G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. III, No. 4, April 2001

For Hospitals, Laboratories and Physician Practices

Compliance Forecast: *OSHA Standard Puts Free Safety Needles Under A Cloud*

The widespread laboratory custom of supplying free blood collection supplies, needles, and vacutainers to hospitals and doctors' offices will have to be re-evaluated, maybe even abandoned, when the Occupational Safety & Health Administration's revised bloodborne pathogens standard takes effect Apr. 18.

The standard requires not only that safety needles be used, but also that they be identified, evaluated, and selected by the "end-user"—the phlebotomist or other front-line healthcare worker.

OSHA is planning a 90-day outreach and education campaign before beginning to enforce the revised standard.

"Technically, to comply with the standard, reference labs would have to check with every doctor and see which product they selected and supply those," says Sheila Dunn, DA, head of Quality America Inc., based in Asheville, NC.

The national labs are unlikely to do this, she believes. "It's a real predicament, because a lot of doctors are used to getting the supplies for free."

Since many hospital outreach programs rely on free supplies as a marketing component, some may choose an aggressive position and supply end-users with more than one product to evaluate, Dunn adds. Even though such a move would cost more time and money, it could give the outreach program a valuable competitive edge over a competing lab in that community.

Dunn estimates that less than half of U.S. hospitals have made the conversion to safety needles for their phlebotomists, and probably less

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Inside this issue

More COs Run Independent Offices

The corporate compliance officer (CO) has become a near-universal fixture of hospital and health system management, according to year 2000 survey results from the Health Care Compliance Association (HCCA).

Ninety-eight percent of healthcare organizations have a CO, but the COs don't all occupy the same spot on the organizational chart.

Is it essential that the CO be in an office separate from the organization's general counsel, as recommended in compliance guidance from the HHS Office of Inspector General? Opinions vary.

Gaining In Rank

There's no question that COs are gaining in rank within their organizations: 78% of respondents to the HCCA survey said the CO is part of senior management or a company officer—an increase over the 72% who said the same in 1999.

And 57% of the organizations surveyed report that the CO has his or her stand-alone department with

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Critical Issues For Laboratories In HIPAA Compliance

Meeting the privacy and security mandates required by the 1996 Health Insurance Portability & Accountability Act (HIPAA) can be approached as a major regulatory headache or as a new business opportunity.

Susan Monte, data privacy officer for Quest Diagnostics (Teterboro, NJ), likes to think of it as the latter. She sees several key benefits: standardized electronic data exchange, greater efficiency in transactions, less paperwork, and less need for vendors to customize their products. So, look at privacy and security mandates as strategies to advance your business, address patients' concerns, and bolster consumer confidence.

An important corollary: shape your HIPAA efforts in light of your organization's compliance culture and current practices. Remember too: get employees involved sooner, rather than later.

Monte, along with Charles Silverman, Quest's regulatory counsel, shared their observations at a workshop held at *Compliance Forum 2001, Putting HIPAA Standards Into Practice*, sponsored Mar. 22-23 and Apr. 5-6 by Washington G-2 Reports.

Tips For The Task

For labs, one of the biggest implications of HIPAA is the need for patient-centric databases. Labs generally are provider-centric, so HIPAA constitutes a major data management challenge. Start thinking about migrating from a provider- or event-centric database approach to new and advanced systems that are patient-centric, Monte advised. A good example of patient-centric databases can be found in pharmacy benefits management programs.

She also urged labs to:

- Early on, establish governance for your HIPAA effort. At Quest, she has insisted on overseeing all the separate pieces of the effort with a core working team to monitor and counsel the various subteams: legal, compliance, information technology, operations, sales, human resources, and purchasing.
- Find a HIPAA project champion to emphasize your organization's firm commitment to the changes required. At Quest, chairman and CEO Kenneth Freeman has "stepped up to the plate and given the effort positive branding."
- Review other laws that interact with HIPAA, such as CLIA, Americans with Disabilities Act, Family Medical Leave Act, federal substance abuse confidentiality rules, and workmen's compensation laws. Remember, your organization is not only a provider of services, but also an employer.
- Establish a" working version" of the regulations. In other words, translate them into "actionable policies" that mean specific things for the organization.

Silverman expanded on the latter point by underscoring that HIPAA implementation efforts should be guided by key terms in the regulations. For example, we all have a general sense of what a privacy zone should entail or what

Doing An Inventory Of Protected Health Information

Inputs: What data come into the lab, from where?

Examples:
Requisitions
Prescriptions
Phone orders
Faxes
Electronic orders
Standing orders
Managed care eligibility, pharmacy data
Law enforcement
Other labs
Public health
Area code changes
Zip code listings
Human resources
Resumes, employment applications
Insurance data
Medical history

Outputs: Who gets the data?

Routine test results
Public health reporting
Client utilization
OSHA reporting
Outside counsel
Worker's compensation
Clearinghouses
Subcontractor for billing services
Test problems
Reagent problems
Lawsuits
Drugs of abuse testing
Health oversight (accrediting bodies, CLIA, etc.)
Waste management
Audit
Eligiblity

How are the data used?

Compare inputs, outputs against privacy, security rules & identify gaps.
In this process, evaluate your lab as:

- Provider of services
- Employer of individuals
- Customer/recipient of services from a vendor

Virtually all lab processes are impacted, so you'll need to map all processes and projects and pinpoint high-risk areas

Acquiring customers
Collecting, transporting specimens
Processing specimens
Testing specimens
Reporting test results
Billing, collecting payment
Managing customer relations

physical and systems security means, but for HIPAA purposes, the actionable course is determined by how privacy and security are defined in the regulations. This applies to other crucial terms such as covered entities, business associates, protected health information, use, disclosure, etc.

In sum, Silverman pointed out, map your HIPAA compliance according to the precise terms of the regulations. Concentrate on getting this right at the outset in order to focus your implementation campaign effectively.

Citing confusion among some providers, Monte stressed that labs should note an important distinction: "Privacy deals with how and to whom data are disclosed. Security deals with how the data are stored and accessed."

While the security standards have yet to be finalized, Monte noted that many of the proposed requirements represent what the business sector already recognizes as "good practices," including use of passwords, encryption, firewalls, and physical disaster contingency plans.

Among specific things to note:

- Test where security measures are vulnerable. One way to do this is to have some of your HIPAA team try to hack into your systems.
- Tackle security not just as an information technology issue, but also its physical aspects.

In a concluding observation, Monte said that most organizations are getting prepared for the system changes required under HIPAA, but what about the people involved? Getting employees engaged with the HIPAA effort through planning, education, and training will remain a major challenge in the months and years it will take most entities to achieve HIPAA compliance.

Work with all your departments, she advised. Help them consider how HIPAA will impact on their various functions and what will happen if compliance is not achieved. "Get them involved sooner, rather than later," she reiterated.

Bush Administration Implements Privacy Rule As Scheduled

In what caught some observers off-guard, President George W. Bush announced earlier this month that a controversial final rule governing medical privacy under the Health Insurance Portability & Accountability Act (HIPAA) would take effect as scheduled on Apr. 14, 2001. Covered entities have up to two years from then to become compliant.

The final rule was published this past Dec. 28 by the outgoing Clinton Administration, but the comment period for it was extended by the Bush Administration to Mar. 30, creating wide speculation that the rule's effective date could be postponed (*G-2 Compliance Report, Jan. '01, pp. 1, 3-4*).

The "go-ahead" from President Bush means that providers will now be required to begin complying with the privacy standards set forth in the rule by Apr. 14, 2003. Small health plans have an extra year to comply.

Changes Still Due

Noting in a White House statement that new technologies have made it more difficult at times to protect personal medical information, the President stressed that his Administration would protect both vital healthcare services and the right of every American to have confidence that their personal medical records remain private.

Bush noted, however, that he shares "the legitimate concerns raised about the final rule" and has instructed Health & Human Services Secretary Tommy Thompson to recommend appropriate changes.

In a separate statement released after the White House announcement, Thompson emphasized that patient privacy has been debated in the Nation's Capital for the better part of a decade and the Bush Administration believes it is now time to act.

However, based on about 7,500 new written comments received during the extended comment period, Thompson pointed to a number of key concerns that his Department intends to address, either through guidelines or through recommended changes to the final rule:

- Consent form provisions are due for modification so that patient care is not unduly hampered by confusing requirements. One example noted relates to pharmacists who would be able to fill prescriptions over the phone to serve their customers in a timely manner.
- Providers will be given access to necessary medical information about their patients, including giving physicians the ability to consult with other physicians and specialists regarding a patient's care.
- Parents will have access to information about the health and well-being of their children, including information about mental health, substance abuse, or abortion.

At press time, it was not clear when or how the HHS Office of Civil Rights, which is charged with both educating covered entities about the privacy requirements and enforcing the rule, will issue guidance. It is also unclear whether the modifications to the final rule mentioned by Secretary Thompson will be announced prior to the issuance of any guidelines.

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than 10% of doctors' offices have done so. "It's going to be a big shock for some of them when they are told they have to buy these items."

Blunt Advice From OSHA

The practice of giving free supplies without involving front-line workers "absolutely needs to change," says an OSHA official.

"Under all our rules, the employer is responsible for any injuries that occur in the workplace, and in this case the hospital is the employer. It doesn't matter who's supplying the devices. The lab as a third party is not responsible, the hospital is, and it needs to have a 'buy-in' because of that.

"It's [the employer's] responsibility to have the actual healthcare workers, the phlebotomists or others, involved in the choice of needles."

But how that involvement is defined is completely up to the employer, the official notes. "It just needs to be active. Whether it means doing a case study with devices or seeing in a simulated setting how to use the devices—it really doesn't matter as long as there's active involvement."

OSHA's Office of Health Compliance Assistance gets about 50 calls a day on complying with the safety needle provision of the bloodborne pathogen standard, the official says, maintaining that fears of added costs—a frequent concern—are not justified.

"As part of our compliance directive of November 1999, there is a cost analysis worksheet, and you'll find that what you pay in medical and worker's compensation costs when you don't have safety needles more than justifies the expense."

Changes At Cal-OSHA

California, which has required safety needles since 1998, is in the process of adding a requirement for end-user evaluation. "That's the one aspect where the federal law goes a little further than ours," says Len Welsh, special counsel for Cal-OSHA. "We're amending our regulation to include that provision."

The products currently available from vendors vary quite a bit in quality and effectiveness, he adds. His agency will avoid making a blanket determination that some devices are effective and others aren't. "Part of our definition of a sharp with engineered sharps protection is that it has to be effective in preventing exposure incidents. It doesn't have to be the most effective out there, but it has to be effective."

Generally Cal-OSHA prefers passive prevention—devices where no extra action is required by the user to engage the safety mechanism—but because of the variation in medical procedures for which the devices are used, "we absolutely don't want to interfere with a hospital in making the choice."

However, that flexibility only goes so far. One of the difficulties California hospitals have had with switching to safety needles, he reports, is that they may get volume discounts in contracts with one supplier, and "sometimes that conflicts with their need to have different safety device options available for people. They'll ask us 'Can we just get the best device available with our contract?' We say 'No, you have to get the device required.' We don't get involved in contract difficulties."

Resources

- Sheila Dunn: 828-645-3661
- OSHA Office of Health Compliance Assistance: 202-693-2100. OSHA Compliance Guidance Group: 301-515-6796
- Our previous coverage: "OSHA Update: New Safety Needle/Recordkeeping Requirements," Mar. '01, pp. 5-8

Reimbursement Alert

Pap Smear Fees Capped

In our February issue, we pointed out that it was up to providers to ensure they get paid no less for Pap testing than Medicare's national minimum payment floor of $14.60.

Effective Apr. 1, many of the codes subject to the floor now have a ceiling, or maximum Medicare allowable, of $28. They are:

Diagnostic (CPT code)	*Screening (HCPCS code)*	*Descriptor*
88142	G0123	Thin layer prep, manual screening
88143	G0143	Thin layer prep, manual screening, rescreening
88144	G0144	Thin layer prep, manual screening, computer-aided rescreening
88145	G0145	Thin layer prep, manual screening, computer-aided rescreening using cell selection, review

Fee caps have also been set for 88147/G0147, performed by automated system ($14.60/$15.73) and 88148/G0148, performed by automated system, with manual rescreening ($20.30/$21).

Unlike other tests on Medicare's lab fee schedule, which are capped at 74% of the national median, the above tests are capped at 100%. This marks the first time that the Health Care Financing Administration has used its new authority to set fees at this level for tests that it determines to be new and uncapped prior to Jan. 1, 2001.

The fee changes were incorporated in the revised 2001 lab fee schedule sent recently to Medicare contractors. While HCFA says the changes are effective for services on or after last Jan. 1, it tells contractors not to retract payment or retroactively pay claims for such services dated prior to Apr. 1.

Source: HCFA Transmittal AB-01-42. CPT codes © American Medical Association.

COMPLIANCE PERSPECTIVES

Top 10 FAQs About Voluntary Disclosure:
Perspectives From An Attorney & An Auditor

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Since the HHS Office of Inspector General (OIG) issued its Voluntary Disclosure Protocol in October 1998, healthcare organizations have struggled with questions about the voluntary disclosure experience, especially the threshold issue of whether to disclose matters under the protocol.

Having worked with a number of such organizations on disclosures of various issues, we have identified and answered the "Top 10" frequently asked questions about the voluntary disclosure process and outcomes.

1 *What should a healthcare organization do, once it has identified a potential problem?*

VALIANT: The first order of business is to attempt to get your "arms around" the issue, and its scope and effect, if any, on federal healthcare programs. Consider involving counsel (in-house and/or outside) at this point to obtain attorney-client privilege for the investigation and its work papers.

As soon as you determine that the issue identified is, in fact, a problem, take immediate corrective action to stop or hold potentially affected billings until the cause of the problem is detected and corrected so that appropriate submission of claims can resume.

Also, depending on the nature and extent of the problem, consider whether any individuals who caused the problem should be isolated from the investigation and/or removed from their departments while the investigation is ongoing. In instances of deliberate wrongdoing, it may even be appropriate to consider termination of culpable individuals, but this is a step generally considered only for egregious activities, and decisions of this nature should generally be made only when the investigation has progressed to the point where all the relevant facts are known.

STANTON: A critical component of the initial internal investigation is to determine if there was a reimbursement impact from the potential problem. To evaluate this, consider all the reimbursement mechanisms in place at your facility during the years affected. For example, does the issue impact only Medicare inpatient services reimbursed through DRG-based payments? If so, there may not be any overpayment at all. Or does the potential problem impact cost-based reimbursement, either directly or indirectly, so that an overpayment may have occurred?

2 *What are the advantages of voluntary disclosure?*

VALIANT: The primary advantage is that you have greater control over dealing with the government. So long as the disclosure is accurate, a healthcare organization should not be subject to government investigatory "raids," surprise "subpoenas," and the like, and should be granted ample time and opportunity to gather information and respond to government questions. Greater control over the process and the materials disclosed also makes it less likely that other issues will be identified by the government in the course of the investigation.

Another advantage (though far from guaranteed) is that the government may decline to pursue the case under the False Claims Act, and instead refer it to the Medicare carrier or fiscal intermediary for overpayment collection. This has occurred in some of the voluntary disclosures regarding hospital pneumonia coding. Thus, while pneumonia coding is being pursued and settled by various U.S. attorney's offices as a false claim matter (with multiple damages and OIG–imposed corporate integrity agreements or CIAs), essentially the same matters disclosed using the OIG protocol are being referred to intermediaries for a straight overpayment refund, with no ongoing CIA obligations.

STANTON: The government will typically view organizations that

voluntarily disclose billing problems more favorably. The OIG has stated "that the self-reporting of wrongdoing could be a mitigating factor" in its recommendations to prosecuting agencies.

3 How quickly should an identified problem be reported?

VALIANT: OIG compliance guidance says 60 days, calculated from when there is "credible evidence of a violation." This standard generally provides an opportunity to investigate whether an identified issue is actually a problem (a "violation") before making a disclosure, and to do some initial quantification work to see if there is any impact on federal healthcare programs, but it is generally not sufficient time for a full quantification.

This is significant because initial quantification attempts usually sweep with too broad a brush and produce much higher amounts than the ultimate, appropriate result. Sharing these early results with the government may create unwarranted government expectations as to the size of the refund, and also may create more of an appearance of impropriety than the matter warrants. In such circumstances, a preliminary disclosure without including a quantification may be desirable, especially when there are potential "whistleblowers" who may jeopardize the "voluntary" nature of the disclosure if the disclosure is delayed. The OIG has been willing to accept such preliminary disclosures under the protocol and to grant a reasonable amount of time for quantification.

For entities already under a CIA, the CIA contains specific instructions on reporting and repayment obligations which must be followed.

STANTON: In all but the simplest of cases, it takes much longer than 60 days to do a thorough investigation of potential Medicare overbilling. It is important that all the pertinent facts be gathered and analyzed. This may entail retrieving old records, interviewing current and former employees, and conducting audits of coding or billing transactions, not to mention the process of drafting all the information required under the voluntary disclosure protocol.

4 Where should the problem be reported?

STANTON: The OIG's protocol is intended for situations where there is potential violation of federal criminal, civil, or administrative law. Overpayments or billing errors that do not suggest intentional violations can be brought to the carrier or fiscal intermediary. If you report a significant issue or one that raises concerns about the integrity of the provider, the carrier or intermediary may refer the matter to the OIG.

VALIANT: In addition to the carrier or intermediary and the OIG, another possible disclosure option is to go directly to the U.S. attorney's office. Few organizations choose this route directly, believing it may heighten the appearance of impropriety, but they should not be surprised if that office gets involved following an OIG or intermediary/carrier disclosure. Remember, the identified deficiency may also impact state Medicaid programs, and a disclosure there may also be warranted.

In determining whether to use the OIG protocol, consider whether the matter is likely to be referred to the OIG if reported to the intermediary or carrier. This is likely, for example, if the matter being reported has been included in the OIG's Work Plan or has been the subject of other government settlements. If so, the matter is likely to be referred to the OIG, irrespective of any initial carrier/intermediary disclosure. Other matters may not lend themselves to carrier or intermediary reporting because they involve possible deficiencies in areas beyond billing, such as marketing, waivers of coinsurance, and the like.

National organizations reporting matters that occurred over a multi-carrier or multi-intermediary geographic area may find useful the national coordination aspect of the OIG protocol. In some circumstances, it may be helpful to orchestrate a disclosure to all the relevant government agencies at approximately the same time, so that all work to resolve the matter efficiently and quickly from the outset.

5 How should an overpayment be quantified? Must the OIG protocol be strictly followed? Can underpayments be netted out?

STANTON: The OIG's protocol describes in great detail the process you should use to quantify the amount of overpayment. The best approach, if the situation permits, is to recalculate the amount for each of the claims affected. Of course, this is only feasible if there is a small number of claims or if data for each affected claim can be electronically extracted and recomputed.

In other situations, the protocol stipulates that a statistical sampling approach be used. The advantage of this is that it enables you to test on a sample basis, rather than on a large volume of claims, and then extrapolate the sample results to the entire population. The protocol sets two of the key statistical parameters: a 90% confidence and a 25% precision level. Population size (such as the number of potentially affected claims, total inpatients, etc.) is also a factor affecting the sample size, but typically has less impact than the other variables. The other parameter that you need to establish a sample size is the expected error rate in the population. It is often difficult to estimate this, unless you have already done some testing. The protocol prescribes using a probe sample of 30 or more items to de-

termine the expected error rate.

Once the sample size is determined, it is highly recommended that the selection be made randomly. The OIG recommends use of a statistical sampling software program, RAT-STATS, made available by the government (*www.hhs.gov/progorg/oas/ratstat.html*). This program can be used to determine the sample size, to generate random numbers for making the sample selection, and to calculate the sample results.

The protocol says that the sampling plan must include a discussion of how missing sample items were handled and the rationale. There is a discussion of this common occurrence in the OIG's CIA guidance: if the provider cannot produce supporting documentation for a unit selected in the sample, this unit should be considered an error. We believe it is not statistically valid to treat it as an error, just as it would be inappropriate to treat it as correct. A better alternative would be to select a random sample slightly larger than the minimum under the sampling parameters to allow for some items that may not be able to be located. You would then use all of the items tested in quantifying the sampling results.

The protocol does not specifically address how underpayments identified in the sample should be addressed. The OIG states in the CIA Guidance that, for purposes of reporting overpayments to the OIG, underpayments should not be netted (or offset) from overpayments, but, in terms of repaying overpayments to the appropriate payer, the provider should consult with that payer as to whether it will allow underpayments to be netted from overpayments for collection purposes. If the underpayments result from the same issue that created the overpayments, our recommended approach is to consider the underpayments in calculating the net amount due to the government. At the same time, it would not be appropriate to offset underpayments from a totally separate matter against amounts being refunded in a voluntary disclosure. In this situation, you should seek recovery of the underpayments through the normal channels with the fiscal intermediary or carrier.

VALIANT: If it is possible to determine overpayments potentially at issue on a claim-by-claim basis, it may be possible to refund the overpayment on that basis over time, as each claim is researched to determine if an overpayment exists. This is not a recognized methodology of the OIG protocol, but one that may be attractive to healthcare organizations nonetheless. This gives you the option of simply returning each separate overpayment identified, using the carrier or intermediary's overpayment return form. Of course, this type of return does not provide any "release" from the government, and the question remains as to how much "credit" the government will give the organization if it receives a government demand (*e.g.*, subpoena or letter from the U.S. attorney's office) at some point before the overpayment return process is complete.

6 *How should an organization accomplish repayment? Send a check with the disclosure? Put the money in escrow? Wait and see?*

STANTON: The OIG will not accept payments of presumed overpayments until it has signed off on the voluntary disclosure. The protocol encourages depositing estimated overpayments in an interest-bearing escrow account. This will stop the accrual of interest the government may assess on the overpayment and demonstrates to the OIG that you are committed to resolving the matter.

VALIANT: Many healthcare organizations want to send a check with the disclosure in the hope that the government will simply accept the check and close the matter. This virtually never happens, as the government is obliged to ensure the accuracy of the amount repaid. Additionally, having the money "in hand" may even slow the government's consideration of the matter. Interest-bearing escrow should serve as a sufficient showing of "good faith" while giving the government an adequate incentive to move the disclosure process toward closure.

7 *What should be expected, once the disclosure has been made?*

VALIANT: It is important to maintain realistic expectations. Again, those who believe they can simply "write a check" and not deal any further with the issue are likely to be disappointed. The government will expect to "kick the tires"—perform some "due diligence"—with respect to the internal investigation. The government may request interview notes from that investigation and/or conduct its own interviews of personnel. It may request meetings with the organization's statistician and/or internal quantification personnel to assess the accuracy of the quantification, as well as to assess whether the overall results suggest "fraud" or merely overpayment. The government's goal usually is not to "re-do" the investigation and quantification, but to do enough of a check to judge that it is reasonable to accept the disclosure and close the case.

STANTON: The OIG will need to take all of the steps it feels are necessary for its due diligence before agreeing to a repayment. There will typically be a close review of all the documentation provided. Depending on the nature of the overpayment issue, the OIG may involve its own consultants (such as auditors or coding specialists) to assist in reviewing your disclosure document and quantification. This use of ex-

perts often expedites the review and evaluation process.

The OIG has an obligation to verify the results of your self-assessment and ensure that your internal investigation was thorough and comprehensive. Expect to have interaction with the OIG and its consultants. It is helpful to offer to meet with them to explain your self-disclosure either in person or by conference call. You may also be asked to provide additional supporting documentation, answer specific questions, or make personnel available to be interviewed. The clarity and completeness of your self-disclosure document will influence the amount of follow-up necessary.

8 *How quickly will the disclosure be resolved?*

VALIANT: Healthcare organizations that expect voluntary disclosures to be resolved rapidly may be disappointed. Since voluntary disclosures generally cause the government to be less concerned that your organization is a "wrongdoer," they often sit on the "back burner." This is especially true where the organization's results are placed in an interest-bearing escrow account or where a check is included with the disclosure.

STANTON: These matters always seem to take longer than anticipated and there are often times when you think it is close to being finalized, only to have new questions or data requests arise. Keep in mind that just as it was important for you to be deliberate and cautious in performing your assessment and preparing the disclosure document, the OIG will have the same need. Be patient and responsive while continuing to be careful and deliberate. Don't let your desire to reach an expeditious outcome cause you to "throw caution to the wind."

9 *What should the disclosure report look like?*

VALIANT: It should be a complete package that tells the whole story of the identified problem—what it is, its scope both in time and impact on the organization's lines of business, how it was discovered, and how you know it has been corrected. The OIG protocol emphasizes "naming names" of who were involved in the problem, but in most organizations, the issue is not a matter of assigning blame to one individual or a group, but usually is a result of systems error or organizational shortfalls (the "fell through the cracks" syndrome). There also is a tendency among healthcare organizations to concentrate wholly on the quantification piece of the disclosure, but the OIG is also very interested in the compliance culture and the processes of the organization—especially in ensuring that the problem is fixed—and the report should be sure to address these areas.

STANTON: The OIG protocol does a thorough job of describing the desired elements of the voluntary disclosure document. The key here is to provide enough details and supporting documentation to explain the situation and allow the OIG to assess what you did, without providing more information than necessary.

The right balance is a matter of judgment and the key people involved should reach this determination with advice from experienced counsel and consultants. You don't want to provide extraneous information that may raise other issues or distract the government from the specific matter being reported. On the other hand, if you provide too little detail, the OIG may become concerned that you are withholding facts because there is something to hide.

10 *What can I expect the outcome to be?*

VALIANT: The best outcome that can be expected is for the OIG to refer the matter to the fiscal intermediary or carrier for an overpayment collection. In such circumstances, there is no official "settlement agreement" and release, but the organization can expect a "close the file" letter from the OIG.

If the matter stays in the OIG protocol and is settled, the settlement becomes a matter of public record and may be the subject of a government press release. If the organization pays a damages-multiple in settling, then a "release" with respect to the settled conduct should be requested from the Justice Department, as well as declination from the OIG to use its exclusion authority.

Healthcare organizations also should expect some kind of Corporate Integrity Agreement—sometimes called a Corporate Compliance Agreement (CCA)—in voluntary disclosure matters, with ongoing compliance obligations and reports to the OIG. The compliance obligations associated with a CCA should be less onerous and cover a shorter time period (three years vs. the minimum five years now expected for non-disclosure CIAs). It also is more likely that any claims review requirement will call for internal claims review only, as opposed to an independent audit.

STANTON: One element of a negotiated OIG settlement will be a requirement to monitor and audit to ensure that the organization stays in compliance with the matter being disclosed. Under voluntary disclosure, you will generally be able to conduct a self-audit as part of your annual compliance plan, using your internal audit function or other internal personnel. Of course, you may choose to have outside auditors or consultants perform this for you, but that will be at your choosing, unlike in more onerous CIAs where you must engage an independent review organization.

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Justice Dept. Is Doing Better Job With False Claims Guidance, GAO Finds

The Department of Justice has strengthened its oversight of how well local U.S. attorney's offices adhere to top-level guidance on using the False Claims Act (FCA) against healthcare providers, concludes a recent report by the General Accounting Office, a congressional watchdog agency.

GAO scrutinized the Department's handling of two national investigations: the Pneumonia Upcoding Initiative and the Prospective Payment System Transfer Initiative. Both target hospitals that may have received more reimbursement from Medicare than they were entitled to.

The Pneumonia Upcoding project assesses whether hospitals have billed improper DRG codes in order to obtain higher reimbursement. The PPS Transfer project identifies hospitals that have incorrectly reported patient transfers between hospitals as discharges.

GAO's finding: Justice is conducting both projects in a manner consistent with the FCA guidance.

The guidance was intended to emphasize the importance of pursuing cases in an even-handed manner and to implement new procedures for national investigations.

Before false claim violations are alleged, Justice now requires government prosecutors to determine that the facts and the law sufficiently establish that the provider knowingly submitted false claims. The national probes are developed after data analyses indicate that numerous, similarly operating providers are engaging in comparable conduct to bill the government improperly.

Lab Unbundling Got The Ball Rolling

Use of the FCA against healthcare providers has been widely criticized by provider interests as being overly aggressive in pursuit of improper Medicare billings through a series of nationwide investigations, known as national initiatives or projects.

The issue was brought to a head in 1998 when many hospitals charged that the Justice Department had conducted unwarranted investigations and demanded large penalties for unintentional errors related to billings for outpatient lab tests.

Stung by criticism from hospitals and legislators alike, Justice issued the FCA guidance to U.S. attorneys in June 1998. Congress subsequently required GAO to monitor the implementation of the guidance.

Interestingly, in an August 1999 report, GAO said that Justice's implementation processes appeared superficial and that U.S. attorneys were not consistent in following and applying the guidance. But by March 2000, GAO found that Justice had made major strides in its oversight duties and that local offices appeared to have addressed their previous shortcomings.

Also Noted By GAO

The latest GAO report says that consistency in FCA use is promoted by working groups which coordinate the national initiatives and keep regular contact with local U.S. attorney's offices to assure compliance with FCA guidance. These groups are composed of Justice Department attorneys and assistant U.S. attorneys. They help develop detailed claims data and other relevant material, including each hospital's unique circumstances.

Finally, GAO says that in response to its previous recommendations, Justice has revamped its process for periodically evaluating FCA compliance by local U.S. attorney's offices and has instituted an annual compliance certification requirement for all such offices participating in national initiatives.

Hospital association representatives contacted by GAO still expressed concerns about the appropriateness of the Justice Department's use of FCA in civil healthcare matters, but "did not identify specific examples of non-compliance with the FCA guidance among U.S. attorney's offices."

Resource

- GAO report, *Medicare Fraud & Abuse: DOJ Has Improved Oversight Of False Claims Guidance*, www.gao.gov

Latest Draft Of Lab ABN: Sleeker, Simpler

The newest version of a uniform, standardized format for a Medicare advance beneficiary notice (ABN) for laboratory use was previewed Mar. 26 at a meeting of the Practicing Physicians Advisory Council in Washington, DC. The Council advises the HHS Secretary on Medicare issues.

Key features of the draft lab ABN:

- It's been trimmed to a single page.
- Beneficiaries have two choices: "Option 1: Yes, I want to receive these laboratory tests" or "Option 2—No, I have decided not to receive [them]."
- The estimated cost of the test would have to be supplied to inform the beneficiary of potential financial liability.
- It's up to the beneficiary, not the lab, to let the physician know that the testing ordered has been declined. When choosing Option 2, the beneficiary agrees to be responsible for notifying the doctor.
- Space is provided for the user to list the tests affected by non-coverage, frequency limits, or experimental/research use.
- There is room at the top for a lab to imprint its logo, name, address, and telephone number.

Sources within lab groups still wonder how feasible the form will be in actual practice, but before any version becomes final, it must undergo further government clearance and a round of public comment. The lab ABN is being developed within the consumer protection unit of the Health Care Financing Administration's Center for Beneficiary Services.

More COs, *from page 1*

budgetary responsibilities and staff, while 74% said their compliance department is separate from their auditing department.

Nearly 60% of the organizations said the CO is part of the senior management team, while 19% say he/she is in middle management and 19% say he/she is an officer of the company.

More and more COs report to high-level management: 58% report to the chief executive officer/president; 15% to the board of directors; and only 4% to the general counsel or legal department.

However, organizations with more than 5,000 employees are twice as likely to have their COs report to the general counsel.

Reporting To General Counsel

John Steiner, director of corporate compliance for the Cleveland Clinic Foundation and chief CO for the Cleveland Clinic Health System, believes an office separate from the general counsel is critical.

"This issue comes up all the time. 'We don't have the money, we don't have this, we don't have that.' But if you look at the intent of the government guidelines, the separateness of the office serves many legitimate purposes. It's legal, it's practical, and to do otherwise would be wrong. There's a clearly stated policy rationale in both the U.S. Sentencing Commission guidelines and the OIG's guidance."

In his organization, the CO reports directly to the audit committee, the CEO, and a compliance committee which includes representation from senior management.

But at BJC Health Care, a 10-hospital system in St. Louis, MO, the CO reports to the general counsel, and there's never been a problem, says corporate compliance officer David Ledbetter. "The OIG recommends against it because [it says] there could be a potential conflict, but I don't see the conflict."

At Laboratory Corp. of America, the corporate CO, Bradford T. Smith, reports to the company's CEO. Smith, who is executive vice president for public affairs, law, compliance, and human resources, also sits on LabCorp's six-member executive committee.

It's important, Smith says, that the CO be "high enough so that you're a player and a part of business decisions at an early enough point so that compliance considerations" are taken into account. Ideally, compliance should be woven into "the way you do your job normally."

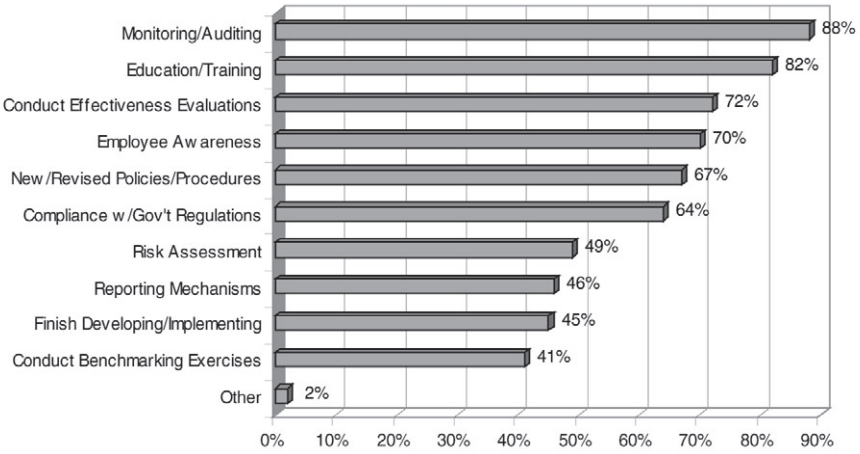
On the other hand, Quest Diagnostics has had its corporate CO report to the general counsel's office since 1999, says Michael Prevoznik, who assumed the firm's top legal position that year. Viewing compliance as part of daily business and attempting to "operationalize" it within the company, Quest now has a non-lawyer as head of compliance, Karen Straub, who has over 25 years' experience in the lab business.

A Declining Trend

The data show that having the CO under the general counsel is a decreasing trend. "The ones who are doing it are being deluded," maintains Brent Saunders, founder and past-president of HCCA. Rather, the CO usually reports to a senior officer, a CEO, and in a small but growing percentage, directly to the board of directors, he adds.

"The OIG has issued several guidance documents that most clearly indicate it is *not* a best practice to have a compliance officer in a subservient role to either the general counsel or any financial officer."

Below are specific goals that healthcare compliance officers hope their program will achieve in the next three years (results add to more than 100% because survey respondents said they had more than one goal).



Top 3 Goals: 1999-2000

2000
1. Monitoring/auditing (88%)
2. Education/training (82%)
3. Evaluate effectiveness (72%)

1999
Development/implementation (52%)
Education/training (51%)
Monitoring/auditing (41%)

Source: *2000 Profile of Health Care Compliance Officers*, Health Care Compliance Association. Surveys were sent to a random selection of 3,429 healthcare compliance professionals; 715 completed surveys were returned. About one-third of respondents were from hospitals, and another third from health systems.

Resources

- John Steiner: 216-444-1709
- David Ledbetter: 314-286-0661
- Bradford T. Smith: 336-436-5050
- Brent Saunders: 202-822-4089
- HCCA survey: *www.hcca-info.org*

Local Coverage Decisions To Be More Open & May Be Appealed, Says HCFA

The current process by which Medicare contractors make local determinations as to Medicare coverage of certain items and services is being gradually replaced by the Health Care Financing Administration in favor of a modified approach that allows more public input into local policies. Once fully operational, providers also will be able to appeal local policies.

HCFA plans to eliminate local medical review policies (LMRPs) altogether over the next three years, said agency official Gina Perantoni, who spoke Mar. 28 at the American Health Lawyers Association's Institute on Medicare & Medicaid Payment Issues. Perantoni is with HCFA's Program Integrity Group.

Since last November, HCFA has required Medicare contractors to allow specific input from the public during LMRP development and to make draft and final LMRPs more accessible, including having them posted on the Internet.

Why Providers Criticize LMRPs

Local medical review policies are defined in neither law nor regulations, but medical directors of local contractors may develop them to limit coverage and payment for items or services not subject to a national coverage decision by HCFA. This includes determining whether an item or service is "reasonable and necessary" in their local jurisdictions.

LMRPs have been widely criticized by provider groups because they are written with little public input or accountability and often lead to lack of consistency among contractors in processing claims.

But the push behind HCFA's move away from the old LMRP process was last year's Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act (BIPA). The Act defined in law a new term "local coverage determination (LCD)," Perantoni said. By this spring, contractors will be instructed to write LCDs, but only need include the "reasonable and necessary" elements of the LMRPs, she noted.

Defining "Reasonable & Necessary"

A "reasonable and necessary" service is defined by HCFA in a notice of intent as one that is demonstrated to be effective and appropriate in that it meets, but does not exceed, a beneficiary's medical need. Rules such as those pertaining to coding, statutory exclusion, and benefit categories that are now part of LMRPs will not be covered in LCDs; rather, they will be published in provider bulletins, Perantoni explained.

Significantly, LCDs will adhere to the public input policies now established for LMRPs, but unlike the current system, will be appealable, effective Oct. 1, 2001, as required by BIPA. LCDs can be appealed through HHS administrative channels and ultimately to federal court, Perantoni said.

OIG To Look More At Quality Of Care

The HHS Office of Inspector General is likely to shift more of a focus to quality of care issues as it revises its compliance guidance to diverse healthcare sectors. The guidance to date has concentrated on billing, payment, and coding problems; however, the OIG has tackled quality issues in its warnings to hospitals against "patient dumping."

The revisions will make the compliance guidance "more relevant, less burdensome, and more attractive," said the assistant IG for legal affairs, Lewis Morris, at an Apr. 6 compliance forum held by the Health Ethics Trust.

Updates are needed, he said, because some of the payment systems for various healthcare providers have been switched by Congress to prospective payment, including outpatient, nursing home, and home health services.

Two new guidance documents are due next, Morris said: one for the ambulance industry, the other for drug manufacturers. While the latter do not bill Medicare directly, they do have a financial impact on the program, one that will intensify if a prescription drug benefit is added.

Audit Help

More streamlined audit requirements are also on the OIG agenda. Morris said the Office is working with a national accountants group to improve the audit mandates for corporate integrity agreements. The aim is to help providers avoid having to do audits that are more detailed than necessary to demonstrate that their billings are accurate.

The audit rules under such agreements can prove quite expensive, often requiring a provider to hire an independent review organization.

The New IG?

Meanwhile, the Bush Administration is said to be close to picking its choice for HHS Inspector General, a post requiring Senate confirmation. The likely nominee reportedly is Janet Rehnquist, an assistant U.S. attorney for the Eastern District of Virginia (Alexandria) and the daughter of U.S. Supreme Court Chief Justice William Rehnquist. The previous IG, June Gibbs Brown, retired on Jan. 3 for health reasons. She had served since 1993.

The Back Page

News-At-A-Glance

HCFA Picks: Hospital executive Thomas A. Scully is President Bush's choice to head the Health Care Financing Administration, a post requiring Senate confirmation. Scully has been president and chief executive officer of the Federation of American Hospitals since 1995. He was deputy assistant to the President and counselor to the head of the Office of Management & Budget from 1992-93 and was OMB assistant director for human resources from 1989-92.

For the #2 slot at HCFA, HHS Secretary Tommy Thompson has named Ruben King-Shaw Jr. as deputy administrator. King-Shaw has been secretary of Florida's Agency for Health Care Administration since 1998. From 1995-98, he was chief operating officer of a managed care company operating in Dade, Broward, and Palm Beach Counties and in Orlando and Tampa.

Stark II Extension: The deadline for comment on the Stark II final rule has been extended from Apr. 4 to June 4 to accommodate requests for more time to analyze the consequences of the complex regulation on the wide variety of financial relationships to which it applies. The extension was announced by the Health Care Financing Administration in the Apr. 4 *Federal Register*. Stark II prohibits physician referrals for designated health services to entities with which the doctor (or an immediate family member) has a financial tie, if payment is to be made by Medicare.

Paying For Another's Fraud: Two Connecticut hospitals—Yale-New Haven and St. Mary's—must repay over $8 million to Medicare after being overpaid based on cost reports falsified by their fiscal intermediary. The settlements were announced Mar. 30 by Stephen Robinson, U.S. attorney for the District of Connecticut. One other hospital is being investigated. Last year, the U.S. attorney settled similar charges against four other hospitals for about $9 million.

The hospitals were overpaid when Blue Cross & Blue Shield of Connecticut falsified cost reports to conceal its failure to meet Medicare's contractor performance standards, the government said. The successor company, Anthem Health Plans, settled the case for $74 million in December 1999.

According to the government, employees of BCBS/Connecticut attempted from 1989-91 to conceal previous excessive payments by underreporting the actual payments, and either making additional payments as refunds to the hospitals or failing to recover overpayments to them. The federal probe began when the Hospital of St. Raphael notified the HHS OIG in May 1998 that it had received overpayments of about $6 million in 1989-90.

More Funding For OIG: The fiscal 2002 budget request for the Department of Health & Human Services allocates $186 million for the HHS Office of Inspector General, an increase of $22 million over FY 2001. The lion's share of the OIG budget—$150 million—goes to health-related anti-fraud activities mandated by the 1996 Health Insurance Portability & Accountability Act, an OIG spokesperson confirms.

In related news, the HHS budget also contains $1.52 billion for Medicare contractors, an increase of $165 million over the fiscal 2001 appropriation. About two-thirds of the FY 2002 contractor budget would be spent on processing Medicare claims, according to HHS.

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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