G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

HHS Proposes Criteria for EHR Incentive Program

The Department of Health and Human Services (HHS) has issued two rules that propose to define criteria and standards for incentive payments to physicians and hospitals funded through the American Recovery and Reinvestment Act (ARRA), which in part was enacted to spur widespread adoption of health information technology (HIT).

These are the first regulations of a three-phase implementation plan. Phase 1 of the incentive program is scheduled to begin in 2011, with payments ending in 2015. Eligible providers who comply with all three phases of the program can receive the maximum total amount of incentive payments of $44,000.

One of the new regulations is a proposed rule defining "meaningful use" of electronic health records, issued by the Centers for Medicare and Medicaid Services (CMS). Once finalized, this regulation would establish the criteria physicians and hospitals would have to meet to be eligible for the incentive payments. *Continued on page 2*

Nine Rules for Managing Risk in Lab Sales and Marketing

Health care providers, including laboratories and pathologists, face restrictions on their sales and marketing practices that many other professionals do not have to contend with. Violation of key laws can result in substantial financial penalties, warns Hope Foster, an attorney with Mintz Levin (Washington, D.C.).

At Washington G-2 Reports' Lab Sales and Marketing Conference, held in Chandler, Ariz., Dec. 7-9, 2009, Foster shared nine rules for managing legal risk while engaging in effective sales and marketing:

Rule 1:
Tell the Truth

Understand exactly what a test can do and sell only that to clients, Foster advises. Don't mislead, don't misrepresent what the test can do, don't exaggerate test characteristics or capabilities, and don't urge doctors to order assays to test for conditions for which the test has not been proven to be effective. *Continued on page 8*

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EHR Incentive Program, *from page 1*

In the proposed regulation, released Dec. 30, CMS has identified a number of complex requirements health care providers would have to meet in order to establish their "meaningful use" of electronic health records and qualify for government incentives. Some groups, including the American Medical Association and the American Hospital Association, have begun to criticize the requirements as being overly complex and creating barriers that could discourage adoption by the medical community.

The proposed Phase 1 criteria for meaningful use focus on electronically capturing health information in a coded format, using that information to track key clinical conditions, communicating that information for care coordination purposes, and initiating the reporting of clinical quality measures and public health information.

The proposed criteria for meaningful use are based on a series of specific objectives, each of which is tied to a proposed measure that all eligible professionals (EPs) and hospitals must meet in order to demonstrate that they are meaningful users of certified EHR technology.

For Phase 1, which begins in 2011, CMS proposes 25 objectives/measures for EPs and 23 objectives/measures for eligible hospitals that must be met to be deemed a meaningful EHR user. In 2011, all of the results for all objectives/measures, including clinical quality measures, would be reported by EPs and hospitals to CMS, or for Medicaid EPs and hospitals to the states, through attestation.

In the proposed regulation, released Dec. 30, CMS has identified a number of complex requirements health care providers would have to meet in order to establish their "meaningful use" of electronic health records and qualify for government incentives.

In 2012, CMS proposes requiring the direct submission of clinical quality measures to CMS (or to the states for Medicaid EPs and hospitals) through certified EHR technology. CMS says it recognizes that for clinical quality reporting to become routine, the administrative burden of reporting must be reduced.

By using certified EHR technology to report information on clinical quality measures electronically to a health information network, a state, CMS, or a registry, the burden on providers that are gathering the data and transmitting them will be greatly reduced, says CMS.

Technical Standards

The second rule, also released Dec. 30, is an interim final rule drafted by the Office of the National Coordinator for Health Information Technology. The regulation attempts to define the technical standards, implementation specifications, and certification criteria for electronic health record technology.

In order for professionals and hospitals to be eligible to receive the incentive payments, they must be able to demonstrate the meaningful use of a certified EHR system that meets the requirements of both regulations, since the standards and certification criteria in this rule are fundamentally linked to and specifically designed to support the first phase of implementing the meaningful use criteria.

Both regulations were published in the *Federal Register* on Jan. 13. The CMS regulation is available at *www.cms.hhs.gov/Recovery/11-HealthIT.asp*. Comments are due 60 days after publication.

Pathology 'Grandfather' Protection Ends, But Extension Is Pending

The statutory moratorium protecting certain pathology billings by independent clinical laboratories expired as of Dec. 31, 2009, but provisions to extend it are pending in House and Senate health care reform bills awaiting reconciliation.

Anticipating legislative action, the Centers for Medicare and Medicaid Services (CMS) is advising qualified providers "to hold, to the extent possible, claims for services furnished on or after Jan. 1, 2010."

"If legislation is enacted, claims submissions for affected services may resume," CMS said. "Otherwise, claims submitted with dates of service on or after Jan. 1 will not be paid."

The grandfather protection allows an independent clinical laboratory to bill Medicare directly for the technical component (TC) of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, when the Medicare program first proposed to end such billings. Congress has repeatedly stepped in to block this policy change. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

Both the House and Senate health care reform bills extend the "grandfather" protection but differ over its length. The House extends it for two years, the Senate for one year. The original Senate Finance bill did authorize a two-year extension, but the Democratic leadership scaled it back to help keep down the bill's total cost. Both the House and Senate aim to keep the cost of health care reform below the $900 billion benchmark set by the Obama administration.

In light of the political pressure to rein in the cost of overhauling U.S. health care, industry sources speculate that if the protection survives in the final reform bill, it is likely to be extended for one year.

CMS had repeatedly sought to end the "grandfathered" pathology TC billings, contending that the TC is paid through the hospital's inpatient diagnosis-related group (DRG) payment and labs should seek reimbursement from the hospital, not the Part B program.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected.

Negotiations Continue on Health Reform Measure; Final Bill Likely to Increase Focus on Compliance

Now that both houses of Congress have passed their versions of health care reform legislation, it's up to a conference committee to work out differences between the two bills. Despite the many differences between the House and Senate bills, the two measures are similar with respect to enhanced fraud and abuse enforcement provisions.

Among key provisions:

- **Transparency and Program Integrity.** Both bills would require drug, device, biological, and medical supply manufacturers to report annually to the secretary of Health and Human Services certain information on payments and other transfers of value to "covered recipients." They also eliminate the broad exception to the Stark law for physician-owned hospitals that allows such hospitals to participate in Medicare, unless the physicians held an ownership interest and the hospital had a provider agreement before Aug. 1, 2010 (Senate bill) or Jan. 1, 2009 (House bill).

- **Claims Submissions.** Both bills would substantially reduce the maximum period for the submission of Medicare claims form the current three-year period to one calendar year and allow for HHS to provide for exceptions. The Senate bill would impose this reduced period beginning Jan. 1, 2010, whereas the House bill would delay the implementation of the restriction for another year.

- **Civil Monetary Penalties.** Both bills would bolster the penalty provisions under the Civil Monetary Penalties (CMP) Act. They also would impose intermediate sanctions on Medicare Advantage and Part D plans that enroll individuals in a plan without their consent, transfer individuals from one plan to another without their consent, and fail to comply with applicable marketing restrictions.

- **Lower Burden of Proof Under the Anti-Kickback Statute.** The Senate bill would make it easier for the government to prove a violation of the anti-kickback statute by lowering the burden of proof to a civil standard. To prove a violation of the statute, the government must show that the defendant acted "knowingly and willfully."

- **Mandatory Compliance Programs.** For most providers and suppliers, the adoption of a corporate compliance program is currently voluntary. Both bills would require HHS to establish "core elements" for a compliance program for providers and suppliers and require them to establish compliance programs containing those core elements. The House bill explicitly exempts physicians from this requirement.

- **Provider Screening and Enrollment.** Although both bills call for enhanced screening procedures for providers and suppliers who wish to participate in Medicare and Medicaid, the Senate bill would mandate that all providers and suppliers be subject to, at a minimum, licensure checks, whereas the House bill would leave the imposition of any enhanced screening procedures to the secretary's discretion.

COMPLIANCE PERSPECTIVES

Jane Pine Wood, Esq.

Legal and Practice Issues for In-House Histology Labs

This is the second of two articles. The first article, which addressed licensure and certification, malpractice liability, and fraud and abuse, appeared in the January 2010 issue of GCR. *Both articles are based on a presentation given at Washington G-2 Reports' Lab Institute, held in September 2009.*

With the crackdown on pod laboratories, many referring physician practices have begun pursuing the establishment of an in-house histology laboratory. These practices often contract with their local pathology practices for assistance in establishing the laboratory and providing professional interpretation. Both pathologists and referring physicians should be aware of a number of legal and business considerations, cautions Jane Pine Wood, an attorney with McDonald Hopkins LLC (Dennis, Mass.).

Pursuant to the new Medicare anti-markup rule, if a referring practice bills for the professional or technical component of a diagnostic test that was ordered by the practice and the diagnostic test is performed or supervised by a physician who does not "share a pratice" with the billing/referring practice, the Medicare payment to the practice for the technical or professional component of the diagnostic test may not exceed the lowest of the following amounts:

1. The performing supplier's net charge to the practice;
2. The practice's actual charge to the Medicare program; or
3. The Medicare fee schedule amount for the service that would be allowed if the performing supplier billed the service directly to the Medicare program.

With respect to the technical component (TC), the "performing supplier" is the physician who supervised the TC, and the "performing supplier" for the professional component (PC) is the physician who performed the PC. The Centers for Medicare and Medicaid Services (CMS) has indicated that the performing supplier's net charge will be regarded as the amount paid to the supervising or performing physician but does not include any amounts paid directly to the technician who furnished the technical component.

In addition, the regulations specify that the net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing/referring practice.

A referring practice that provides TC pathology services in its own in-house laboratory can avoid the anti-markup rule by satisfying either of two alternative stan-

dards for "sharing a practice." One alternative (Alternative 1) focuses on whether the supervising physician furnishes at least 75 percent of his or her professional services through the billing/referring practice. The other alternative (Alternative 2) focuses on where the diagnostic test is performed and supervised.

The practice also should confirm that its major payers will reimburse the practice for the pathology services. Increasingly, payers are refusing to reimburse for diagnostic services provided by a referring physician practice.

Under Alternative 1, a supervising physician is deemed to share a practice with the referring practice if the supervising physician furnishes substantially all (at least 75 percent) of his or her professional services through the referring practice. CMS has said that supervision of histology processing need not be performed by a pathologist (because certification under the Clinical Laboratory Improvement Amendments is not required for histology processing) but could be performed by any physician within the practice.

Therefore, if a referring practice has an in-house laboratory, a physician within that practice could be designated as the supervising physician for purposes of the anti-markup rule. Assuming the physician provides at least 75 percent of his or her services through the referring practice, the practice will avoid the application of the anti-markup rule with respect to all of its technical component services.

Under Alternative 2, a supervising physician will be deemed to share a practice with the billing/referring practice if the supervising physician is an owner, employee, or independent contractor of the practice, and the on-site supervision of the technical component by the supervising physician occurs in an office where the ordering physician provides services, presumably during all times when diagnostic tests are performed. This Alternative 2 may be difficult for multioffice practices to meet, although most practices should be able to comply with Alternative 1 to avoid the application of the Medicare anti-markup restriction.

Payer Issues

If the referring practice's operations comply with the Stark law in-office ancillary services exception, then the practice can submit claims for its technical component of anatomic pathology services to the Medicare and Medicaid programs, as well as nongovernment payers (assuming the payers do not require designated laboratories to provide these services).

The practice also should confirm that its major payers will reimburse the practice for the pathology services. Increasingly, payers are refusing to reimburse for diagnostic services provided by a referring physician practice. Instead, such payers will only reimburse for diagnostic services provided by a hospital or an independent freestanding diagnostic provider. Many national payers contract exclusively with selected laboratories for all pathology services.

Even if the referring practice's major payers currently reimburse for pathology services provided in its histology laboratory, the practice should be prepared for a change in the payers' policies and the potential loss of the practice's investment in the histology laboratory.

Professional Interpretations

If the pathology practice will bill payers directly for its services, the referring practice will not be responsible for payment for these services. This is the preferred

approach from a compliance and malpractice standpoint and avoids the issue discussed below.

If the referring practice wishes to bill government payers for the professional interpretations, the practice will need to comply fully with an applicable Stark exception. Besides paying the pathology provider fair market value for the professional pathology interpretations, compliance with the Stark law typically will require the interpreting pathologist to provide the professional interpretations in the offices of the referring practice.

The anti-markup restrictions also will require the services to be performed by a pathologist who meets Alternative 1 (the 75 percent of his or her practice test) or Alternative 2 (interpretations provided in the offices of the ordering physician) if the referring practice wishes to obtain the full Medicare allowable payment for the interpretations.

If the referring practice wishes to bill for the professional pathology interpretations, the practice also incurs the professional liability associated with these services.

The new anti-markup rules will cause some problems for multilocation practices. For example, if a referring practice has five locations and the pathologist provides professional interpretations in only one location and if the pathologist does not meet the first "sharing a practice" test (the 75 percent test), then the anti-markup rule will apply with respect to any interpretations performed by the pathologist that were ordered by practice physicians who do not practice in the building in which the pathologist is providing his or her professional interpretations.

If the practice physicians do not rotate through the office where the pathologist performs his or her professional interpretations, then the professional interpretations ordered by the physicians in the other four offices will be subject to the anti-markup rule.

A second alternative is for the pathologist to move from building to building, interpreting in each location only specimens ordered by the physicians who practice in that location. The referring practice will be responsible as well for supplying a microscope and office space to the pathologist, as well as transcription services.

If the referring practice wishes to bill for the professional pathology interpretations, the practice also incurs the professional liability associated with these services. In virtually all such arrangements, the referring practice must purchase additional malpractice insurance to protect the practice in the event of acts or omissions by the pathologist.

It is important to note that the pathologist's professional liability insurance covers only the pathologist and not the referring practice. Compliance with the Stark law requires the referring practice to take full responsibility for the professional pathology interpretations, which must be reported out under the name of the referring practice. If the referring practice attempts to disclaim responsibility for the professional interpretations, it will be destroying its compliance with the Stark law. Similarly, the pathology practice should ensure that its malpractice insurance also covers the pathologists when services are being rendered on behalf of the referring practice.

Prior to commencing to bill for the professional pathology services, the referring physician practice must enroll the interpreting pathologists under the practice's managed care contracts, as well as its Medicare and Medicaid group numbers.

Hope Foster, Esq.

Nine Rules for Managing Risk, *from page 1*

Rule 2:
Don't Sell Off-Label or Beyond Validated Results
If using a kit cleared by the Food and Drug Administration (FDA), only sell to the labeled indications.

If using a non-FDA cleared kit, only sell in conformance with the validated results. Keep up with FDA pronouncements about tests.

Rule 3:
Disclose, Disclose, Disclose
If a test stops performing in accordance with claims, stop making the claims. Disclose what is happening, select appropriate methods for making such disclosure, and keep the information flowing and current.

When marketing a multicomponent package of tests, be sure to disclose the contents and the CPT codes that will be used to bill for each component. Also, disclose the reimbursement amounts that Medicare will pay for each component and the total that Medicare will pay for the entire package. If the doctor pays for this package of tests himself, make sure that he understands that Medicare may pay more and make it easy for him to know how much more.

Make sure the doctor knows the alternative tests that may be ordered and their prices, make it easy for the doctor to decide what is medically necessary for his patients, and enable the doctor to understand the economic consequences of his test-ordering decisions.

Rule 4:
Don't Buy or Pay for Referrals
Paying for referrals of government work is a felony, and paying for referrals of any testing is unlawful in many states. This is a broad rule, so providers should use extreme caution. Paying for referrals can be interpreted to include any of the following: cash, trips, lavish meals, tickets and other types of entertainment, golf games and golf balls, professional courtesy, free goods and services, equipment at less than fair market value, gifts, certain types of discounts, rebates, prebates, up-front payments, signing bonuses, and anything of value.

Rule 5:
Don't Pay Others to Recommend or Arrange for Referrals
This is a very broad ban. Paying others to arrange for referrals is a felony under the anti-kickback law. "I am defending numerous cases right now that fall under this category," says Foster. "This can be hard to defend. You need to be careful when you think about who you're paying and what you're paying for."

Rule 6:
Obtain Legal Advice When Contemplating Paying for Leads
This could also implicate the anti-kickback law, so use caution. "This is a very sensitive area," warns Foster. "You need to structure this very carefully if you are thinking about it." In some cases, purchasing leads from brokers can be legal if there is no correlation between the purchase and the success of the leads—in other words, if it's a passive transaction.

However, if payment is somehow tied to the success of the leads, this becomes more complicated. "I'm not saying you can't do it, but you should definitely obtain legal advice before you do," she says. "You want to establish protections for yourself and for the person you're buying the list from."

Rule 7:
Avoid Sales Techniques That Emphasize How Much Doctors Can Earn

There is nothing illegal about this, but it can easily be misunderstood by the government and viewed as a potential inducement. Suspicions are raised when a sales person underestimates quality and service and overemphasizes economic benefit to the test referrer. If you do plan to use these techniques, it's best to consult with an attorney to ensure that you are protected legally.

Rule 8:
Avoid Using Physician Practices to Induce or Get Referrals of Government-Reimbursed Tests

Many of the LabScam cases of the 1990s were tied to allegations of illegal inducements, notes Foster. Project LabScam was the first systematic nationwide enforcement project targeting medical laboratories. A number of major laboratories paid millions of dollars to settle allegations that they unbundled clinical laboratory tests, billed for tests not performed, inserted false diagnosis codes to obtain payment, paid kickbacks to physicians for patient referrals, and billed for tests that were medically unnecessary.

OIG Advisory Opinion 99-13, issued in December 1999, specifically addresses the issue of offering discounted laboratory services to physicians. In the 1999 opinion, the OIG said that offering substantial discounts to referring physicians may violate the Medicare prohibition against giving kickbacks in exchange for referrals. In the opinion, the OIG says that price reductions offered to physicians that are not offered to Medicare or Medicaid raise issues under federal law.

This issue of discounts is also implicated in an ongoing investigation in California. The state alleges that seven clinical laboratories have charged the state Medicaid program up to six times more for tests compared to other clients over the past 15 years. The state attorney general alleges that the labs provided deep discounts to physicians in exchange for referral of their government business.

Rule 9:
Use Care with Requisition Forms, Test Directories, and Custom Profiles

Beware of inappropriate unbundling of laboratory tests, advises Foster, noting that the Health and Human Services Office of Inspector General said in its work plan for 2010 that it is looking closely at this practice. "They're not just looking at the new stuff, they're looking at the old stuff, too," she says.

Don't steer test ordering through requisition form design. Disclose test offerings and price and offer choice. In addition, be sure that test ordering and listing tools are designed for clarity.

Failure to follow these rules can result in severe penalties, warns Foster. These penalties can include civil monetary penalties of between $5,500 and $11,000 per false claim, criminal fines, and imprisonment. A substantial number of federal enforcement actions have stemmed from sales and marketing activities, she says, noting that individuals—as well as employers—can be held accountable.

Compliance Even More Important in Tough Economic Times

Anyone doubting the commitment of business to compliance and ethics will be surprised by the findings of a survey that shows spending on compliance has remained stronger than anticipated. Roughly three out of four companies responding to the survey either kept compliance spending even or actually increased it in 2009, and for 2010 the prognosis is even brighter.

These findings come from a new survey conducted by the Society of Corporate Compliance and Ethics (SCCE) and the Health Care Compliance Association (HCCA). This research was conducted among compliance professionals in the last quarter of 2009. The survey report also compares the most recent data with a similar survey conducted in December 2008.

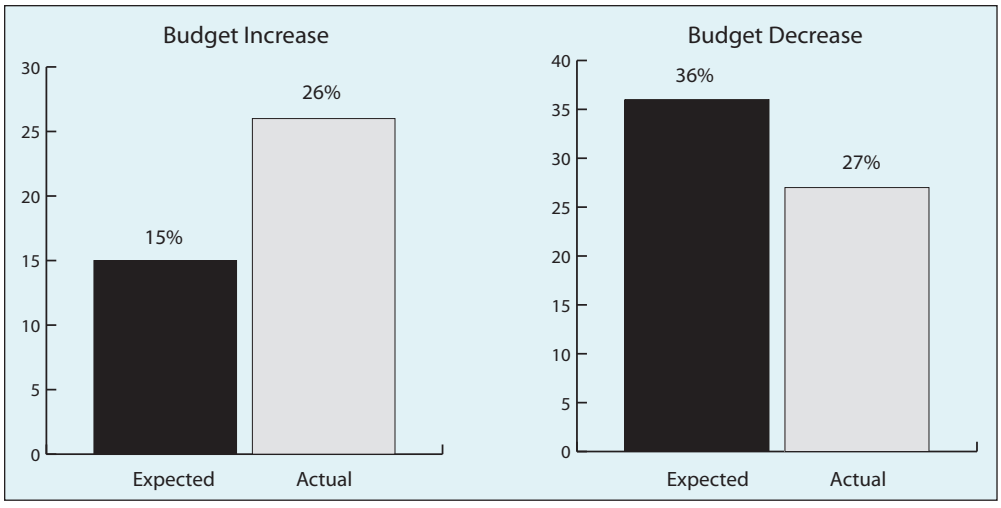
"Happily, the overall impact [of the struggling economy] has been less than anticipated, and the prognosis is good," said Roy Snell, chief executive officer of SCCE. "According to our survey results, 33 percent [of compliance officers] expect a budget increase in 2010, and 18 percent expect their staffing to increase. This shows that the business community has come to realize that the price of cutting back on compliance far exceeds any potential rewards.

Background

In December 2008, the economic meltdown was in full swing. SCCE and HCCA jointly launched a survey of compliance professionals to assess the likely impact of the faltering economy on compliance and ethics.

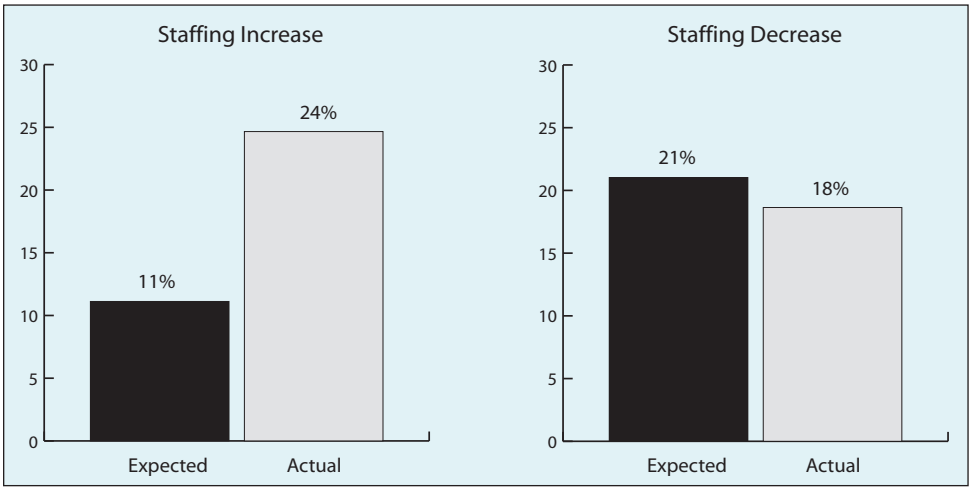
The 2008 survey indicated that 85 percent of respondents felt that the current economy greatly or somewhat increased the risk of compliance and ethics failure. So pervasive was this perception that only 1 percent took the contrarian view and felt that the legal and ethics risks might decline in this period. At the same time, there was great fear that compliance budgets would be reduced. As a result, the risks would rise at the same time that the resources to manage them would decrease.

To determine the actual effect of the economy on compliance spending and staffing in 2009 and to learn the compliance profession's expectations for 2010 budgets and staffing, the SCCE and HCCA conducted a new survey during October and November 2009. A total of 387 responses were received.



Survey Results

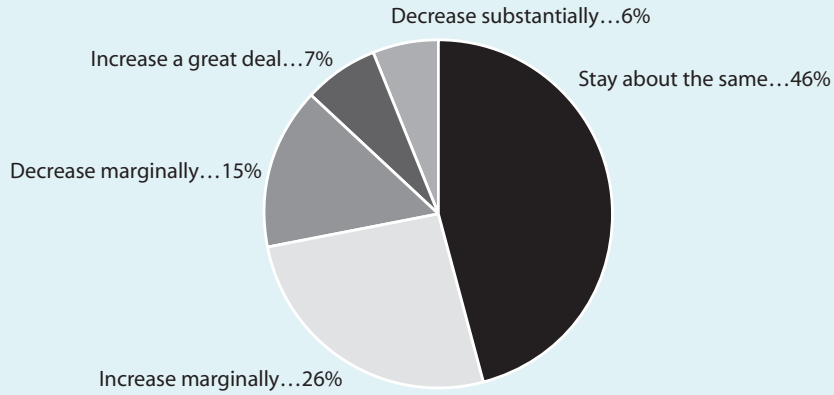
According to the survey, as a whole compliance budgets actually fared better than compliance professionals expected. In 2008, just 15 percent expected their budgets to increase



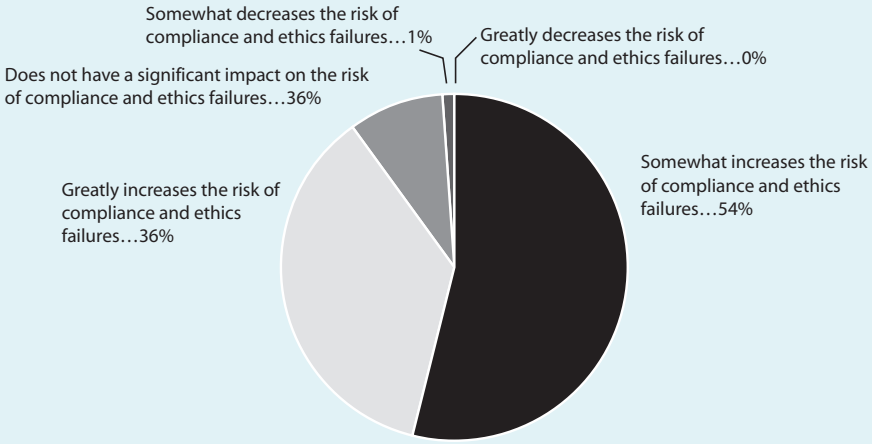
somewhat or a great deal in 2009. But by the end of the year, 26 percent reported that their budget had, in fact, increased. Likewise, 36 percent anticipated that their budgets would increase somewhat or a great deal in 2009, but by the end of the year, just 27 percent reported that their budgets had decreased.

For staffing, the picture was also brighter than expected. At the end of 2008, 21 percent anticipated a decrease in staffing and just 11 percent expected the compliance staff to increase. By December 2009 respondents reported that 24 percent had seen a staffing increase and just 18 percent saw a decrease in staffing.

What do you anticipate will happen to your organization's compliance and ethics program budget in 2010?



Do you think the current economy:



While dark clouds remain, compliance professionals are seeing a sunnier picture when it comes to 2010 budgets. Roughly one-third of respondents expect to see a budget increase in 2010, more than twice the number that expected budgets to rise in 2009. Seven percent of respondents anticipate their budgets will increase a great deal, and another 26 percent expected budgets to increase marginally. Still, approximately 21 percent anticipate a budget decrease in the coming year.

One measure that has not changed since the end of 2008 is the perceived risk of a compliance failure. Last year, 33 percent of respondents anticipated that the economy greatly increased the risk of failure, and that number changed only marginally to 36 percent in 2009.

The full survey is available online at *www.corporatecompliance.org*.

The Back Page

News-At-A-Glance

New Safe Harbors: The Department of Health and Human Services Office of Inspector General (OIG) has requested proposals and recommendations for developing new safe harbor provisions to be applied to the federal anti-kickback statute, according to a notice in the Dec. 29, 2009, *Federal Register*. The annual solicitation is mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Comments must be received by March 1. In addition to safe harbor provisions, the OIG also requested public comments on the creation of new special fraud alerts. The safe harbor provisions originally were created in response to the Medicare and Medicaid Patient and Program Protection Act of 1987 (Pub. L. 100-93) and were intended to identify business practices that would not be treated as criminal offenses under the anti-kickback statute. The OIG notice is available at *http://edocket.access.gpo.gov/2009/pdf/E9-30560.pdf*.

Strike Force Expands: Operations of the federal government's Medicare Fraud Strike Force will be expanded to seven locations, according to Health and Human Services Secretary Kathleen Sebelius and Assistant Attorney General Lanny Breuer of the Justice Department's Criminal Division. At a press conference, the two top officials responsible for policing health care fraud also announced strike force enforcement sweeps resulting in the indictment of 32 people in Miami, Detroit, and the borough of Brooklyn in New York City. Charges unsealed in seven federal court cases allege more than $61 million in false Medicare billings through a variety of scams, prosecutors said. The strike force expansion consists of the addition of operations in Brooklyn, N.Y.; Tampa, Fla.; and Baton Rouge, La.

False Claims Settlement: A Texas hospital will pay the United States $990,509 to settle allegations that it submitted false claims for payment to the Medicare program, a violation of the False Claims Act, U.S. Attorney for the Northern District of Texas James Jacks announced Jan. 4. The civil settlement resolves allegations that Arlington Memorial Hospital in Arlington knowingly failed, through the actions of its former president, to eliminate payment to a physician group for interpretation of arterial blood gas tests that were not performed. The government claimed the hospital knew such payments were not in compliance with federal requirements. Prosecutors said Arlington Memorial Hospital submitted the false claims between July 1, 2005, and July 1, 2007. Medicare paid the hospital for the tests. Under terms of the settlement, the hospital did not admit any wrongdoing and denied liability.

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