule slated to take effect this month for most healthcare providers, health plans and health data clearinghouses, experts say you should undertake an 11<sup>th</sup>-hour review of your policies and procedures to ensure that you’re ready to comply with the new requirements.

In accord with regulations promulgated under HIPAA (Health Insurance Portability & Accountability Act of 1996), covered entities must take specific steps to protect individually identifiable health information. The new requirements—detailed in a final rule published Dec. 28, 2000, and modified on Aug. 14, 2002—go into effect this Apr. 14 for most covered entities that conduct certain healthcare transactions electronically (small health plans have an additional year to comply).

HIPAA experts who spoke at Washington G-2 Reports’ Compliance & Policy Forum, held Mar. 20-21 in Tampa, FL, suggest that covered entities double-check the following areas. → p. 10

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## IG Resignation May Spell Tougher Times Sen. Grassley Seeks “Bulldog” To Fill Post

**T**he resignation of HHS Inspector General Janet Rehnquist, effective June 1, could lead to increased investigations of healthcare providers and more aggressive enforcement, some experts believe.

Rehnquist, who has been the focus of a General Accounting Office probe into her conduct, submitted her resignation in a Mar. 4 letter to President Bush, saying she is leaving to spend more time with her teenage daughters and to pursue other professional opportunities.

Washington insiders believe she opted to resign rather than face possible removal from office. Sen. Charles Grassley (R-IA), the Finance Committee chairman who first requested the GAO investigation, had planned to call for her resignation the week of Mar. 10.

Grassley and other lawmakers have questioned a number of Rehnquist’s actions since her appointment as IG in August 2001, including replacing 19 experienced managers, unauthorized possession of a gun in her office and a request to delay a federal audit of the Florida state employees pension fund. Critics charged that the delay ensured that the audit would not be released before election day last fall, potentially helping Jeb Bush, the President’s brother, who was facing a tight race for re-election as governor (*GCR, Jan. 03, p. 3*). → p. 2

*For The Last Word In Healthcare Compliance*



Janet Rehnquist

### IG Resignation, from p. 1

“This is the right step,” Grassley said in a statement responding to Rehnquist’s announced departure. “The Inspector General job wasn’t a good fit for her abilities. It’s very important that we get a bulldog for the taxpayers on the job.” Rep. Fortney “Pete” Stark (CA), the ranking Democrat on the House Ways & Means health subcommittee, was equally as blunt, asking the White House to accelerate the effective date of her departure. “There is no need to prolong the damage she has caused in real and perceived terms for an additional three months,” he said in a Mar. 7 letter to the President, adding that he believes Rehnquist’s tenure has sullied the OIG’s reputation. Stark asked the White House to appoint a current or former career professional from within the OIG as acting Inspector General.

While the White House has not yet indicated who it intends to nominate to succeed Rehnquist, Dennis Duquette, the deputy IG for the Office of Audit Services, could be tapped for the position, at least in the interim, according to an OIG spokesperson. Normally the IG’s principal deputy would be next in line, but that position has been vacant since Michael Mangano left last year. Mangano was one of a number of senior staff who resigned during Rehnquist’s tenure.

### Tougher Stance Predicted

Attorney Stuart Gerson, a partner with Epstein, Becker & Green, PC (Washington, DC) and former acting U.S. Attorney General during the early months of the Clinton Administration, believes Rehnquist was

forced out because several key lawmakers viewed her as too lenient in enforcing healthcare fraud and abuse violations. The next IG, he believes, will feel pressure to be tougher.

“[Rehnquist’s] successor will largely be co-opted by the Congress, and by Senator Grassley in particular,” Gerson predicted during the Compliance & Policy Forum, sponsored by Washington G-2 Reports on Mar. 20-21 in Tampa, FL. “No Rehnquist agenda item is going to be abandoned, but there’s going to be an intensifying focus on those things. If you’re in a case and you expected to get out of having a corporate integrity agreement, forget about it.”

Attorney Kirk Nahra, a partner with Wiley, Rein & Fielding (Washington, DC), agrees that Rehnquist may have been seen as too accommodating in her dealings with healthcare entities, but he cautions that providers should not jump to any conclusions about what her resignation will mean for them.

“If I’m a provider who’s nervous about an investigation, I wouldn’t look at this as either a good thing or a bad thing,” he tells *GCR*. “[The White House] could replace her with someone who’s weaker, with someone who’s tougher or with someone who has exactly the same views. Still, that person is likely to be more effective because [he or she] won’t have all the rest of the baggage.”

### Resources

- ❖ Stuart Gerson: 202-861-4180
- ❖ Kirk Nahra: 202-719-7335 🏠

## Justice Directive May Expose Providers To Increased Risk

**A** recent directive from Deputy U.S. Attorney General Larry Thompson could have a chilling effect on attorney-client privilege, exposing healthcare providers to increased legal risk, warns attorney Stuart Gerson, a partner with Epstein, Becker & Green, PC (Washington, DC) and former acting U.S. Attorney General during the Clinton Administration.

Thompson issued a memorandum in early February designed to strengthen the Justice

Department’s efforts to combat fraud, particularly in healthcare, Gerson explained during Washington G-2 Reports’ Compliance & Policy Forum, held Mar. 20-21 in Tampa, FL. The memo, “Principles of Federal Prosecution,” places increased emphasis on cooperation with government investigators as a mitigating factor in enforcement.

“The authenticity of the cooperation is key, and the measure of authenticity, at least according to the government, increasingly in-

volves the waiver of attorney-client privilege,” Gerson said. By waiving privilege, healthcare providers, in effect, expose employees and company officers to greater liability. “They’re left to fend for themselves.”

While waiver of privilege could—at least in theory—benefit providers involved in a government investigation, it can actually lead to increased civil action, he noted. “There’s no such thing as a partial waiver. Once you waive privilege, you waive it for the world, so that if you give the government access to your documents and information, private parties are going to claim you have to give it to them too. It means there is then a wider array of

information available for people to develop new cases.”

Ironically, the Justice Department directive could have the unintended effect of undermining one of the core concepts of compliance—namely, protecting the confidentiality of employees who bring complaints or alert executive management to potential problems. “Confidentiality will be harder and harder to maintain,” Gerson cautioned. “This will make your job [as a compliance officer] more difficult. It will also make it more important.”

#### Resource

❖ Stuart Gerson: 202-861-4180 🏠

## CMS Targets Perceived Abuse Of Hospital Outlier Payments

**C**oncerned about what it calls “gaming” of the Medicare payment system, the Centers for Medicare & Medicaid Services is proposing to change the way it reimburses hospitals for outlier payments. In a proposed rule in the Mar. 5 *Federal Register*, CMS said it wants to make three major changes in how outlier payments are calculated:

- ❖ Allow Medicare to use more recent data.
- ❖ Eliminate use of a statewide average ratio of costs-to-charges for hospitals with very low computed cost-to-charge ratios.
- ❖ Allow Medicare to recover overpayments if the actual costs of a case, as reflected in the settled cost report, are less than the provider had claimed. Overpayment recoveries would be subject to an adjustment to account for the value of the money during the time it was inappropriately held by the hospital.

Outlier payments are made for patients with higher-than-average costs. Hospitals get these additional payments if the costs of an individual case exceed the Medicare payment rate by a specific threshold. CMS sets the threshold each year so that outlier payments make up around 5.1% of total inpatient payments. In recent years,

however, outlier spending has far exceeded the target amount.

As outlier claims increased, the outlier threshold has gone up sharply, from \$14,050 in fiscal 2000 to \$33,560 in fiscal 2003. As a result, says CMS, more hospitals have had to absorb the costs of complex cases, while a relatively small number of hospitals have been aggressively taking advantage of the current rules.

“The new policy will achieve a balance between paying hospitals fairly for high-cost cases and limiting outlier payments to the 5%-6% of total inpatient spending that Congress mandated,” says CMS chief Tom Scully. “We anticipate that the changes we are [proposing] will stop, and likely reverse, the recent trend toward a rapid upward spiral in the threshold for eligibility for outlier payments. As a result, we believe more hospitals will appropriately receive higher payments in the future.”

The redistribution of money anticipated may be quite dramatic, CMS believes. The agency has identified 123 hospitals that appear to have been most aggressively gaming the current system. On average, current outlier payments for these hospitals comprise 24% of their total DRG payments.

#### Resource

❖ Proposed rule on outlier payments: *Federal Register* (Mar. 5, 2003), [www.access.gpo.gov/su\\_docs](http://www.access.gpo.gov/su_docs) 🏠

*CMS revved up its review of hospital outlier payments last December. The new scrutiny was due, in part, to allegations that hospitals—notably 24 Tenet Healthcare Corp. facilities—received unusually high outlier payments in the past several years. For compliance tips to hospitals on reviewing their charge policies in light of the current crackdown, see G-2 Compliance Report, Feb. 03, p. 1*

## New Microbiology QC Testing Requirements Under CLIA Result Is Mixed Bag For Specialty, Subspecialty Labs

**N**ew CLIA quality system changes that take effect this Apr. 24 are expected to result in cost-savings for some laboratories performing specialty and subspecialty tests, while others will see higher costs related to quality control testing.

Under changes made in the QC revised final rule, published Jan. 24 in accord with CLIA (Clinical Laboratory Improvement Amendments), the required frequency for reagent QC for several bacteriology tests and two mycology tests is reduced (*see chart*). At the same time, some requirements for mycobacteriology QC are increased. The Centers for Medicare & Medicaid Services says it made these changes in response to public comments and recommendations from the American Society for Microbiology.

CMS estimates that total cost-savings for each microbiology laboratory performing bacteriology testing would be \$2,274 in the first year; for mycology testing, \$153. Mycobacteriology labs, meanwhile, will likely incur increased QC costs. CMS estimates that the cost of performing additional acid-fast and/or fluoro-chrome stains could be as much as \$1,501 per lab per year, while the cost of performing additional organism identification tests could be as much as \$2,752 per lab.

Physician office labs that collect specimens and send them to reference labs are not required to perform the reagent QC testing, but must ensure that the media are viable before taking a specimen, says Cecelia Hinkel, a specialist in CMS's division of laboratory services. The lab certified in bacteriology is responsible for the actual QC testing, Hinkel explained during Washington G-2 Reports' Compliance & Policy Forum, held March 20-21 in Tampa, FL.

CMS will give labs a full survey cycle to come into compliance with the revised CLIA QC requirements. While surveyors may cite a lab for a deficiency under the recently finalized rule, the agency will not take any enforcement action but instead will provide education and technical assistance, say CMS officials.

### Resources

- ❖ Revised CLIA QC rule: *Federal Register* (Jan. 24, 2003), [www.access.gpo.gov/su\\_docs](http://www.access.gpo.gov/su_docs). The rule and additional information also are available at [www.cms/hhs.gov/clia](http://www.cms/hhs.gov/clia)
- ❖ Cecelia Hinkel: 410-786-3531 🏠

### Changes To Microbiology QC Requirements

Old Regulations	New Regulations
<b>BACTERIOLOGY</b>	
- Each day of use, check catalase, coagulase, beta-lactamase and oxidase reagents and DNA probes using a positive and negative control.	(NC) Each day of use, check beta-lactamase (other than cefinase (D)) and DNA probes using a positive and negative control.
- Each week of use, check bacitracin, optochin, ONPG, X and V disks or strips using a positive and negative control.	(D) Check each batch, lot number and shipment of reagents (catalase, coagulase and oxidase), disks (bacitracin, optochin, ONPG, X, V and XV), stains, antisera and identification systems for positive and negative reactivity and graded reactivity, if applicable.
- Each month of use, check antisera using a positive and negative control.	(D) Check each batch, lot number and shipment of antisera when prepared or opened and once every six months thereafter using a positive and negative control.
<b>MYCOBACTERIOLOGY</b>	
- Each day of use, check iron uptake test using a positive and negative acid-fast organism and check all other reagents or test procedures using a positive acid-fast organism.	(I) Each day of use, check all mycobacteriology reagents (NC - iron uptake test) using a positive and negative acid-fast organism.
- Each week of use, check acid-fast stains using a positive control.	(I) Each day of use, check acid-fast stains using a positive and negative control.
- Each week of use, check fluoro-chrome acid-fast stains using positive and negative controls.	(I) Each time of use, check fluoro-chrome stains using positive and negative controls.
<b>MYCOLOGY</b>	
- Each day of use, test staining materials (lactophenol cotton blue) for intended reactivity.	(D) Check each batch, lot number and shipment of lactophenol cotton blue when prepared or opened for intended reactivity.
- Each week of use, check biochemical tests and mycological identification tests (germ tube) with a positive control.	(D) Check each batch, lot number and shipment of reagents, disks, stains, antisera and identification systems for positive and negative reactivity.

Source: *Federal Register*, Jan. 24, 2003. D = Decreased QC testing. I = Increased QC testing. NC = No change.

# COMPLIANCE PERSPECTIVES

## Don't Overlook Compliance Risks In Basic Hospital-Physician Ties Q&As For Everyday Transactions



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**I**n the face of steadily expanding healthcare regulations, more frequent government advisory opinions and other pronouncements, and almost daily headlines about new governmental investigations and settlements involving alleged healthcare fraud, it may be time for hospitals and physicians to reassess their compliance activities in several key areas.

Despite the current industry focus on joint ventures and other strategies for jointly delivering services using state-of-the-art technology, it's important not to forget that more mundane, day-to-day arrangements can also create compliance risks. In fact, because these arrangements are so routine, they should not be overlooked when it comes to the details of compliance.

This article answers some basic regulatory questions applicable to certain "day-to-day" arrangements—namely, medical directorships and space/equipment leases—and offers some compliance tips for these arrangements.

**Q** What is the Stark law?

**A** Effective January 1992, the Stark law originally prohibited physicians from referring Medicare patients for clinical laboratory services to an entity with which the physician (or an immediate family member) had a financial relationship (ownership interest or compensation arrangement), absent a specific statutory exception. In 1993, the Stark law was amended to extend beyond clinical laboratory services to an expanded list of "designated health services" (DHS), including those covered by Medicaid. These amendments, popularly known as Stark II, were effective January 1995.

For purposes of this article, it's important to know that hospital inpatient and outpatient

services are DHS subject to the Stark statute. This means that, to avoid violating the statute, medical director arrangements and space/equipment leases between physicians and hospitals (or any other entity that furnishes DHS) must be structured to meet a Stark exception. In fact, any arrangement between a hospital and a physician (or physician group) is subject to the Stark law, even if the arrangement itself does not directly involve any DHS.

Separately, the Stark law also applies to physician ownership arrangements with entities that furnish DHS (an area not discussed in detail here). There also are self-referral laws in some states that need to be considered when structuring these arrangements.

**Q** Is the anti-kickback statute the same as the Stark law?

**A** No. These two laws are separate and require separate compliance analyses. The anti-kickback statute provides for criminal and civil penalties for individuals (or entities) that "knowingly and willfully" offer, pay, solicit or receive remuneration to induce business for which payment may be made under a federal healthcare program. Remuneration is defined broadly and is prohibited whether made directly or indirectly, in cash or in kind.

There are statutory and regulatory exceptions to the anti-kickback statute, known as "safe harbors," that describe certain financial arrangements that fall outside the broad reach of the statute. The protection afforded by the safe harbors is limited to certain circumstances, however. Not all arrangements subject to the anti-kickback statute may meet all the requirements necessary to fit within a safe harbor. But that doesn't necessarily mean that the arrangement is illegal. Instead, because the statute itself describes the scope of illegal

activities, the legality of a particular business arrangement will be determined by assessing the particular facts in relation to what the statute proscribes.

Parties to an arrangement may request an advisory opinion from the HHS Office of Inspector General as to whether their arrangement violates the anti-kickback statute. The OIG also publishes guidance, both for internal use and for public dissemination, describing certain conduct that the OIG views as suspect or impermissible. State anti-kickback provisions, while not specifically addressed in this article, should

also be considered when determining whether arrangements are legal.

**Q** *Does compliance with the Stark law ensure compliance with the anti-kickback statute?*

**A** No. As noted before, the two laws are different. One key difference is that the anti-kickback statute is an intent-based statute, while the Stark law generally is not. Another difference is that compliance with a safe harbor under the anti-kickback statute is, in some respects, voluntary, and not all arrangements falling outside a safe harbor are illegal. Under the Stark law in contrast, an arrangement must meet a Stark exception in order to avoid violating the statute.

There also are some differences between the two laws in the specific requirements for personal service contracts and for space and equipment leases. For example, the anti-kickback statute requires that “aggregate compensation” for a personal service arrangement, or the “aggregate rental charge” for a space or equipment lease, be set in advance. The Stark law also requires that the “compensation” or “rental charge” be set in advance, but does not specifically require that such amounts be set in the “aggregate” at the inception of the arrangement. The Stark II final regulations make clear, however, that if the aggregate compensation is not fixed, the amount of payment based on “per use” or “per time period” must be fixed in advance.

**Q** *What are the requirements under the Stark law and the anti-kickback statute for medical directorship arrangements and for space/*

*equipment leases?*

**A** The Stark law includes exceptions for personal service arrangements and fair market value arrangements, which can protect medical director arrangements, as well as for space and equipment leases. There also are final as well as proposed Stark regulations relevant to these arrangements. While certain general Stark law requirements apply to all of these arrangements, there also are specific requirements unique to each kind of arrangement.

In general, to comply with the Stark law, an arrangement:

- ❖ Must be reflected in a written agreement signed by the parties;
- ❖ Cover a term of at least one year; and
- ❖ The compensation or lease rate to be paid under the arrangement must reflect fair market value and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

For medical director arrangements to meet the Stark personal services exception, the arrangement also must:

- ❖ Specify the services to be provided;
- ❖ Cover all the services to be provided;
- ❖ Not exceed services that are reasonable and necessary for legitimate business purposes; and
- ❖ Not involve counseling, promotion or other activities that violate state or federal law. Medical director compensation based on a fixed annual salary would need to state the annual salary. Arrangements using formulae other than aggregate annual salary, such as hourly or other unit-of-service rates, would have to include in the contract the per-unit amount to be paid.

Arrangements that include percentage compensation are subject to more complex Stark law analysis. The Stark II final regulations as first published included a general rule that compensation arrangements based on a percentage methodology would not satisfy Stark law requirements for being “set in advance” if the percentage were based on “fluctuating” or “indeterminate” measures, such as percent of revenue, collections or expenses. However, the effective date of this provision has been delayed until July 7, 2003, pending the government’s further analysis and review of public comments on this issue.

**OIG advisory opinions and fraud alerts are useful in helping parties identify areas that the OIG believes are risk areas for compliance (see <http://oig.hhs.gov/authorities/docs/frfinal.pdf>)**

Another possible way to protect medical director arrangements under the Stark law is to use the regulatory exception granted for fair market value arrangements. However, among the requirements for this exception are the following: the arrangement must fit within a safe harbor under the anti-kickback statute and be approved by the OIG via a favorable advisory opinion. These issues are discussed in detail later.

For space and equipment leases, the Stark law exception includes additional specific requirements:

- ❖ The rental charges for the term of the arrangement must be set in advance.
- ❖ The amount of space or equipment leased must be reasonable and necessary for legitimate business purposes and reflect terms that are commercially reasonable even if no referrals are made between the parties.
- ❖ Except for common space, the space or equipment leased must be used exclusively by the lessee during the lease period. Space lease rental amounts may include payments for common area space, generally as long as the amount does not exceed the lessee's pro-rata share of expenses for the common area.

Like the exceptions under the Stark law, the anti-kickback safe harbors applicable to medical director arrangements and to space and equipment leases require that such arrangements:

- ❖ Be reflected in written agreements for a term of at least one year;
- ❖ Specify the services, space or equipment subject to the arrangement; and
- ❖ Include compensation or lease amounts that reflect fair market value and that are not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties.

For leases, the aggregate space rented must not exceed what is reasonable and necessary to accomplish reasonable business purposes. Special rules apply to part-time leases. For personal service arrangements, the aggregate services contracted for must be reasonable and necessary, and may not involve activities that violate state or federal law.

**Q** Since "fair market value" is a key requirement for compliance, how do parties know what fair market value is?

**A** For Stark law purposes, "fair market value"

means the value in arm's-length transactions, consistent with "general market value." The Stark II final regulations define fair market value to mean:

- ❖ A price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not in a position to generate business for each other, or
- ❖ The compensation in a service agreement negotiated by well-informed buyers and sellers who are not in a position to generate business for each other.

Further, the definition states that the general benchmark for fair market value is the price at which *bona fide* sales have been consummated for assets of like type, quality and quantity in the particular market at the time of the transaction, or the compensation included in *bona fide* service agreements with comparable terms at the time of the agreement.

In connection with space leases and equipment rentals, fair market value means the value for commercial purposes, not taking into account its "intended use" or its proximity or convenience to referral sources. The Centers for Medicare & Medicaid Services makes clear that this "intended use" limitation still allows development upgrades and maintenance that customize premises for healthcare usages to be factored into fair market value and allows rental payments that reflect the fair market value of the area in which the property is located (*i.e.*, medical property in a medical community).

In general, despite the lack of clear guidance as to what is appropriate fair market value in a given arrangement, the burden of establishing "fairness" rests with the parties.

**Q** Should parties to these arrangements always get outside valuations of fair market value? Does this require the expense of hiring an outside consultant?

**A** The first question is whether parties should consider outside sources for benchmarks in setting medical director compensation or determining commercially reasonable lease rates for office space or equipment. The second question is whether parties always should hire an outside consultant to provide such data or render an "opinion" on every proposed arrangement.

With regard to use of independent valuation consultants to determine fair market value, the government has said there is no requirement to use outside sources, if other “appropriate” valuation methods are available. Nonetheless, while internally generated analyses theoretically can be used to determine fair market value in certain circumstances, the government has stated that such analyses may not have “strong evidentiary value” due to their susceptibility to manipulation and the absence of independent verification.

Using outside resources to establish benchmarks for compensation in medical director and lease arrangements is generally a good idea, particularly where the outside resources are easily available, reliable and generally recognized as an industry standard. The question of when to hire an outside consultant, however, is a bit more complicated. Whether this step is necessary, or helpful, would depend on the facts and circumstances of the particular arrangement. Factors relevant to this issue might include:

- ❖ Whether the arrangement is consistent with other arrangements that the parties already have in place (with each other or with others);
- ❖ How familiar the consultant is with the local market for physician compensation, commercial real estate leases or the equipment leasing industry;
  - ❖ The cost and time frame for the consultant’s services;
  - ❖ To what extent internally generated surveys or analyses rely on objective vs. subjective data; and
  - ❖ How comfortable the parties otherwise are with their arrangement from a compliance perspective.

**A final determination over when to engage outside experts likely requires the involvement of an organization’s management and legal counsel**

**Q** What are some other practical tips for compliance “best practices” for these arrangements?

**A** 1. Many organizations have implemented a contracts management system, so that their legal counsel or compliance office staff has a current listing of all existing arrangements that require compliance oversight. There is no single approach to creating such a system. But its effectiveness likely requires the training of business staff, who need to understand that even oral or “*de minimis*” arrangements can be “financial relationships”

subject to compliance requirements.

2. Any such system must take into account the expiration dates for agreements. Since it is a compliance requirement that financial relationships be reflected in written agreements, an organization could benefit from a contracts management system that flags in advance when arrangements are set to expire. Arrangements that continue past their contract expiration date may—or may not—under law be extended pursuant to the parties’ written terms.

3. Some organizations have found it helpful to develop template (or form) agreements for their medical director and space/equipment lease arrangements. These forms allow the business staff to move forward in negotiating such arrangements under pre-approved parameters.

However, organizations using this approach also tend to require that each contract be reviewed by legal counsel before the arrangement goes into effect. It may be possible to build such an internal approval process as a condition precedent right into the text of the template, so that all parties understand what final steps are required to effectuate the arrangement.

4. It’s important to understand the difference between “structure” and “operations” when it comes to compliance for these kinds of arrangements. A properly structured agreement (e.g., a written contract, for a term of one year, with fair market value compensation) must be overseen to ensure that it is being implemented. Savvy healthcare organizations have established procedures for ensuring that services contracted for are performed, and that payments exchanged between parties match what is required by the contracts.

5. An effective compliance approach to these “everyday” relationships requires effective training and communication. Effective training means that business staff become—and remain—sensitive to the compliance issues raised by various financial arrangement proposals. Effective communication means that such staff know where to go within the organization to get their questions answered and feel comfortable using these channels.

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## HealthSouth Execs Charged With Massive Accounting Fraud Criminal, Civil Indictments Expected In Earnings Scandal

**S**everal officials with HealthSouth Corp. (Birmingham, AL), the nation's largest provider of outpatient surgery, diagnostic imaging and rehabilitative services, have been charged with accounting fraud after allegedly inflating earnings by at least \$1.4 billion to meet Wall Street earnings expectations.

*HealthSouth's board of directors says it is taking steps to help stabilize the company. The board's special investigative committee has hired an auditing team from PriceWaterhouseCoopers to investigate the SEC allegations and a turnaround advisory firm to help position HealthSouth for successful restructuring*

The Securities & Exchange Commission on Mar. 19 filed civil fraud charges against HealthSouth and Richard Scrushy, its founder, chief executive officer and chairman, saying they systematically overstated earnings and assets in an attempt to dupe investors into believing the company had met earnings targets. By the third quarter of 2002, the company's assets were overstated by at least \$800 million, or about 10%, according to the SEC.

Separately, William Owens, HealthSouth's chief financial officer, pled guilty Mar. 26 to criminal fraud charges filed by the U.S. Department of Justice. Owens, who faces a maximum of 30 years in prison and up to \$5.5 million in fines, is charged with conspiracy to commit securities and wire fraud and with filing false certifications with the SEC. Weston Smith,

HealthSouth's former CFO, also has agreed to plead guilty to similar charges. Additional criminal and civil charges against the company are expected, say government officials.

According to Justice Department charges, top officials at HealthSouth began in 1997 to recognize that the company was not producing sufficient earnings to meet Wall Street earnings expectations. The difference between true earnings per share and earnings expectations was referred to internally as the "gap" or the "hole." Officials then conspired to fill the gap with "dirt"—fraudulent postings that artificially inflated company earnings.

"As part of the conspiracy, HealthSouth's accounting staff, including Smith, would meet to discuss ways to fraudulently inflate the earnings," according to a Justice Department statement. "These meetings were internally known as 'family meetings' and attendees were known as the 'family.'"

Last August, Scrushy relinquished his post as CEO to oversee a corporate realignment, but those plans were scrapped after officials lowered earnings estimates by \$175 million, which they said were due to a change in Medicare billing practices for outpatient therapy. Shortly after, HealthSouth disclosed that the

SEC and the Justice Department were investigating the company on a variety of issues, including billing practices and stock sales by executives.

Scrushy returned to the helm of HealthSouth on Jan. 7, but has since been placed on administrative leave, along with Owens. The New York Stock Exchange has suspended trading of the stock and is applying to the SEC to delist the security. The stock last traded at \$3.91. Analysts speculate that the company could be forced to file for bankruptcy protection. 🏠

### OIG Issues Final Compliance Guidance For Ambulance Suppliers

**T**he HHS Office of Inspector General has released final compliance program guidance to assist ambulance suppliers in establishing compliance programs.

The guidance, published in the Mar. 24 *Federal Register*, focuses on risk areas relevant to the ambulance industry and recommends ways to address them. For example, with regard to the potential for abuse of non-emergency transports, the guidance urges suppliers to follow Medicare criteria for coverage of scheduled and unscheduled non-emergency transports. This includes obtaining a physician certification statement (PCS) to verify that the transport was necessary.

In addition, the guidance reviews some of the fraudulent and abusive practices that have occurred in the ambulance industry, including medically unnecessary trips, trips claimed but not rendered, false documentation and payment of kickbacks.

This is the 10<sup>th</sup> compliance program guidance released by the OIG. Other guidance has targeted healthcare sectors ranging from clinical laboratories to hospitals to individual and small group physician practices.

Next in line to get formal compliance guidance: the pharmaceutical industry. This guidance is expected to be released by early summer.

For a copy of the final guidance for ambulance suppliers, go to <http://oig,hhs.gov/fraud/docs/complianceguidance/032403ambulancecpgr.pdf>.



Jeffrey Boothe, Esq.

## HIPAA Privacy "Prime Time," from p. 1

### Notice Of Privacy Practices

Direct treatment providers must make a "good-faith" effort to inform patients of their rights by providing them with a privacy notice. Affected providers include hospitals, physician office laboratories and skilled nursing facilities. Labs that provide direct access testing are also considered direct treatment providers, said attorney Jeffrey Boothe, a partner in the Washington, DC office of Holland & Knight LLP.

Indirect treatment providers aren't required to distribute a privacy notice to all patients, but must have one that can be furnished upon re-

quest. Affected providers include independent reference laboratories and hospitals providing "non-patient" services (for example, a hospital lab that receives a specimen for testing, but no physician-patient encounter occurs in the hospital). It remains somewhat unclear whether a hospital lab that actually *draws* a specimen, but no physician-patient encounter

occurs in the hospital, is considered a direct or indirect treatment provider, Boothe cautioned, but "my view is that's a non-patient service and direct treatment obligations don't apply."

What must the privacy notice contain? An explanation of the patient's right to:

- ❖ Request restrictions on how his/her protected health information (PHI) is used and disclosed.
- ❖ Inspect and copy his/her own PHI.
- ❖ Amend incorrect or incomplete PHI.
- ❖ Receive an accounting of disclosures.

Attorney Daron Tooch, a partner with Hooper, Lundy & Bookman Inc. (Los Angeles, CA), advised covered entities to prepare separate forms addressing each of these rights. For example, have the following ready to give patients, he says:

- ❖ **Privacy Complaint Form.** This should have two parts: one where the patient can provide details of the complaint, another where the provider can document its response. Use a separate internal tracking

form to log complaints and responses. "Complaints must be in writing and must name the entity and the facts surrounding the [alleged] violation," Tooch said. "Also, the complaint must be filed within 180 days of when the [alleged] violation occurred."

- ❖ **Request For Access To Medical Records.** This form lets the patient select the type of access sought and how he/she wants the information delivered. A separate form, "Grant Of Request For Access To Medical Records," is completed by the covered entity. This form documents the response to the request and includes information on fees that may be levied for access to medical records.
- ❖ **Request To Amend Medical Information.** This should have two parts: one where the patient can note what information he/she wants changed and why; another where the response to the request is noted.
- ❖ **Request For Accounting Of Disclosures.** This should include one part to be filled out by the patient and another part to record the covered entity's response. Patients have the right to request an accounting of PHI disclosures in the previous six years, except for certain TPO disclosures (made for treatment, payment and operations).

### Authorization For Non-Routine Uses & Disclosures

Covered entities must obtain written authorization from patients to use or disclose PHI for purposes other than TPO (treatment, payment and operations). These purposes include certain marketing communications and research. No written authorization is required when PHI is used for TPO, including when a physician shares PHI with a laboratory or when a laboratory shares PHI with an outside reference lab, Boothe pointed out.

The authorization must:

- ❖ Describe the information to be used or disclosed.
- ❖ Identify the person authorized to allow the use/disclosure.
- ❖ Identify the person(s) to whom the disclosure is being made.
- ❖ State the purpose of the requested use/disclosure.
- ❖ Indicate when the authorization expires.

**For more information about requirements under the HIPAA medical privacy rule, including frequently asked questions and a model business associate contract, go to [www.hhs.gov/ocr/hipaa/](http://www.hhs.gov/ocr/hipaa/)**

- ❖ Be signed and dated by the patient.

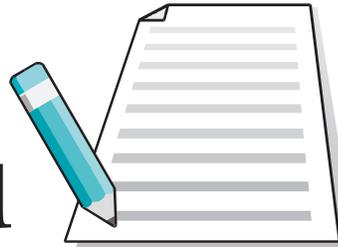
### Business Associate Agreements

Covered entities have until Apr. 14, 2004, to alter existing contracts with business associates to conform to HIPAA privacy requirements, Boothe noted, but he urged providers, health plans and health clearinghouses to start making necessary modifications now. Business as-

sociate contracts are required with companies that assist covered entities with an activity that involves the use or disclosure of individually

identifiable information, such as firms furnishing legal, accounting and consulting services.

## For the Record



**T**he Centers for Medicare & Medicaid Services has made a number of changes to the edit module used to process claims for 23 frequently ordered laboratory tests now subject to national coverage determinations (NCDs). Among the changes included in the Apr. 1 release of the software used by contractors:

- ❖ New ICD-9-CM diagnosis codes have been added to the NCD for serum iron studies: 282.60, 282.61, 282.62, 282.63, 282.69 and 285.21.
- ❖ Seven CPT codes in the blood count NCD have been deleted: 85021, 85022, 85023, 85024, 85031, 85590 and 85595. CMS also is reviewing the addition of new blood count codes for 2003. The progress of this review can be tracked online at <http://cms.hhs.gov/ncdr/trackingsheet.asp?id=88>.
- ❖ The descriptions of serum iron study diagnosis codes 562.02 and 562.03 have been corrected to accurately reflect the diagnosis of diverticulitis and diverticulitis of the small intestine with hemorrhage.
- ❖ A number of typographical errors to various codes have been corrected. Many of these have already been incorporated in the Laboratory NCD Manual available at <http://cms.hhs.gov/ncd/manual.pdf>.

The changes are presented in Transmittal AB-03-030 (Feb. 28, 2003), available at <http://cms.hhs.gov/manuals/memos>. 🏠

## Penalties For HIPAA Privacy Violations

### Civil

- ❖ \$100 each violation
- ❖ Up to \$25,000 per person, per year for each requirement or prohibition violated

### Criminal

- ❖ *Misuse*: Fine of up to \$50,000 and up to one year in prison
- ❖ *False pretenses*: Fine of up to \$100,000 and up to five years in prison
- ❖ *Intent to sell, transfer or use for commercial advantage, personal gain or malicious harm*: Fine of \$250,000 fine and up to 10 years in prison

Source: HHS Fact Sheet

Business associate contracts aren't required with people or organizations whose functions do not involve PHI use or disclosure, such as janitors, plumbers, electricians and photocopy repair technicians. In these instances, where disclosure is secondary or incidental, you should establish reasonable safeguards to limit disclosure. "These can be very simple," Boothe explained, "such as shredding documents that aren't needed anymore, educating employees not to leave documents on their desks overnight or reminding them to turn their computer screen around so that people visiting the facility can't observe the information displayed."

Business associate contracts aren't required between two covered entities, he added, such as between a physician and a laboratory or between a hospital and a reference lab. Each of those entities has its own responsibility under the privacy rule. While many labs mistakenly believe they need a business associate agreement with a physician, Boothe advised against it. "If I'm a lab, and I make you a business associate, I am taking legal responsibility for you as well. What I'd rather do is say, no, you're a covered entity and when I share information with you, if you mess up somehow and disclose that information, it's your responsibility, not mine."

### Resources

- ❖ Jeffrey Boothe: 202-955-3000
- ❖ Daron Tooch: 310-551-8111 🏠

**Pneumonia Upcoding Recovery:** A Florida hospital has paid Uncle Sam almost \$1.5 million to resolve allegations that it violated the federal False Claims Act by “upcoding” a pneumonia diagnosis code, the U.S. Department of Justice said Mar. 17. The agreement by Leesburg Regional Medical Center stemmed from a whistleblower lawsuit filed by Health Outcomes Technologies (Doylestown, PA), which will receive \$206,655 as its share of the recovery. The settlement is the latest in the government’s nationwide pneumonia upcoding investigation.

**Tenet Hospitals Cleared:** The Joint Commission on Accreditation of Healthcare Organizations has cleared for continued accreditation 19 Tenet hospitals that were the target of special surveys. JCAHO initiated unannounced visits at the hospitals last November as a precaution after questions arose regarding the medical necessity of certain cardiology procedures performed by two doctors at one Tenet hospital. While surveyors found some areas for improvement at each of the 19 hospitals, they made no recommendations that would suspend accreditation at any of the facilities.

**DME Suppliers Warned:** HHS Inspector General Janet Rehnquist has put durable medical equipment suppliers on notice about improper telemarketing practices. DME suppli-

ers already are prohibited from making—or hiring outside firms to make—unsolicited telephone calls to Medicare beneficiaries about the furnishing of Medicare-covered items, except in three specific situations. Despite this prohibition, some DME firms are hiring independent marketing firms to make prohibited marketing phone calls, says the IG in a special fraud alert in the Mar. 4 *Federal Register*: “Simply put, DME suppliers cannot do indirectly what they are prohibited from doing directly.” The alert is posted online at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/telemarketing.pdf>.

**Privacy Professionals Survey:** A new survey by the Health Care Compliance Association finds that the majority of Privacy Officers (POs) in healthcare organizations (85%) have that duty in addition to an existing position. Only 14% reported that it was a new full-time position, while 1% said it was a new part-time position. Of those responding that the PO position was an added responsibility, 57% said it’s the responsibility of the Compliance Officer; 16% said it fell to the Medical Records Director. A small number reported that the responsibility belongs to the Chief Information Officer or Chief of Operations. Salary for the full-time position ranged from \$50,000 to \$130,000, with 39% reporting a salary of \$50,000-\$75,000 and 23% reporting a salary of \$75,000-\$90,000. Survey results are posted at [www.hcca-info.org](http://www.hcca-info.org). 🏠

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