G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. III, No. 2, February 2001

For Hospitals, Laboratories and Physician Practices

Bush Approach To Anti-Fraud Enforcement: Vigilance But With A Lighter Touch?

Not surprisingly, fighting fraud within the healthcare industry will continue as a priority of the new Republican Administration under President George W. Bush, but the tone and approach will likely be different from the previous Clinton Administration.

That's the sense *G-2 Compliance Report* got from canvassing healthcare attorneys and consultants.

"The Bush Administration will continue to clamp down on any fraud in the healthcare arena," L. Stephan Vincze told us. He is president and CEO of Vincze & Frazer (Montgomery, AL).

And the HHS Inspector General will continue its close scrutiny of healthcare entities that violate the false claims and anti-kickback statutes, he said.

But under Bush, Vincze sees a desire to "move away from the appearance of demonizing an industry…you will see a more conservative attempt to rethink what fraud is. You may see a less aggressive approach in identifying certain problems as fraud, but a more aggressive approach in addressing those problems."

Attorney Robert L. Roth, with Crowell & Moring (Washington, DC), thinks healthcare anti-fraud

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Gainsharing Gets A Qualified Go-Ahead

In its first advisory opinion of 2001, the HHS Office of Inspector General said it would not impose sanctions on a narrowly crafted gainsharing arrangement involving a hospital and a group of cardiac surgeons.

Under the proposed arrangement, the acute care, nonprofit hospital would give the surgeons' group 50% of the first-year cost savings directly attributable to operating room changes the group makes to curb inappropriate use or waste of medical supplies.

"For hospitals and physicians, this clearly provides a window of opportunity for gainsharing programs, albeit a small window," attorney Robert Louthian III told *G-2 Compliance Report*. Louthian is with McDermott Will & Emery in Washington, DC.

The OIG, while stating that the proposal could implicate anti-kickback and other statutes, gave it a green light anyway, arguing that the risk of inappropriate limits or reductions in service to patients is offset by the arrangement's specificity, safeguards, and limited scope.

Defending Its Decision

Previously, the OIG had condemned gainsharing in general: that is, hospital efforts to curb costs by giving doctors who help curb costs a percentage of the savings achieved (*GCR, Aug. '99, p. 1*). In a July 1999 special advisory bulletin, the OIG told hospitals to get out of such ar-

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Anti-Fraud Enforcement, *from page 1*

enforcement will continue strong. "Generous and ongoing funding for [it], earmarked in the 1996 Health Insurance Portability & Accountability Act (HIPPA), makes such enforcement a self-perpetuating cause. If the money is there, enforcement will continue."

Some Predictions

❖ ***More providers in policy positions.*** President Bush might be more likely to appoint a greater number of healthcare professionals than the Clinton Administration recruited, Roth says. These persons "may have a more empathetic approach to regulating their fellow professionals."

Whoever is chosen to head the Health Care Financing Administration will have a "formidable assignment" to reexamine how the agency is run, revamp its operations, and continue to fight fraud and abuse, adds Roth.

According to Vincze, any changes in the enforcement approach are more likely to be evident at the Department of Justice than at Health & Human Services.

❖ ***Career employees in enforcement will stay in place***. Healthcare experts we talked to agree that most career government employees in charge of enforcement and oversight are expected to remain in their positions despite the change in administrations.

❖ ***Where policy will be made remains in question***. The overarching question for the Bush administration, Roth thinks, is whether to continue to allow healthcare policy to be made by lawyers and enforcers or return this function to regulators at HHS and HCFA.

❖ ***False Claims Act***. This will remain a primary enforcement tool for government agencies, notes Richard P. Kusserow, president of Strategic Management Systems (Alexandria, VA) and a former HHS Inspector General. The new Attorney General, John D. Ashcroft, went on record in support of the Act and its whistleblower provisions even before being confirmed earlier this month. In a Jan. 31 letter to Senate Finance Committee chair Charles E. Grassley (R-IA), Ashcroft said that using the Act to tackle fraud and abuse will be an important priority for the Justice Department: "Indeed, I expect that sustained efforts [of the Department] will in some respects lessen the need for (but not the importance of) private attorneys general acting pursuant to the [whistleblower] provisions."

❖ ***Corporate integrity agreements (CIAs) will proliferate***. The trend toward more detailed and rigorous CIAs will likely accelerate. Roth expresses the view of many healthcare attorneys when he predicts that this trend will continue to be an issue as CIAs become "broader, more onerous, and more expensive." The OIG is expected to continue to push for reviews of CIA performance by independent review organizations. Roth says a continuing debate will focus on how "independent" should be defined and how broad the reviews should be.

❖ ***Voluntary disclosure***. Healthcare attorneys are looking to the Bush Administration to set a clear, consistent policy on treatment of entities that voluntarily approach the government and disclose a compliance problem. Roth calls voluntary disclosure the "unkept promise of the enforcers and prosecutors." Although the OIG signaled during the past year that disclosing entities with effective compliance programs will be treated less harshly, Roth says the government has not followed a consistent policy in this regard. In fact, self-reporting providers have been saddled with onerous CIAs, he contends.

What About Capitol Hill?

Inside Congress, changes in committee leadership are likely to foster some changes in enforcement.

❖ Rep. James Greenwood (R-PA), new chair of the House Commerce oversight & investigation subcommittee, has drafted an action plan for his panel that includes a focus on Medicare/Medicaid fraud, abuse, and waste. He wants to urge states to upgrade provider enrollment requirements to screen out "unscrupulous providers."

❖ Sen. Larry E. Craig (R-ID) will chair the Senate Special Committee on Aging which, under former head Charles E. Grassley (R-IA), was instrumental in pushing improvements in nursing home care.

❖ Rep. Dan Burton (R-IN), who retains the chairmanship of the House Committee on Government Reform, plans a hearing on management challenges and program risks in Medicare, in follow-up to a report from the General Accounting Office in mid-January.

Resources

❖ L. Stephan Vincze: 334-240-0952
❖ Robert L. Roth: 202-624-2500
❖ Richard P. Kusserow: 703-683-9600

Compliance Challenges For Lab Accreditation

Joint Commission Resources announces the availability of *How To Meet The Most Frequently Cited Laboratory Standards*, 2nd edition. JCR is a subsidiary of the Joint Commission on Accreditation of Healthcare Organizations.

The book identifies the 27 most challenging compliance issues that labs face in accreditation. Topics include quality control, waived testing, management of the lab environment, management of information, management of human resources, and leadership.

The book costs $50. Order by code FCLS-01. To order, call the Customer Service Center, 630-792-5800 or visit Infomart at *www.jcaho.org*.

Going Down The Road Of HIPAA Compliance: Here's A Checklist

The government has finalized two rules required by the Health Insurance Portability & Accountability Act (HIPAA) in order to facilitate electronic health data exchange.

They are: standard formats/transactions (compliance by Oct. 16, 2002) and medical records privacy (compliance by Feb. 26, 2003).

And more regulatory requirements are yet to come, in accord with HIPAA's administrative simplification provisions: security standards, claims attachments, and unique identifiers for providers and patients.

HIPAA compliance is already shaping up as one of the biggest challenges to healthcare providers of all types and sizes.

To tackle a job that will take months, even years, you need a process that incorporates a multi-pronged, cross-functional approach, says Christopher Coleman, a healthcare policy analyst with Strategic Management Systems Inc. (Alexandria, VA).

"HIPAA administrative simplification includes both operational and technical requirements covering electronic data interchange, security, and privacy."

Coleman recommends managing the process through five phases:

- Awareness and Education
- Self-Assessment/Gap Analysis
- Project Preparation
- Implementation
- Ongoing Monitoring

In this issue, we present a checklist for the first two phases; next month, we'll address the other three phases.

Awareness & Education

- *Is your organization subject to HIPAA?*

Most likely, yes. HIPAA covers entities that electronically transmit personal health data in connection with standard transactions. This encompasses healthcare providers, health plans, and claims clearinghouses.

- *Obtain organizational buy-in.*

"Those at the executive level need to understand why they must comply and the risks of non-compliance," Coleman stresses.

There are both civil and criminal penalties for misusing or failing to safeguard "health information," defined broadly as any information relating to a person's health (past, present, future), the service provided, and the payment for the service.

- *Get a sponsor within your organization.*

Get a top executive—be it the CFO or the COO—on board with your plan.

HIPAA = Handling Questions Big & Small

The implementation of HIPAA is seen as one of the most extensive overhauls ever in public and private health systems, but the tasks range from the macro to the micro, such as:

- Who among our business associates are covered? What contractual ties need to be refined or established in light of HIPAA?
- How is privacy assured for paper claims and paper records? The final rule covers individually identifiable information created or held by covered entities in all forms, including oral communications and paper records that have not existed in electronic form.
- When you send a fax containing health information, how do you know where it went and who received it?
- What about security and privacy of data on laptops?

"This will make it easier for the person designated to run the organization's HIPAA initiative. It's usually someone in middle management."

- *Designate HIPAA project managers.*

HIPAA compliance cuts across many different areas in an organization: from information technology improvements to the training of employees so they know how and when to disclose patient information, the difference between routine and special authorization, and how to respond to patients seeking a copy of their medical record.

Start with your top-level project managers, including the compliance officer and the chief information officer who is responsible for medical records security and privacy.

Then, include departmental managers. Because HIPAA compliance is such a wide-ranging endeavor, you will need to look at all areas where patient information is handled—for example, medical records creation and retention, the information technology (IT) infrastructure, billing and reimbursement departments, etc. You'll want a team from each department to look at its HIPAA duties.

- *Establish HIPAA project teams.*

This is a way to "drill down" to the "bench level." Who's on what team depends on the mission and size of your organization, but avoid making any team top-heavy: you'll want to include employees.

"You need their buy-in," Coleman says. "You need them to understand the reasoning behind HIPAA requirements, so they can act accordingly."

In billing and coding, the team could be 2-3 people who ensure that appropriate policies and procedures are in place for the reimbursement department.

For IT, you may need more on the team, depending on how exten-

sive your IT infrastructure is.

❖ *Visualize HIPAA compliance as part of an e-business strategic plan.*

If you have an e-based strategy to make your business more efficient, identify where you have leverage or any streamlining that can be used to comply with HIPAA. Your experience with Y2K compliance may give you a leg up.

❖ *Budget adequately for HIPAA compliance.*

Logically, the two existing budget items that relate most to HIPPA are the compliance program and IT, so Coleman suggests you start by allocating them more resources.

Self-Assessment/Gap Analysis

❖ *Map the flow of health information internally and externally.*

Once you've identified how current policies and procedures govern this flow, you have a roadmap. At each destination, ask: How do you control access? Stem any breaches?

❖ *Identify your IT controls on information flow.*

With few exceptions, health information that identifies a particular patient may be used only for healthcare purposes (treatment, payment, and internal operations like data-gathering).

You will want to see that access to such data is restricted to those who need it to accomplish a healthcare purpose and that only the amounts of data needed for this purpose can be accessed.

❖ *Evaluate current policies and procedures governing the use of health information.*

You'll want to make sure they conform to HIPAA privacy standards.

❖ *Identify those within the workforce who must have access to health information, and why.*

"The big thing with the privacy rule is *who* should be able to access this information," Coleman observes.

❖ *Identify potential business associates with which you share health information.*

These could be any type of provider, health plan, or health insurer.

While you don't have to actively monitor them for HIPAA compliance, you should stipulate in business arrangements with them that you follow and enforce HIPAA standards and that you will act promptly if you learn they have non-compliant practices.

❖ *Identify vendors involved in information flow.*

A lot of healthcare organizations outsource their billing and coding to a third-party vendor. You need to track that as well and make sure your vendor is taking steps to become HIPAA-compliant.

❖ *Identify current management resources available to your HIPAA effort, then determine if more are needed.*

❖ *Compare current policies and procedures to HIPAA rules.*

This is what the self-assessment is all about. Coleman's firm has come up with more than 200 different requirements and upward of 3,000 individual tasks that an organization potentially must accomplish to become fully compliant with HIPAA.

Wherever you uncover a gap, that is where you need to put resources to bring your current practices in line with at least the minimum standards required.

❖ *Balance business priorities.*

Once you identify the gaps, determine which are priorities and the order in which they are best realized.

Resources

❖ Chris Coleman: 703-535-1417

❖ Our previous coverage: "HHS Unveils Final HIPAA Privacy Rule," Jan '01, p. 1; "Start HIPAA Compliance Now," Mar '00, pp. 5-8

❖ HIPAA final rules: Patient privacy, *Federal Register*, Dec. 28, 2000; code sets, *Federal Register*, Aug. 17, 2000

Reimbursement Alert: Pap Smear Pay In 2001 Set At $14.60 Minimum

It's up to you to ensure that you get paid properly for Pap smear tests in 2001.

Payment for the codes opposite will continue to have a national minimum payment floor of not less than $14.60. This amount was set by the 1999 Balanced Budget Refinement Act and has been effective since Jan. 1, 2000.

Local Medicare contractors have been told by the Health Care Financing Administration that if their systems have an amount less than $14.60 for 2001, it must be raised to that amount.

If you have claims that were paid at a lower amount, because the contractor applied a fee or a fee cap below $14.60, you need to bring this to the contractor's attention in order to receive an adjustment. The contractor is not required to do a retroactive "search-and-correct."

Codes Affected

P3000

G0123, G0143, G0144, G0145, G0147, G0148

88142, 88143, 88144, 88145, 88147, 88148

88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167

Source: HCFA Program Memo, Transmittal AB-00-134

COMPLIANCE PERSPECTIVES

Stark II Final Rule = Some Compliance Guidance + Remaining Uncertainties

Robert E. Mazer, Esq., is a shareholder in the Baltimore-based law firm of Ober/Kaler

For more than six years, clinical laboratories and other providers of healthcare services have struggled to comply with the federal self-referral prohibition frequently called "Stark II," after its principal congressional sponsor, Rep. Fortney "Pete" Stark (D-CA).

Stark II compliance has been particularly troublesome. The statute is extremely broad, covering any financial relationship a provider may have with a referring physician. Use of various statutory exceptions has frequently been uncertain, often leading providers to virtually guess whether the government would view an arrangement favorably.

The consequences of non-compliance can be financially devastating. A provider could forfeit Medicare reimbursement for any service referred by a physician with whom the provider had a prohibited financial relationship. The provider also might be assessed civil money penalties.

The Stark II final rule that was published by the Health Care Financing Administration on Jan. 4, 2001 (referred to by HCFA as Phase I of its Stark II rulemaking) did not eliminate compliance uncertainties as had been hoped. It addressed only the general self-referral prohibition; exceptions for physicians' services, in-office ancillary services, and pre-paid plans; and certain related definitions.

The rule does address physicians who operate in-office labs (*see box, p. 7*); however, the exceptions frequently relied on by labs—such as payments to physicians for services or for rental of office space—are not fully discussed. HCFA says they will be in a "Phase II" rulemaking. For now, application of the self-referral law to clinical laboratory services is governed by final regulations promulgated in 1995.

The Phase I rule does not become effective until Jan. 4, 2002, to give individuals and entities sufficient time to modify any non-compliant arrangements. (Provisions on home health referrals were set to become effective Feb. 5, 2001, but have been delayed until Apr. 6, in line with the Bush Administration's regulatory review plan.)

Though the Phase I final rule disappointed many, it is nevertheless an important document for labs seeking to comply with the federal self-referral law. In the discussion that follows, the term "rule" is used as shorthand for the Phase I final rule.

HCFA Ups The Ante For Statutory Violations

In the rule, HCFA did little to quell laboratories' fear regarding non-compliance. A lab will be deemed to have violated the law by accepting a referral from a physician with whom it has an inappropriate indirect financial interest if the lab knew or should have known of the arrangement. Otherwise, "no wrongful intent or culpable conduct is required" to violate the Stark law or to result in "recoupment of overpayments," *i.e.*, recovery of Medicare reimbursement.

HCFA asserts that wrongful conduct such as knowingly submitting a claim in violation of the statute could lead to charges under the

Stark Physician Referral Curbs

Prohibited: *Referring Medicare and Medicaid patients for designated health services to facilities with which the physician (or an immediate family member) has a financial relationship, whether by ownership/investment interest or a compensation arrangement. Also outlawed: submission of a claim to any payer for a designated health service furnished pursuant to a prohibited referral.*

Designated Health Services: *Clinical lab; physical & occupational therapy; radiology & certain other imaging services (MRIs, CT scans, ultrasound); radiation therapy; durable medical equipment & supplies; parenteral/enteral nutrients, equipment & supplies; prosthetic/orthotic devices & supplies; home health; hospital inpatient & outpatient services; and outpatient prescription drugs.*

False Claims Act or other federal statutory remedies. Violation of the civil False Claims Act can lead to penalties of $10,000 per claim. Lawsuits under the Act can be initiated by either federal prosecutors or whistleblowers.

Also, HCFA states repeatedly that arrangements that comply with the rule may, however, run afoul of the Medicare/Medicaid anti-kickback statute. Compliance with Stark II does not create even a presumption of compliance with that statute.

Lab Referrals Clarified

Whether a particular service is a clinical laboratory service subject to the self-referral ban can now be determined by reference to a list of CPT and HCPCS codes that HCFA attached to the rule (*GCR, Jan '01, p. 2*). HCFA also listed codes for radiology and radiation therapy, physical and occupational therapy, and a few other designated health services (DHS).

According to the rule, a physician does not make a referral if he or she personally provides the clinical laboratory test or other DHS. If the service is furnished in a hospital, the technical component would be deemed to have resulted from the referral, but the personally performed professional component would not. The Stark statute says that a pathologist who requests clinical lab services or a pathology examination does not make a referral if the services are furnished or supervised by the pathologist, based on a consultation request from another physician. Specific criteria for such a consultation are spelled out in the rule.

HCFA also states that the exception protects only the pathologist's financial relationship with the entity furnishing the service. If the physician requesting the consultation has a financial relationship with that entity and the relationship is not covered by a statutory exception, the entity furnishing the service requested by the pathologist would violate the statute if it knew or had reason to suspect that there had been an impermissible referral.

Indirect Financial Relationships

The rule adopts a new approach to indirect financial relationships, opposed to direct financial ones where remuneration passes between the referring physician and the entity furnishing the DHS without passing through another person or entity. Also adopted is a broad exception covering many such arrangements. Generally, a physician's indirect compensation tie with a DHS provider will not bar referrals to that entity if the physician's compensation is at fair market value, not taking into account the value or volume of referrals or other business generated by the referring physician.

Accordingly, a physician may be able to make referrals to a hospital or clinical laboratory that compensates his or her employer for services—even if the arrangement between the two entities does not fall within the personal service exception—so long as the compensation the physician receives from his or her employer does not reflect referrals or other business generated.

Moreover, as discussed below, HCFA has more narrowly defined those compensation arrangements that will be deemed to unlawfully reflect referrals.

Compensation Based On Referral Volume/Value

Many exceptions to the self-referral ban—including rental of office space and equipment, employment relationships, and personal service (independent contractor) arrangements—stipulate that compensation must reflect fair market value and may not take into account the volume or value of referrals. Most of these exceptions also preclude payments from taking into account "other business generated between the parties."

Though the rule does not fully address these exceptions, it includes important information regarding compensation that can be paid under these exceptions and documentation of fair market value.

According to HCFA, fair market value for assets or services can be established using any method that is commercially reasonable and provides evidence that the amount paid is comparable to what is ordinarily paid in the same location by parties who engage in arm's-length negotiations and who are not in a position to refer to one another.

For office space leases, a list of "comparables" or an appraisal report from an independent expert may be sufficient documentation of fair market value. HCFA says an independent appraisal is not required, but cautions that internal surveys may come under more intense scrutiny.

Additionally, since lease payments cannot reflect the volume or value of referrals, HCFA warns against reliance on "comparables" involving transactions where physicians participating in the arrangement are in a position to refer or generate business for the other participant.

The rule confirms that a clinical laboratory does not violate the Stark law by paying physicians higher rent for office space in a "medical community" than the lab would have to pay for space in another area. But it is impermissible for a lab to pay physician landlords rent higher than what medical practitioners pay physician landlords for space in the same building (or a building in the same or a similar location).

Thus, it may be appropriate for a lab to base its rent on what internal

medicine physicians are required to pay other such physicians for office space, as it is unlikely that that arrangement involved substantial referrals between the arrangement's participants. Conversely, it may not be appropriate to rely on what independent labs or other diagnostic testing facilities have paid medical groups for similar space when they are likely to receive referrals from their physician landlord.

In the proposed Stark II rule, HCFA said that compensation paid to a physician impermissibly reflected referrals when the aggregate payment fluctuated, based on the physician's referrals. Accordingly, compensating a physician referral source using time-based (hourly) compensation or compensation based on units of service (for example, payment "per click" for each use of leased equipment) was prohibited if the physician's referrals affected the entity's need for the services or equipment.

The final rule permits time-based or unit of service-based payments even when the number of such payments reflects referrals from physicians receiving compensation under the arrangement. However, HCFA says, the payment amount per service or time period must be specified in advance (such as a fixed amount per hour or per use), must reflect fair market value (unrelated to referrals or other business generated by the physician), and may not vary over the contract term based on referrals or other business generated by the physician receiving the payments.

Thus, a clinical lab would be permitted to compensate a physician for its rental of the physician's office space or for physician services on an hourly basis.

This does not mean that these types of arrangements are always advisable. Notwithstanding the favorable treatment they receive in the rule, they will not receive "safe harbor" protection under the anti-kickback statute. Thus, they may be ill-advised in certain instances, particularly when most referrals come from physicians receiving time-based or unit of service-based compensation and there is a significant relationship between referrals and aggregate payments received by the physicians.

Percentage arrangements are not generally permitted under the rule. An independent lab cannot lease space from a medical practice to test patients of the practice and then pay the medical practice a percentage of revenue received for the testing.

Moreover, according to HCFA, the reference to "other business" included in most compensation-related exceptions precludes compensation from being based on any business the physician may generate for the entity, regardless of whether the business relates to DHS covered under the statute or whether it is payable by a federal payer.

Therefore, it would not be permissible for a lab to pay a physician rent that reflects a percentage of revenue, even from tests not covered by Medicare or Medicaid.

Referrals By Compensated Physicians

HCFA has reversed its previous position that compensation unlawfully reflects the volume or value of referrals when physician referrals to a particular entity are required: for example, when a physician must refer lab tests to a facility owned by his or her employer.

HCFA now says these arrangements will not be disqualified from protection under the exception for *bona fide* employment arrangements or personal service contracts. However, the physician's compensation must be fixed in advance and reflect fair market value (not taking into account anticipated or required referrals). Other requirements applicable to the particular exception (such as written documentation reflecting a personal service arrangement) must also be satisfied.

This interpretation may prove troublesome for independent labs seeking referrals from hospital-employed physicians who may be required to use the hospital lab. It should not interfere with managed care or other health insurance ar-

Stark II Final Rule

Impact On In-Office Lab Testing Unclear

Significant questions remain regarding physician supervision of in-office testing. The rule says that the in-office ancillary services exception requires the referring physician (or another physician in the group practice) to supervise the services of a non-physician, as required under "applicable Medicare payment and coverage rules."

This potentially relaxes the Stark statute's requirement for direct (on-site) supervision. But its impact on in-office lab testing is unclear. The Medicare statute says that a physician may bill for a lab test only if he or she performed or supervised the performance of the test (or if another physician in the practice did so). Therefore, despite the rule, it may remain impermissible for an in-office lab to test specimens in the evening when physicians are not present. Similarly, participation in a shared lab arrangement by a physician practicing in the same building as the lab, but in another office suite, may not be possible since on-site supervision would be impractical.

Stark II Final Rule: FQAs

The Health Care Financing Administration has posted a series of frequently asked questions on its Website. Go to www.hcfa.gov/medlearn/faqphys.htm

HCFA also is accepting comments on the Phase I rule if received by Apr. 4, 2001 at HCFA, DHHS, Attn: HCFA-1809-FC, PO Box 8013, Baltimore MD 21244. For more information, contact Joanne Sinsheimer, 410-786-4620

rangements, however.

A physician may not be required to refer a patient to a particular facility when the patient or third-party insurer requires use of another facility, or when referral to the designated facility is not in the patient's best medical interest.

The Stark law *may* also be violated when an entity leasing space or equipment from a physician requires the physician's referrals as part of the arrangement.

Although the rule generally permits physicians who participate in a compensation arrangement protected under the statute to be required to refer patients to a particular facility, the related commentary specifically authorizes this practice only in connection with physician *service* arrangements.

Limited Freebies To Physicians

The previously proposed exception for *de minimis* compensation has been replaced in the rule by a similar exception for "non-monetary compensation." This will permit a DHS provider to give a physician one or more non-cash gifts per year with an aggregate value of up to $300, so long as the gifts are not based on referrals or other business generated by the physician.

The exception does not protect gifts to a medical group; a 10-person medical group cannot be given a $3,000 instrument, for example. Similarly, it does not protect "gifts" that have been solicited by the physician or medical group (or employees or staff members), or where the provider is to receive something in return, such as physician referrals.

The Stark statute excludes from the definition of "remuneration" a laboratory's provision of items, devices, or supplies used solely to collect, transport, process, or store specimens for the lab. HCFA states that this exception was intended to permit labs to furnish physicians with items, supplies, and devices that have little or no independent economic value and that are provided principally to ensure proper specimen collection.

According to HCFA, the exception does not permit a laboratory to furnish physicians, without charge, with sterile gloves or biopsy needles and like devices, such as snares and reusable aspiration and injection needles. A lab may, however, provide physicians with single use needles, vials, and specimen cups.

HCFA warns that a lab may lose the benefit of this exception by providing more supplies than the number of specimens sent by the physician. The agency may then infer that the supplies are not being furnished solely to collect, transport, process, or store specimens for the lab.

A laboratory that does not have a pattern of referrals for a particular client on which to base its provision of collection supplies should be prepared to demonstrate that the volume of supplies provided reflects what a medical practice of like type and size in the community would require.

In addition, the rule permits a laboratory to provide medical waste disposal supplies and services to physicians, so long as these are solely related to the collection of specimens for the lab. The lab may not bear the cost of disposal of other hazardous waste generated by referring physicians, such as syringes used for inoculations.

HCFA confirms that a lab may place a phlebotomist within a medical practice if he or she draws specimens and performs related functions for the lab only. If the phlebotomist furnishes other services which benefit the physician, a compensation arrangement between the physician and the lab may result. The physician should be required to pay the lab fair market value for any such services. Even then, Medicare "incident to" rules may preclude the physician from billing Medicare for specimen collection that is performed by a phlebotomist employed by an outside lab.

Further Advice Promised

According to HCFA, Phase II of the Stark II rulemaking will follow "shortly" and will address remaining self-referral issues. However, since Phase II will also address comments on the Phase I rulemaking (due by Apr. 4, 2001), further HCFA advice may not be available soon.

So far, federal enforcement authorities have recognized the statute's ambiguities and have not taken aggressive enforcement actions against violations. Whistleblowers who may initiate legal action under the False Claims Act may not be similarly minded. Accordingly, clinical labs and other DHS providers should accept referrals from physicians with whom they have a financial relationship only if they have a documented, good-faith, reasonable belief that the arrangement is protected by a statutory exception.

❖ *Mr. Mazer can be contacted at Ober/Kaler, 120 E. Baltimore St., Baltimore MD 21202. Tel: 410-347-7359. E-mail:* remazer@ober.com

Taking Your Compliance Program To The Next Level

"When we talk about traditional compliance—the seven core elements—that was the first generation of compliance."

The next generation is program effectiveness, Jonathon Kellerman told us. He is a manager in the Healthcare Consulting Practice at PriceWaterhouseCoopers in Philadelphia, PA.

For the next generation of compliance, the chief concern is: How well does the program work—does it satisfy all regulatory requirements, prevent fraud, correct mistakes and keep them from recurring?

Essential Attitudes

1 Regularly test your program's strengths and weaknesses.

As regulatory requirements change or as your organization modifies its systems or protocols, you need to know that what you have designed is capable of responding promptly and correctly.

"If you don't test your program, you simply won't know," Kellerman notes.

One provider he knows invested thousands of dollars to create the "greatest lab compliance program" on paper. But the lab never tested the program to make sure it was working.

"They did the training and created the policies, but walked away from it after that. A year later, they were under investigation for submitting improper claims. They were actually in a worse situation because they had already demonstrated that they knew what they had to do to prevent improper claims submissions. But they didn't follow-up to *make sure* their system worked. At the end of the day, it didn't."

2 Understand how compliance can improve operations and revenue. Shift the focus of process reviews and operational analyses from back-end, reactive activities to front-end process improvements.

"Compliance isn't just about finding overbilled claims, despite what the government says. For every honest overbilling mistake, there is probably at least one underbilled claim on which a provider loses revenue. You should leverage compliance proactively to strengthen your systems for proper and complete charge capture."

3 Recognize that program effectiveness ensures a better return on investment.

"Obviously, compliance is an investment," Kellerman says. "You should get something for that investment—either in boosting the bottom line or in streamlining operational activity."

Since healthcare entities must spend on compliance activities, it's important to gauge if the money is well spent.

4 See efforts to achieve (or maintain) program effectiveness as good preparation for any outside scrutiny.

In its 2001 Work Plan, the HHS Office of Inspector General pinpoints three areas where labs can expect reviews: cholesterol testing, lipid panels, and proficiency testing.

The OIG will look to see if coding is appropriate, if medical necessity is established for the cholesterol tests within the lipid panels, and if moderate and high complexity testing is being performed within the parameters established by the lab's CLIA certificate.

Practical Tips

What can you do to ensure the effectiveness of your compliance program? Kellerman suggests:

- Develop and update a government contracts binder, an annual compliance checklist, and an annual process survey.
- Quantify effectiveness by testing employee adherence to policies and procedures and by testing claims that are submitted.

When doing the latter, he suggests that claim reviews be judged against a baseline benchmark, so results can be compared to subsequent reviews. Also use available industry standards (for example, the Health Care Financing Administration's Annual Data Compendium) to judge your utilization against other providers in your area and nationally.

Then, analyze and document the causes for "spikes" in utilization and related trends, and chart your progress from review to review. Include comments on corrective action, and create a monitoring tracking log, which shows how often you monitor, what departments participate, the scope of your inquiry, who does the audit, and follow-up actions taken.

Though some attorneys may advise against keeping track of your internal reviews, Kellerman suggests that you do.

"If a baseline review shows high error rates, you are probably going to need more training. You might revisit your policies and procedures or redesign forms, charge capture processes, or information system capabilities.

"Unless you do follow-up monitoring and auditing on a regular basis, you will not know if employees are following compliance procedures and if they have been effective."

Resources

- Jonathon Kellerman: 267-330-2466. E-mail: *jonathan.l. kellerman @us.pwcglobal.com*
- Our previous coverage: "OIG Guidance On Effectiveness Points Back To The Basics," Jan. '00, pp. 5-8

Setting Limits On Giving, Accepting Gifts: It's Not Always An Easy Call

Tickets to the theater and sports events, fruit baskets, coffee mugs, all-expense-paid meetings—these are common offerings that a business makes to woo, win, and keep customers.

Sometimes, the gifts may be more substantial, such as interest-free or interest-deferred loans.

But the giving and accepting of gifts, whether modest or grand, is decidedly risky in healthcare. That's because, to the government, healthcare isn't just another business. It's tightly regulated to prevent any corruptive influence from swapping favors, especially between providers and referral sources.

For any compliance program, a key question is: How does our organization handle the giving and accepting of gifts? Some prohibit the practice outright. Many limit what may be accepted. For examples of current policies, we went to codes of conduct enforced by a large hospital chain and a university hospital.

Tenet Healthcare

At this major hospital chain (Santa Barbara, CA), employees may not accept gifts exceeding $35 in value (per individual gift) or $100 in cumulative value in a calendar year. Gifts exceeding the limit must be documented and reported to the employee's supervisor or manager who then decides how they will be handled.

Entertainment and meals that are associated with legitimate business activities and are of modest value are permitted, but must comply with Tenet's Administrative Policy and Procedure on Gift Limitations and Business Entertainment.

Acceptance of cash gifts, including tips, is prohibited.

Here are two examples from the Tenet standards:

Illustration: A national pharmaceutical company that has a national contract with Tenet is sponsoring a seminar. The seminar is reporting on research evaluating the outcomes of a new cholesterol-lowering drug. Tenet is invited to have a representative attend at the expense of the pharmaceutical company. Is this permitted?

Answer: There are criteria that the approving official should use to decide whether to allow employees to attend vendor-sponsored meetings. The criteria include:

—Is the focus on education vs. marketing the vendor's products? Are the presenters sales-oriented people or educators?

—Is the sponsor providing gifts of more than nominal value? If coverage of travel costs is more than nominal, Tenet must fund the travel on the premise that attendance is valuable to Tenet. If the travel costs are not significant (say, the meeting is close to where the employee works), Tenet must pay other portions of the cost, such as meeting registration, hotel and meal expenses.

Illustration: What happens if an employee receives a monogrammed afghan knitted by a patient?

Answer: Even though the organization bans accepting gifts from patients, it makes an exception in this case. "Because of the personalization of the gift and in the interest of good patient relations, it can be accepted on a one-time basis … It should be explained to the patient that an exception to Tenet's rule … is being made due to the personalization and work involved." The patient should also be told that a second gift cannot be accepted. Tenet requires that all gifts from patients be reported to the employee's supervisor.

Univ. Of Louisville Hospital

At this Kentucky hospital, the value of a gift cannot exceed $50. If more "or if there is any question regarding whether the gift meets the standard of reasonableness, the employee must either disclose the details of the gift, seek prior approval to accept it, refuse it, or promptly return it to the donor."

Gifts Of Any Kind Pose Kickback Hazard

Your compliance program should drum in the message to all in the organization to be wary of giving or accepting gifts in connection with any federal healthcare program business (Medicare, Medicaid, Tricare, etc.). In fact, the cleanest way to avoid trouble (hefty fines, prison time, program exclusion, even civil monetary penalties) is to ban any gift-giving or gift-acceptance with referral sources.

Under federal anti-kickback law, it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive *any remuneration* to induce referrals of items or services reimbursable by any federal healthcare program. "*Remuneration*" includes the transfer of *anything of value*, in cash or in-kind, directly or indirectly, covertly or overtly. The statute has been interpreted to cover any arrangement where even one purpose of the remuneration is to induce referrals.

For laboratories, a list of gifts or "freebies" that definitely should be spurned is found in the HHS OIG's Special Fraud Alert: *Arrangements for the Provision of Lab Services*, posted at *www.hhs.gov/progorg/oig*.

The recently published Stark II final rule on self-referrals creates an exception for small, non-monetary compensation to referring physicians (not exceeding $300 in aggregate per year). Three conditions must be met: the compensation is not based on referral value/volume or other business the doctor generates; the compensation may not be solicited by the doctor or his/her practice (including employees and staff members); and the arrangement does not violate the anti-kickback statute.

In cases involving disclosure or approval, the matter must be cleared through the hospital's Officer for Compliance and Ethics.

The hospital is adamantly against employees—or even members of their family—accepting a personal gift or favor (including complimentary business or personal trips) from any of the hospital's competitors, contractors, customers, suppliers, or anyone with whom the employee does business on for the hospital.

Otherwise, "acceptance of perishable gifts, other gifts of a nominal value, or gifts for reasonable personal entertainment may be ethically accepted if the gift would not influence, or reasonably appear to others to be capable of influencing, the employee's business judgment in conducting the hospital's affairs."

Resources

- Tenet Healthcare Corp., Ethics & Business Conduct Department: 1-800-838-4427
- University of Louisville Hospital, Compliance & Ethics Office: 502-562-3256

Gainsharing, *from page 1*

rangements as soon as possible. The advisory opinion makes a point of noting that the proposed arrangement is "markedly different" from many gainsharing plans; the OIG says the linking of specific actions to actual, verifiable cost savings removes the risk that the payments would be made to induce physicians to reduce or limit services to beneficiaries in federal healthcare programs, in violation of the civil monetary penalty provision.

Healthcare providers "should exercise extreme caution in drafting arrangements, given the limited scope of the advisory opinion," Louthian warned.

"The OIG's attempt to distinguish this gainsharing program from the ones it killed [in its special advisory bulletin] isn't very persuasive. At the time those plans were in, they had already made substantial revisions to address OIG concerns. Many of them would have gladly made similar changes to their programs to meet these guidelines."

Areas Targeted For Savings

The OIG stipulated that the proposed arrangement, and the advisory opinion on it, have a term of one year only; further, benchmark costs should be recalculated in any renewal or extension.

As proposed, the cost savings would be derived from 19 recommendations in three categories:

- Fourteen involve opening packaged items, like surgical trays or comparable supplies, only as needed during a procedure.
- Four concern substituting, in whole or in part, less costly supplies for the supplies currently used by the surgeons.
- One would limit Aprotinin (a medication given to many patients before surgery to prevent hemorrhaging) to only those patients at higher risk, as indicated by objective clinical standards.

About 75% of the savings would come from the limit on Aprotinin, and another 10% from not opening disposable components of a cell saver unit until a patient experiences excessive bleeding.

Safeguards Against Service Cuts

In concluding that patients would not be exposed to inappropriate limits or reduction in services, the OIG noted these safeguards:

- Historical and clinical measures will be used to establish a "floor" below which no savings will accrue to the surgeons' group.
- Cost savings will be calculated separately for each of the 19 recommendations. Total savings that can be achieved from any one of the recommendations are limited by appropriate utilization levels. Any savings from utilization below these levels will not be credited to the group.
- The hospital will make an aggregate payment to the group, which distributes its profits to members on a per capita basis, thus blunting any incentive for any physician in the group to overutilize services. Also, the parties requesting the advisory opinion have certified that the payment will be consistent with fair market value.
- Participation in the arrangement will be limited to surgeons already on the medical staff, reducing the likelihood that the arrangement will be used to attract or increase referrals.
- To minimize financial incentives to steer more costly patients to other hospitals, a committee composed of representatives of the hospital and the surgeons' group will monitor case severity, patient ages, and payers of the patient population being treated.
- The hospital and the surgeon group will disclose to patients, in writing, the arrangement and the surgeon group's compensation.
- Payments under the arrangement will be based on all surgeries, regardless of the patients' insurance coverage. Moreover, the surgical procedures are not disproportionately performed on Medicare and Medicaid patients.

The OIG's analysis scrutinized the proposed arrangement under the anti-kickback statute and the civil monetary penalty provision.

An advisory opinion applies only to the parties requesting it; others cannot rely on it.

Resources

- OIG Advisory Opinion 01-1: *www.hhs.gov/oig/advopn/2001/index.htm*
- Robert Louthian: 202-756-8600

The Back Page

News-At-A-Glance

Documentation Woes: The University of California's five medical schools will pay back $22.5 million to the Federal Government to settle a lengthy dispute over Medicare billing documentation from 1990-98.

No evidence of fraud was found, says a UC spokesman: "It was strictly over paperwork," and no allegations involved patient care or clinical matters.

The UC audit was conducted under the government initiative called PATH (Physicians At Teaching Hospitals). Campuses involved were at Davis, San Francisco, Los Angeles, Irvine, and San Diego.

Dialysis Deal: Renal Care Group (Nashville, TN) and its wholly owned subsidiary, RenaLab Inc. (Richland, MS), have agreed to pay $1.9 million to settle Medicare false billing charges. "This is the largest Medicare settlement against a lab in Mississippi," noted assistant U.S. attorney Cliff Johnson.

The entities allegedly sought reimbursement for tests that were not needed and not used in treating kidney patients for whom they were ordered. Billing was questioned when a local carrier spotted a dramatic increase in pre-albumin tests after Renal Care Group assumed control of several Mississippi dialysis centers and the Richland lab.

More OIG Chronicles: The HHS Office of Inspector General last month released its latest Semiannual Report outlining accomplishments over a six-month period ending Sept. 30, 2000. Some highlights: The OIG saved $1.232 billion due to investigations and $142 million due to audit disallowances. Additionally, 3,350 healthcare providers and entities were excluded from Medicare for fraud and abuse violations; 414 were convicted of crimes against federal healthcare programs.

Denying Access Can Hurt: Don't deny an inspector's request to look at your logbooks. The HHS Departmental Appeals Board (DAB) recently upheld an administrative law judge's ruling that U.S. Bio-Chem Med Labs should lose its CLIA certificate. Why? Because the lab's president refused to let government examiners inspect its logbooks until the examiners revealed who had complained about the lab. In addition to losing its CLIA certificate, the lab was barred from Medicare.

Proficiency Testing: In other HHS appeals board news, another lab lost its CLIA certificate and Medicare privileges recently. The physician office-based lab in the Oakland Medical Group in 1998 allegedly referred proficiency testing samples improperly to another lab for analysis. HCFA objected to the fact that the lab (1) failed to treat those samples the same as other patient samples and (2) refused to let a state regulatory agency survey the facility.

Bad Bundle Strikes Again: Two western New York hospitals will pay $2 million to settle government allegations that they improperly billed Medicare for lab tests known as "additional indices." The two cases were pursued under the False Claims Act and both were part of the nationwide review of lab claims known as Operation Bad Bundle (*GCR, Jan '01, p. 11*).

In one case, Genesee Hospital of Rochester agreed to pay $1.25 million for indices claims submitted from 1992 through 1996. In the other case, Kenmore Mercy Hospital of Buffalo agreed to pay $693,000 for identical violations.

G-2 Compliance Report (ISSN 1524-0304). © 2001 Washington G-2 Reports, 1111 14th St, NW, Suite 500, Washington DC 20005-5663.

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