G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. III, No. 3, March 2001

For Hospitals, Laboratories and Physician Practices

CO Salaries Dip, CO Dept. Status Rise

Despite reported decreases in salaries for healthcare compliance officers, compliance departments themselves are gaining status within healthcare organizations, according to preliminary data from the Council of Ethical Organizations (Alexandria, VA).

In its latest *Compliance Officer Salary Survey* (for the year 2000), the Council reported that the average salary of healthcare COs was $103,400—$5,980 less than in 1999.

But more compliance departments are being run within their organization's corporate office as a stand-alone unit with more staff.

Even when it comes to salaries, not all is bad news, Mark Pastin, president of the Council, told *G-2 Compliance Report*.

Though salaries on average slipped, most COs probably saw a slight increase in their pay level last year, he said.

Two factors contributed to the reported decline, Pastin told us.

❖ First, with each passing year, the proportion of healthcare entities that have COs on a mandatory basis is decreasing. More are voluntarily hiring COs, rather than hiring one when the government is about to impose a corporate integrity agreement (CIA). "Those hired in a voluntary environment typically get paid less than those hired in a settled CIA environment," Pastin observed.

❖ Second, COs who make less are more likely to fill out a survey than those at the higher end of the pay scale.

When these two factors are considered, the average CO probably saw a slight growth in salary during the past year, Pastin said.

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GOP-Led Congress Axes Ergonomics Rule

The House and Senate, voting largely along party lines, have killed the highly controversial ergonomics rule intended to reduce and prevent work-related musculoskeletal disorders, including back injuries and repetitive stress injuries. President George W. Bush has said he will approve the congressional action.

The rule was finalized late last year by the Labor Department's Occupational Safety & Health Administration. Some 10 years in the making, it was staunchly supported by organized labor, but business/health industry groups attacked it as too costly and intrusive.

To kill the rule, lawmakers invoked for the first time their override authority under the 1996 Congressional Review Act, which established a streamlined way to undo federal rules.

The rule would have impacted over 6.1 million worksites, including most healthcare employers, requiring them to "fit the job to the worker."

Critics charged that employer compliance costs could soar to $100 billion. OSHA pegged the costs at around $4.5 billion annually, but said this would be offset by $9.1 billion in annual savings.

Inside this issue

Going Down The Road Of HIPAA Compliance: *More For Your Checklist*

Last month, we presented the first two phases of a five-phase process that can help you manage your organization's compliance with electronic data exchange requirements of the 1996 Health Insurance Portability & Accountability Act (HIPAA).

The five-phase process was developed by Strategic Management Systems (SMS—Alexandria, VA).

We looked at the stages of awareness/education and self-assessment/gap analysis.

This month, we focus on the remaining three phases:

—Project Preparation

—Implementation

—Ongoing Monitoring

As Christopher Coleman, a healthcare policy analyst at SMS, told us: "HIPAA includes both operational and technical requirements covering electronic data interchange, security, and privacy."

Project Preparation

❖ *Establish compliance objectives.*

Once healthcare providers conduct a self-assessment/gap analysis, they have a list of what must be done. The next step is to rank tasks in order of priority and define how and when to complete them.

❖ *Identify resources, both money and people, needed for each objective.*

Coleman recommends starting with personnel. "With an implementation plan that could take two years to accomplish, it's tough to take one requirement—like developing a privacy notice—and put a dollar amount on it." It's easier to assign the task to particular personnel who then can calculate and refine additional resources required.

❖ *Set a timeline for each objective.*

This will enable you to track whether the varied components of your HIPAA efforts are coming together by the compliance date set in federal regulations.

❖ *Establish a monitoring and reporting schedule for your HIPAA project team.*

This enables management to oversee progress and pinpoint major roadblocks.

❖ *Determine the knowledge/experience base needed to accomplish each objective.*

Many areas of HIPAA compliance are quite specific to a particular knowledge/experience base: for example, the intricacies of information technology systems and security systems (like encryption).

A key question is: Do we have the knowledge/experience base in-house or must we go outside our organization to get it?

❖ *List the vendors to which your work is outsourced.*

If it's claims, for example, you will want to know how they are moving toward HIPAA compliance and coordinate with them as needed, Coleman noted.

❖ *List all the companies with which you do business* (the HIPAA rules have specific provisions for "business associates" or, in common parlance, business partners).

If, for example, protected personal health information is to be disclosed to such an associate (like a physician or an insurance company), you'll need a written assurance that the information will not be used improperly.

Implementation

❖ *Take the steps necessary to meet each HIPAA objective you identified in the project preparation phase.*

Do what you've decided has to be done, Coleman said.

❖ *Revise existing policies and procedures as necessary.*

Under HIPAA, new ways of doing business are to be expected, and policies and procedures must be altered to reflect this.

❖ *Develop new policies and procedures as necessary.*

As a corollary, determine if you can do this in-house or should outsource it.

❖ *Implement information technology controls to restrict access to patient information to only those with a "need to know."*

❖ *Conduct employee training at each objective milestone.*

Two types of training are necessary, Coleman told us: first, awareness training that covers all new policies and procedures; second, training that is specific to various HIPAA functions.

❖ *Report regularly to top management on HIPAA efforts*, including the objectives met and any roadblocks remaining.

This is essential to proper allocation of human and financial capital, Coleman said.

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Comment Period Reopened On Privacy Rule

Responding to pleas from business and healthcare groups, HHS Secretary Tommy G. Thompson has reopened—through Mar. 30—the comment period on the HIPAA final rule governing patient privacy.

Pressure to allow additional public comment came from many quarters, including hospitals and other healthcare providers, pharmaceutical companies, health insurers, and charitable organizations. In a Feb. 2 letter, 38 such groups jointly urged Thompson to permit further review, contending that the final version was changed considerably from the original proposal. Among the concerns cited by providers: patient consent requirements and the implementation timeframe.

The rule's new effective date is this Apr. 14, but affected parties have two years thereafter to come into full compliance.

Web-Based Compliance Training: *What You Should Know Beforehand*

Considered a pipe dream not long ago, compliance training on the Web is now a reality. As with any product, e-training requires a thorough review of its capabilities and reliability.

For the lowdown on what to watch for, we talked with two e-compliance specialists—Charles Root, president of MCF Compliance (Barrington, IL) and Rebecca Goodell, vice president of Integrity Interactive (Boston, MA). Here's their list of factors to consider before embarking on e-training.

E-training is great for factual learning, but don't assume compliance buy-in.

"What we're learning from hospitals and labs is that it's the ideal medium for efficiently getting facts into somebody's head," Root says.

"It's great for explaining how Medicare works, the regulations to abide by, and what the coding rules are. But don't expect it to convince people that compliance is an important part of their job. For that, I still recommend one-on-one training."

E-training should test employees' comprehension of the material presented.

"Testing employees upon completion of the module is an important feature of Web-based compliance training," Goodell points out.

The testing should cover key points and, for something as complicated as Medicare compliance, there should be detailed, reality-based testing on many questions, not just one per concept.

Know who wrote the courses.

The generic content must be accurate, Root says, adding "You don't want some MBA writing your courses. You need someone with a legal background because some of this is very subtle."

Know who reviews the courses.

For any technical or compliance training, Goodell says, a regulatory or legal expert in that field should review it for thoroughness and accuracy.

MCF Compliance has set up a non-profit organization composed of attorneys and others in the compliance field who review the courses MFC writes to ensure that they are factual, accurate, and comply with guidance from the HHS Office of Inspector General. The group, called the National Committee on Compliance Certification (NCCC), "is a true third-party review," Root says. "We pay them for every course they review." The group also issues a compliance certificate to every employee who takes and passes the training.

Is the course certified?

Certification can be one good protection against governmental compliance audits. With NCCC, for instance, the certification process is essentially an education/training documentation trail that is independent of the employer.

"The idea is, this is a permanent record you can access. Everyone who gets trained is logged into the database as to which course they took, when they took it, and what the content was," Root points out. "If the OIG ever questioned whether you really trained, you can quickly retrieve the details."

Is the course easy to understand?

Before buying off-the-shelf training or creating it yourself, ascertain if it is engaging. For complicated regulations or guidelines, shop for courses with good visuals and plain-English text to help employees absorb the complexities and nuances.

Some general compliance training programs, like teaching codes of conduct, contain graphics and audio cards to make the learning experience more interesting. But even if it's just text, like much of the preformatted lab training is, you have to ask: Is it written well enough and is it short enough to keep people's attention? Does it keep yours?

Who keeps track of the training?

"Determining who's been trained, when, what they learned, and when they need to be trained again drives most hospitals and labs nuts," Root observes. "So, the management part of your e-training is as important as the content."

There are essentially two ways to go: either buy a management software program or use the e-learning company itself.

Do you buy off-the-shelf or customize?

Off-the-shelf programs are convenient and save time and money. But they should meet some of the other criteria outlined in this article. Customization can put more of your own stamp on the training module.

Some e-training companies allow a degree of customization, including a home page with your organization's logo, a compliance message from the CEO or another

executive, and hotlinks to the code of conduct and relevant policies and procedures, Goodell says. Others create totally custom modules for a fee.

If you choose to customize, don't end up doing all the work.

Remember, Root warns, you may have to provide "all of the content and planning," and that could cost you lots of time and work.

How will employees access the training?

Many employees may not have computer stations on their desk. Determine home accessibility to computers to see if you need to set up a workstation or, say, three in a training room. If worksite terminals are used, limit access to just the training modules to avoid security breaches. To encourage home training, some labs and hospitals give employees $10 gift certificates if they go home and take the test; others will pay them their hourly rate for the hour of training they complete online at home.

Do the e-learning companies you're interested in serve an organization of your size?

An e-company's financial situation may well determine whether it is willing to take you as a client, Root notes. Some won't if you need services costing less than $100,000; others will. So find out, up front, the minimum size training contract they require.

Get references.

"E-training is the child of the whole Internet phenomenon, and a lot more is promised than delivered in many cases," Root cautions. "You have to be very careful about what you'll get." He advises that you check references from other organizations like yours that have used the e-training company's services.

Can the training tie into your existing compliance program?

General compliance training modules should include discussion of a complaint hotline, code of conduct, and internal reporting procedures, Goodell recommends. "Ideally, there should be hotlinks in each module to enable employees to access relevant sections on policies, procedures, and the code of conduct. If possible, there should be a direct means within each module to contact the compliance or legal office with questions or concerns."

What do the training programs cost?

Costs range across a wide spectrum, depending on the number of people being trained. For a typical lab, Root notes, off-the-shelf programs would cost about $30-50 per person per course per year. That contrasts with traditional compliance training at $100 per seat to "put someone in the classroom for an hour and train the staff present."

More E-Products Foreseen

Laboratories currently can get pre-formatted training videos that cover the seven key compliance areas outlined in the OIG guidance. Root says his company is working on a phlebotomy e-training course that should be ready soon.

Root foresees products that labs can use to train physician clients so that test orders are more complete. "The theory is that physicians may be more amenable to the Internet. They do not watch videos or go to meetings. The hope is to give them a sexier media they can use on their own time," adding that they are familiar with using the Internet to get medical information.

Resources

- Charles Root: 847-381-5465
- Rebecca Goodell: 310-459-3640

HIPAA Compliance, *from page 2*

Ongoing Monitoring

- *Do regular integrity checks of your information technology controls.*

One method is to have staff try to hack into their own system to discover any vulnerabilities.

- *Update your HIPAA policies and procedures regularly.*

Like integrity checks, this will be a continual process. As Coleman pointed out: "HIPAA rules are not set in stone. Like almost every other regulation the government puts out, there will be revisions."

- *Hold refresher education and training sessions for employees.*

Coleman advised incorporating this into the corporate compliance training done annually.

- *Measure the effectiveness of your HIPAA compliance.*

You must ensure that what you are doing right has the intended effect, Coleman emphasized. "When you implement a system to limit access to certain patient information to only those employees who have a need to access it, you must make sure that the system is actually doing that. You have to go back and audit to find out.

"Output and outcome are two different things. Just because you have output doesn't mean it's good. That's where a lot of providers get into trouble. They put their compliance program in place, undertake procedures they are supposed to be undertaking, but the outcome of those procedures is not effective."

Resource

- Christopher Coleman: 703-535-1417

COMPLIANCE PERSPECTIVES

OSHA Update: New Safety Needle/Recordkeeping Requirements

Dr. Sheila Dunn heads Quality America Inc., based in Asheville, North Carolina

In late January, the Labor Department's Occupational Safety & Health Administration mandated sweeping revisions to two regulations that affect healthcare employers and employees nationwide:

— The bloodborne pathogens standard (29 CFR Part 1910 - *Occupational Exposure to Bloodborne Pathogens; Needlesticks and Other Sharps Injuries; Final Rule*, published in the Jan. 18 *Federal Register*, with a compliance date of Apr. 18, 2001).

— The recordkeeping rule on work-related injuries (29 CFR Part 1904 - *Recording and Reporting Occupational Injuries and Illnesses*, published in the Jan. 19 *Federal Register*, with a compliance date of Jan. 1, 2002).

The revised bloodborne pathogens standard clearly stipulates the requirement to evaluate and implement safety needles, in accord with the Needlestick Safety and Prevention Act, which became law late last year. Although the Act gave OSHA a statutory deadline of May 6, 2001 to revise the standard to include specific language about safety devices, the agency surprisingly released the revision months before expected.

One day later, OSHA released a revised recordkeeping rule that reflects changes also made by the Act. Among other things, the rule expands requirements for documenting sharps injuries and provides new forms to do so.

Don't Get Stuck With Sharps After Apr. 18

The revised standard on bloodborne pathogens requires employers to locate, evaluate, and provide to front-line workers sharps with engineered injury protection features.

OSHA's revision expands the standard in four main areas:

1 Definitions of engineering controls are altered and expanded. A new term is added, "sharps with engineered sharps injury protections," defined as a:

> "*…nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.*"

The definition of "engineering controls" is modified to include examples: *"safer medical devices such as sharps with engineered sharps injury protections and needleless systems."*

2 During annual review of the exposure control plan, compliance officers must now look at and consider newly available medical devices with sharps injury protection features.

3 Workers in direct patient care must be given the opportunity to identify, evaluate, and select effective engineering controls and work practices.

4 More detailed methods for reporting injuries from sharps are now required. The sharps injury log must contain, at a minimum, (1) the type and brand of device involved in the incident; (2) the department or work area where the incident occurred; and (3) an explanation of how the incident occurred.

The major elements of compliance with safety device requirements have been discussed in previous issues of *G-2 Compliance Report* (*Nov-Dec '00, p. 10; Feb. '00, Perspectives, pp. 5-8*).

Still, most healthcare entities have not fully implemented a sharps safety program. To gear up for the Apr. 18 compliance date, consider the following tips (adapted from the alert from the National Institute for Occupational Safety & Health).

Compliance Tips On Sharps Safety

❖ *Don't use sharps when safe, effective alternatives are available.*

What To Look For In Safety Devices

— *The device is needleless.*

— *The safety feature is an integral part of the device.*

— *The device preferably works passively (i.e., requires no activation by the user). If user activation is necessary, the safety feature can be engaged with a single-handed technique and allows the worker's hands to remain behind the exposed sharp.*

— *The user can easily tell whether the safety feature is activated.*

— *The safety feature cannot be deactivated and remains protective through disposal.*

— *The device performs reliably, is easy to use, and practical.*

— *The device is safe and effective for patient care.*

An example of unnecessary needle use: when exposed needles are used to access or connect parts of an IV delivery system. For nearly a decade, needleless IV delivery systems and protected needles have been available to remove or isolate this hazard.

❖ *Include employees in the development and implementation of your sharps injury reduction program.*

Form a multidisciplinary team comprised of workers from all departments/units in your organization.

❖ *Analyze needlestick and other sharps-related injuries in your workplace to identify hazards and injury trends.*

Compile data from injury reporting and assess the data to identify (1) where, how, with what devices, and when injuries are occurring and (2) which groups of healthcare workers are being injured.

❖ *Set priorities and prevention strategies by examining data from your workplace about actual needlestick injuries.*

Absent such information, tap local and national data on injury and disease transmission trends. Give procedures and devices that have contributed to disease transmission the highest priority for intervention. In general, safety devices for hollow-bore needles used in veins and arteries are considered to have the greatest impact on preventing occupational infection.

❖ *Modify work practices that pose a needlestick hazard.*

Hazards that can be thus eliminated include injuries due to recapping, failing to dispose of a needle device properly, passing or transferring such a device, and transferring blood or body fluids from a device into a specimen container. Also, specimen collection can be coordinated to reduce the number of times that needles are used on a patient, thereby reducing both worker risk and patient discomfort.

❖ *When selecting a safety device to evaluate, identify its intended scope of use in your facility and any special technique or design factor that may influence its safety, efficiency, and acceptability to users.*

OSHA does not endorse or recommend products, so you will need to consult published, Internet, or other sources of data on the safety and overall performance of a particular device. Consider each safety device on its own merit and ultimately on its ability to reduce workplace injuries. A device that performs well for a particular procedure in one department may not be the best choice in another circumstance.

❖ *Be sure that testers can evaluate products in a simulated patient environment and that they understand the proper use of each device.* OSHA requires that front-line employees (*i.e.*, those who currently use a similar category of product in your workplace) have input on product selection and perform the evaluations. Provide training dummies, if needed (*e.g.*, injection pads). Note that cost is *not* a valid consideration for evaluation; worker safety is first and foremost from OSHA's perspective. (For more on a Sharps Evaluation pro-

Types Of Safety Needles On The Market

At this time, there are three basic types of safety needles available:

— *Syringes with protective shields contain a cover, which the worker slides down over the needle after use.*

— *Retractable devices have a mechanism that the worker activates to cause the needle to safely retract into the plastic syringe after use.*

— *Blunt tip devices contain a clear plastic sheath that covers the used needle, sometimes before it leaves the patient's arm.*

Some devices require the user to activate the safety mechanism; some work automatically. This latter type is considered "passive" since no action is required by the user. Under most circumstances, passive devices are preferable, but in some cases, products that require the worker to assemble components or activate the safety mechanism might be preferable.

Safety Features: Do They Really Reduce Needlesticks?

Yes, and there are studies that support this, according to the National Institute for Occupational Safety & Health:

- *Needleless or protected-needle IV systems decreased needlestick injuries related to IV connectors by 62% to 88% (Gartner 1992; Yassi et al 1995; Lawrence et al 1997).*
- *Phlebotomy injuries were reduced by 76% with a self-blunting needle, 66% with a hinged needle shield, and 23% with a sliding-shield, winged-steel (butterfly-type) needle (Centers for Disease Control, 1997).*
- *Phlebotomy injuries were reduced by 82% with a needle shield, but a recapping device had minimal impact (Billiet et al 1991).*
- *Safer IV catheters that encase the needle after use reduced needlestick injuries related to IV insertion by 83% in three hospitals (Jagger 1996).*

cess, see *G-2 Compliance Report, Nov-Dec '99, p. 2*. Sample forms for this process can be found at *www.osha.gov*).

❖ *Promote safety awareness in the work environment.*

Many needlestick injuries result from unexpected circumstances, such as sudden movement by a patient or collision with a co-worker or needle device. A number of job-related factors influence the adoption of safety behaviors by healthcare workers. Since workers often place patient needs before their personal safety, they may be less likely to perform a safety measure that they perceive to interfere with patient care or to require added steps. Therefore, your sharps injury reduction program must address both the hazards that contribute to needlestick injuries and the institutional barriers and attitudes that affect safe work practices.

❖ *Establish procedures for, and encourage, the reporting and timely follow-up of all needlestick and other sharps-related injuries.*

Reporting of all needlestick injuries is now required, not just those that resulted in a seroconversion.

❖ *Monitor use of new safety devices and other prevention efforts.*

The aim is to determine the need for additional training; solicit informal feedback on workers' experience with the device (*e.g.*, a suggestion box); and identify possible adverse effects of the device on patient care.

❖ *Evaluate the effectiveness of prevention efforts and provide feedback on performance.*

Consider providing a forum to assess worker perceptions, evaluate worker compliance, and identify problems. As with any evolving technology, the process will be dynamic, and with experience, improved devices with safety features will emerge.

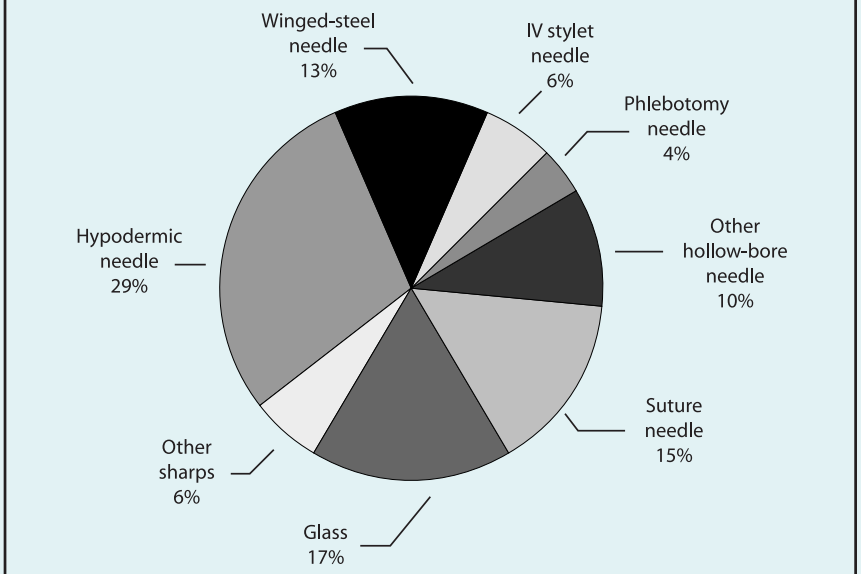
The bottom-line for making the switch to safety products depends on the results of the evaluation. If a safety device was evaluated favorably, you must switch to it immediately. If a safety device performed poorly on the evaluations, keep written documentation of this with your OSHA records; then continue to attempt to locate and evaluate alternative devices.

Don't be surprised if safety devices are hard to obtain after Apr. 18. In fact, industry insiders predict widespread product shortages. If a safety device that your facility has favorably evaluated and ordered is not commercially available, you'll have to find and evaluate another product.

Recordkeeping Changes

In revising the recordkeeping rule, OSHA is aiming at improving the system that employers use to track and record workplace injuries and illnesses. The more than 1.3

Devices Involved In Sharps Injuries: *June 1995-July 1999*



Total percutaneous injuries = 4,951

Source: CDC, 1999

million workplaces affected have almost a year to get ready—by Jan. 1, 2002.

The changes are intended to generate better information about occupational injuries and illnesses, and at the same time, simplify overall recordkeeping for employers and improve the protection of employee privacy. Unlike most previous OSHA standards, the revised recordkeeping rule is written in a user-friendly fashion, with a helpful question-and-answer section.

Consistent with the amended standard on bloodborne pathogens, the revised recordkeeping rule requires the recording of *all* needlestick and sharps injuries. Previously, only sharps injuries that resulted in seroconversion or medical treatment were reportable, so this new provision is expected to significantly increase the number of recordable workplace injuries.

The ubiquitous OSHA 200 Log will be history after next January. Originally put in place in 1971, this log was designed to help employers recognize and correct hazardous workplace conditions by keeping track of work-related injuries and illnesses and their causes.

Next January, three new forms will be implemented:

—OSHA Form 300 (Log of Work-Related Injuries and Illnesses).

—OSHA Form 300A (Summary of Work-Related Injuries and Illnesses).

—OSHA Form 301 (Injury and Illness Incident Report). This will be optional. It is intended to document in detail how injuries occurred, such as needlesticks and musculoskeletal disorders.

In the new OSHA forms, work-related injuries are more clearly defined to help ensure that only appropriate cases are recorded, and not those that may be unrelated to work. (For a sneak preview of these forms, go to *www.osha-slc.gov/recordkeeping/OSHArecordkeepingforms.pdf*).

Until next year, continue to use the old Log 200 to record and summarize workplace injuries, but be aware that the revised bloodborne pathogen standard requires more thorough recording of needlestick injuries.

Revised Recordkeeping Rule: Summary Of Key Provisions

- *Requires recording of all sharps injuries.*
- *Clarifies what constitutes a "workplace" injury or illness in an easily-understood flowchart format.*
- *Requires employers to teach employees the procedures for reporting work-related injuries.*
- *Contains provisions to record employee hearing loss.*
- *Requires recordable injuries or illnesses to be recorded within seven calendar days of receiving information that a recordable injury or illness has occurred.*
- *Protects employee privacy by omitting the recording of employee names for certain injuries/illnesses, limiting access to such data, and other means.*
- *Applies the same recording criteria to musculoskeletal disorders and to work-related transmission of tuberculosis as to all other injuries and illnesses.*
- *Includes new definitions of medical treatment, first aid, and restricted or light duty work.*
- *Adds flexibility to use computer technology to meet recording requirements.*
- *As before, the Summary must be posted during the month of February and kept for a period of five years.*
- *You may be required to share occupational injury and illness information with Uncle Sam.*

Uncle Sam May Be Watching

Each year, the Bureau of Labor Statistics sends injury and illness survey forms to randomly selected employers and uses the information gathered to create the Nation's occupational injury and illness statistics. In any year, some employers will receive a BLS survey form; others will not.

If your organization gets one, you must send the survey reports to OSHA, or OSHA's designee, by mail or other means described in the survey form, within 30 calendar days, or by the date stated in the survey form, whichever is later.

Resources On The Web

Safer Needle Devices

—NIOSH: *www.cdc.gov/niosh*

—University of Virginia's International Health Care Workers Safety Center and its EPINet needlestick injury data collection system: *www.med.virginia.edu/~epinet*

—OSHA for needlestick information, *www.osha-slc.gov/SLTC/needlestick/index.html*

Revised Recordkeeping Rule

—OSHA: *www.osha-slc.gov/recordkeeping/index.html.*

—Preview of new reporting forms: *www.osha-slc.gov/recordkeep-ing/OSHArecordkeepingforms.pdf*

Dr. Sheila Dunn can be reached at Quality America, Inc., an Asheville, NC-based consulting firm that publishes an OSHA Safety Manual and has produced a Sharps Injury Reduction Program Video. For information about Quality America's products and services, call 828-645-3661 or visit www.quality-america.com.

Changes Coming In ESRD Lab Rules & Edits, HCFA Tells OIG

Responding to an audit report critical of how Medicare oversees laboratory claims for end-stage renal disease (ESRD) testing, the Health Care Financing Administration says it plans to eliminate the complex 50% rule on test panels.

The agency also said it:

- Is working with Medicare fiscal intermediaries to increase awareness among hospital outpatient and ESRD facilities of proper billing practices, including which tests are included in the composite rate and the frequencies at which these tests are included.
- Will establish a system to monitor provider ESRD billings and make it easier for intermediaries to enforce Medicare rules.

Answering The OIG

HCFA pledged to make these changes in its reply to a report from the HHS Office of Inspector General, which concluded from a statistical sample that approximately $6.1 million was improperly paid to hospital laboratories for services to ESRD beneficiaries from 1995 through 1997.

The findings of the audit were released Jan. 31. The OIG limited the sample population to 836 hospital labs with at least 300 patient months of lab services that had the potential to be included in the composite rate (automated chemistry profiles, profile tests, hemoglobins, hematocrits, automated platelet counts, and blood drawings).

Key problems found:

- Hospital labs were paid separately for services included in the dialysis facility's composite rate.
- Contrary to the 50% rule, separate payments were made for additional profile tests performed in conjunction with the monthly testing included in the composite rate.
- Improper coding.
- Unbundled claims.
- Lack of documentation for services provided.

Of the 400 patient months in the OIG's sample, 240 had payments for lab services that did not meet Medicare reimbursement requirements.

Following the OIG's request to providers for information on claims in the sample, three providers initiated internal billing reviews. Two identified and agreed to return a total of $475,860 in improper payments for lab services covered under the composite rate. The third provider asked to enter the OIG's voluntary disclosure program.

The problems occurred at two levels, the OIG said:

- Hospital billing departments did not follow Medicare billing guidelines.
- The nature of Medicare billing systems does not allow fiscal intermediaries to develop edits to ascertain on a prepayment basis whether the tests billed were included in the composite rate.

Corrective Action

HCFA will ask intermediaries to perform data analysis to identify providers that are billing inappropriately, then follow up with pre- or postpayment reviews.

To replace the 50% rule, HCFA said it plans to establish a system for paying non-composite rate tests that are part of a panel at the unit price for a 22-panel test.

"Providers would only be required to bill for the non-composite rate tests in the panel even though these panels would include a number of composite rate tests as well," the agency said.

"This change would eliminate the contractor burden of enforcing the 50% rule, but would ensure that [Medicare does] not overpay for panel tests that include composite rate tests."

The OIG added that based on clarification from HCFA officials, "the agency's intent is to pay for medically necessary automated chemistry profile tests (which are not to be included in the composite rate payment) at the 76 cents unit price for a 22-test profile, the incremental cost of performing additional chemistry profile tests, or some other amount to be determined."

The proposed policy relates to:

- The 12 chemistry profile tests when done in excess of designated composite rate testing fre-

ESRD Lab Billings: *Key Terms*

Composite Rate: This is a comprehensive payment for all services related to dialysis treatment except for bad debts, physician services, blood, and certain drug and lab services that are separately billable. Medicare pays 80%, the beneficiary 20%. Medicare designates which lab tests are included in the rate and at what frequency (per treatment, weekly, monthly, or quarterly). When tests are run at these frequencies, they cannot be billed separately. When run at a frequency greater than specified, the additional tests are separately billable and covered if medically necessary. Lab tests that are not part of the composite rate may be billed separately.

50% Rule: Limits are set on separately billed lab tests when run as part of an automated chemistry profile. If 50% or more of the tests run as a profile of tests are included in the composite rate, the entire profile is considered to be included in the composite rate. In this case, no separate payment is made for those lab tests outside the composite rate.

Preparing For Stepped-Up ESRD Scrutiny

Diana Voorhees, head of the consulting firm DV& Associates (Salt Lake City, UT), advises labs to look back as well as forward.

Retrospectively, you should:

- ❖ Spot-check a sample of claims internally to determine if they have any vulnerabilities. In her view, many will likely be looking at liability.
- ❖ Engage counsel. Voorhees suggests you do so either after the spot-check or even before it. "If labs get counsel before the self-audit, it's all under privilege. If they choose not to, the small internal audit will at least show if problems exist and if counsel is necessary."
- ❖ If problems are uncovered, decide with counsel whether you should do a more extensive internal audit.
- ❖ Consider tapping an external auditor. "Sometimes internal audits take so long to get done that labs just keep racking up liability."

Depending on what you find, you will need to take some prospective steps to prevent these errors from recurring:

- ❖ Develop internal edits in your billing system to flag these types of services. "This may entail setting up separate Chargemaster entries for dialysis services."
- ❖ Have a separate requisition for dialysis services. This will help control how physicians order these services and will also spur the lab to look at these charges up-front.
- ❖ Educate staff and physicians on your new ESRD requisition and Chargemaster entries.
- ❖ Establish written policies on how to handle ESRD lab test ordering and billing. "Written protocols need to stress medical necessity as well," Voorhees said.
- ❖ Set up ongoing auditing and monitoring of ESRD services.

Ms. Voorhees can be contacted at 801-272-3672.

quencies. Tests include albumin, calcium, carbon dioxide, chloride, creatinine, LDH, alkaline phosphatase, phosphorus, potassium, total protein, AST/SGOT, and BUN.

- ❖ The 10 additional profile tests not designated for inclusion in the composite rate payment. Tests include bilirubin (total and direct), cholesterol, CPK, glucose, GGT, sodium, ALT/SGPT, uric acid, and triglycerides.

Welcome News

David Sundwall, MD, president of the American Clinical Laboratory Association, said the OIG report came "as no surprise. ESRD payment policies for labs are a nightmare. They are among the most confusing."

The 50% rule costs labs money, he added, because they are not reimbursed for tests they actually perform.

"The [Medicare contractors] don't understand it, they differ on what tests are covered by the rule, and labs write-off tests rather than risk billing error."

Due to the complexity of ESRD lab billing, Sundwall said ACLA is pushing to have a single regional lab carrier handle ESRD claims.

Resources

- ❖ OIG report, *Review of Separately Billed ESRD Hospital Outpatient Laboratory Tests Included in the Composite Rate* (A-01-99-00506): *www.hhs.gov/progorg/oas/cats/hcfa.html*
- ❖ David Sundwall: 202-637-9466

FBI's Healthcare Fraud Budget To Increase 16% To $88 Million

For the current federal fiscal year (which ends this Sept. 30), the Federal Bureau of Investigation says its budget to combat healthcare fraud will grow 16% to $88 million, $12 million more than the level for FY 2000.

The increase will go to hire 30 new special agents (for a total of 445) and 18 new support personnel (for a total of 331).

The funding for most FBI healthcare fraud investigations comes from provisions of the 1996 Health Insurance Portability & Accountability Act.

In accord with the Act, the funding will keep growing until it reaches a permanent level of $114 million per year in 2003.

In FY 2000, the FBI helped obtain 560 federal convictions on healthcare fraud charges and $290 million in fines and recovered payments.

The head of the Financial Crimes Section, Dennis Lormel, said, "We continue to prioritize healthcare fraud as the #1 white collar crime."

Clyde Langley, an FBI supervisory special agent, said the Bureau has seen fewer cases related to laboratory false claims than it did a few years ago.

Increasingly now, probes are targeting patient transportation, home health, and durable medical equipment.

This year, he added, the healthcare fraud caseload is expected to number 3,000. In 2000, it was 2,980 vs. 3,027 in 1999.

CO Salaries, *from page 1*

More Survey Findings

❖ *Recognition of the job's complexity*: In 2000, 58% of the COs polled said they did not have other responsibilities. Compliance was their sole focus. In 1999, the figure was 50%.

❖ *A department in its own right:* 80% said their compliance department was a stand-alone and did not report to any other department, up from 63.5% in 1999. "As people learn more about compliance, they learn there is the appearance of conflict when compliance is part of another department like legal or finance," Pastin said.

❖ *Part of corporate headquarters:* 66% said their compliance office was part of their organization's corporate headquarters, up from 54.5% in 1999.

❖ *Larger staff:* COs reported having, on average, 3.2 people on their staff in 2000 vs. 2.2 in 1999. "Now that people understand that compliance represents ongoing work and not the mere installation of a program, they are staffing a little bit more and, as a result, the budget line for the department is growing," Pastin said.

❖ *Separate budgets:* 62% reported that the compliance function has its own budget; 38% said their compliance function was included in another department's budget.

Other Trends

The survey showed that, for the most part, COs are being promoted from within.

Healthcare organizations are looking for COs "they can trust and control," Pastin noted, a key reason prompting promotions from within. Fiscal concerns are also driving this trend. To hire a CO from the outside with experience and credentials would, with headhunter fees, cost around $125,000-130,000, he said.

As for their name, compliance departments are calling themselves just that, shunning modifiers like ethics or integrity: 71% said they use the name "compliance" alone, up from 63.5% in 1999.

Although Pastin feels that, over time, COs will recast themselves as integrity departments, for now the term compliance has "more punch." COs are fighting for respect, so "there is some excessive emphasis on the word 'compliance' at this point," he added.

Approximately 100 COs responded to the Council's 1999 and 2000 salary surveys. They worked in a variety of healthcare settings, including hospitals/hospital systems, long-term care, integrated systems, physician practices, payers, and suppliers.

The majority of respondents in the 1999 survey (54.5%) were from integrated systems. In the 2000 survey, the majority (64%) were from hospitals and hospital systems.

Resource

❖ Mark Pastin: 703-683-7916. E-mail: *CouncilE@aol.com*

Salary Survey, 1999 & 2000: Compliance Officer Responses

Question	Response	1999	2000
What is your salary?	$50-000- 65,000	10%	32%
	$66,000-80,000	25%	20%
	$81,000-95,000	35%	22%
	$96,000-110,000	10%	16%
	$111,000+	20%	10%
Do you have other duties?	Yes	50%	42%
Is your dept part of another dept?	Yes	36.5%	20%
	No	63.5%	80%
Do you have a corporate or main office where the compliance/ethics office is located?	Yes	54.5%	66%
	No	45.5%	44%
Does the compliance function have its own budget, or is it part of some other dept's budget?	Has its own budget	n/a	62%
	Incl. in another's budget	38%	
Were you promoted from within or hired from without?	From within	n/a	74%
	From outside	n/a	26%
What is your dept's name?	Compliance	63.5%	71%
	Compliance & Ethics or Integrity	18%	13%
	Audit/Finance	14%	4%
	Counsel/Legal	4.5%	4%

Source: Council of Ethical Organizations

The Back Page

News-At-A-Glance

CIAs On The Web: The HHS Office of Inspector General is now posting on its Website the text of corporate integrity agreements (CIAs) reached with providers. Settlement agreements with integrity provisos that are reached by the Justice Department are not posted; these deal with criminal and civil charges, while CIAs target administrative issues. The OIG site does, however, list entities under both CIAs and settlement accords, updated quarterly. Go to *www.hhs.gov/oig/cia*.

Whistleblowers' Share: The whistleblowers in the record $325 million settlement with SmithKline Beecham Clinical Labs have agreed to accept a total of $23 million as their share of the government's recovery. They include former SBCL employee Robert Merena and two others. SBCL settled in early 1997, but the Justice Department appealed awards made to the whistleblowers by a district court judge, beginning with the initial $42.3 million award. Justice took credit for uncovering alleged Medicare fraud involving SBCL's automated chemistry profiles and said the whistleblowers contributed little to this part of the case.

PATH Challenge Spurned: A federal court in Philadelphia has rejected a bid by Temple University Health System to escape an audit by the HHS OIG on grounds that the hospital got conflicting guidance from its Medicare carrier. The audit is part of the Physicians At Teaching Hospitals (PATH) initiative. Temple had asserted that under HHS guidelines it should be exempt, citing a 1995 audit done by the carrier, Xact. The OIG disagreed, saying Xact did a limited review and did not look at broader issues of teaching physicians and Part B billing. When the OIG pressed ahead, Temple sued for violation of the hospital's due process rights.

The court said Temple had plenty of opportunities to explain why it thought it was exempt and also noted that the OIG audit was only the beginning of a process that may or may not lead to a false claims action. Should any such action result, the court said Temple has viable defenses. Finally, the court said it could not review the OIG's decision under the Administrative Procedures Act, because HHS guidelines give the OIG complete discretion to determine whether a hospital got conflicting advice from its carrier.

Regional Lab Carrier Delay: The start date for phasing-in consolidation of lab claims processing at two regional carriers has been pushed off until sometime in 2002, says the Health Care Financing Administration.

Bids from qualified contractors won't be solicited until May, the agency says, adding that it hopes to select the winners by the end of this September. As currently planned, the regional carriers would handle independent lab claims first and fold in other lab providers later.

Error Rate Drops: The rate of improper Medicare fee-for-service payments fell to 6.8% in fiscal 2000, from 8% the year before, reports the HHS OIG. Improper payments totaled $11.9 billion vs. $13.5 billion in FY 1999 and $12.6 billion in FY 1998. According to the OIG, the majority of errors uncovered when examining patient records were: lack of documentation, miscoding of services, medically unnecessary services, or billing for services that Medicare doesn't cover.

HCFA's acting head, Michael McMullan, attributed the decreases to the agency's better oversight of billings and to provider efforts to bill correctly.

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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