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Inside this issue

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OIG Releases 2016 Work Plan, Again Targeting Laboratory Billing

The OIG released its 2016 Work Plan, which continues to name laboratories as a source of concern with regard to Medicare billing and payment. The OIG's annual Work Plan provides a summary of new and continuing reviews that the agency is undertaking to protect the integrity of, and find opportunities to improve the efficiency of, U.S. Health and Human Services programs.

This year's Work Plan contains a holdover from last year's Work Plan: "Selected independent clinical laboratory billing requirements." The agency is concerned about Medicare payments to independent clinical laboratories—specifically, it's looking for labs that "routinely submit improper claims." The OIG claims that audits and investigations indicate independent clinical laboratories are at risk for noncompliant Medicare billing.

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HCCA Releases Compliance Officer/Staff Compensation Data

Just in time for budget season, the Health Care Compliance Association has released a report demonstrating the resources health care organizations are devoting to their compliance programs. The report summarizes results of a survey regarding compensation for chief compliance officers and compliance staff but includes related information that is equally revealing about the compliance programs as well. For example, the typical compliance budget among respondents was $220,000 but 20 percent of chief compliance officers reported having a budget of at least $1 million.

"The salary data shows that the compliance profession is strong and growing stronger every year," according to Roy Snell, HCCA's chief executive officer, in a statement announcing the survey results. "Compensation reflects the growing stature of compliance and its importance to the health industry." The survey gathered data regarding compensation, title, the organization's size—in terms of revenue and number of employees, type of organization, geographic region, scope of the compliance professional's role, certification or professional credentials of compliance staff, and other details relating to the surveyed organizations.

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HCCA Releases Compliance Officer/Staff Compensation Data, *from page 1*

Chief Compliance Officers

Chief Compliance Officers (CCOs) earning the higher salaries were those at larger organizations and academic health care providers and those with compliance certification or professional compliance credentials. CCOs for organizations with annual revenue exceeding $3 billion earned an average of nearly $300,000 annually. Smaller organizations earning below $5 million in revenue averaged almost $90,000 for CCO compensation. CCOs at academic entities earned $191,423 on average, the highest average cash compensation—just beating out CCO compensation at publicly traded companies which averaged $187,832. The survey also revealed longevity is common in the CCO role—the "typical CCO" helmed their organization's compliance functions for six to ten years or more.

More than half of Compliance officers handle at least 76 percent of the organization's legal and regulatory risk. CCOs reporting that they were involved in 26-50 percent of the company's legal and regulatory risk earned more than those with higher levels of involvement and those CCOs typically worked for larger organizations, on average, than those that reported 51 percent to 100 percent involvement. Those reporting involvement in 51-75 percent of the company's legal and regulatory risk earned the lowest compensation.

Among compliance staff other than CCOs, at least a third across all levels of staff reported receiving the Certified in Healthcare Compliance certification (55 percent for directors, 47 percent for managers and 34 per cent for assistants/specialists).

Most CCOs weren't eligible for bonuses but almost 40 percent were entitled to bonuses up to 20 percent of their salary. Only 10 percent of CCOs have a contract and those that do typically earned more than those who didn't have one.

Most survey participants had some type of certification relevant to their compliance function. More than 50 percent of CCOs held the certification Certified in Healthcare Compliance and just over a quarter surveyed reported having no certification.

Compliance Staff

The survey also reported on compensation and other data regarding compliance staff including directors, managers and assistants/specialists. Average compensation for directors was just over $120,000 and $67,000 for assistants/specialists. Most of the staff respondents (nearly three quarters overall and 78 percent for directors) reported their role involved covering a broad range of compliance issues. Not surprisingly, the assistants and specialists were those most likely to have a role that focused on a particular risk area but only 28 percent of individuals surveyed had a specialized role.

Most directors were bonus-eligible and one-third of managers and about 25 percent of assistants/specialists were entitled to bonuses. Similar to CCOs, only 4 percent of managers, directors and assistants/specialists reported having a contract, however, having a contract didn't make as significant a difference in compensation here.

Among compliance staff other than CCOs, at least a third across all levels of staff reported receiving the Certified in Healthcare Compliance certification (55 percent for directors, 47 percent for managers and 34 percent for assistants/specialists). The survey report is available on HCCA's website.

Takeaway: Compliance compensation survey reveals strength of compliance programs overall and factors that that lead to higher compensation. G2

FDA and CMS Address LDT Regulation Before Energy and Commerce Committee

Last week, the U.S. House of Representatives Energy and Commerce Committee heard testimony about oversight of laboratory developed tests (LDTs) from representatives of the U.S. Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS). The opportunity to speak at the hearing, titled "Examining the Regulation of Diagnostic Tests and Laboratory Operations," was invitation only. The agencies presented a united front in supporting FDA oversight of LDTs.

"In many cases, the only difference between many modern LDTs and other IVDs is where they are manufactured, and the accuracy and reliability are every bit as important for modern LDTs as for any other IVD."

—Jeffrey Shuren, FDA

Jeffrey Shuren, director of the Center for Devices and Radiological Health at the FDA, spoke about the agency's regulation of medical devices and in vitro diagnostic devices (IVD) and explained the history leading up to the framework released last year. He also noted current proposals from the lab community that "acknowledge that LDTs must demonstrate that they are analytically valid and clinically valid." He cited problematic LDTs like those referenced in the FDA's report released last week (see Box, p. 4), to demonstrate the need for oversight. For example, his written comments highlighted one test discussed in the report that is used to determine a patient's response to statin therapy. The FDA found there wasn't an adequate link between the genetic variant and statin response. But 150,000 patients received the test, and the FDA asserts the problematic results cost $2.4 billion due to under or overtreatment with statins.

Identifying LDTs as a type of IVD, Shuren explained "[m]odern LDTs are often complex, have a nationwide reach, and have high-risk uses, and without oversight could present risks for patients and health care providers who rely on the results of LDTs to make medical decisions." "In many cases, the only difference between many modern LDTs and other IVDs is where they are manufactured, and the accuracy and reliability are every bit as important for modern LDTs as for any other IVD." Citing examples of the complexities involved, the written testimony discusses high risk tests such as companion diagnostics and moderate risk tests such as a blood test to detect heart attack, suggesting they require FDA oversight because inaccurate test results could delay treatment. "In both cases, the Agency's premarket review and post-market controls are essential to ensuring patients don't experience grave consequences from inaccurate results."

Discussing test modifications, the FDA's written submission contrasted simple changes that likely don't require review: "such as modifying the salt used in a buffer solution, or making an increase in the number of samples that a laboratory analyzer can process at one time." On the other hand, review would be required for "highly complex modifications that affect a test's performance—such as changing the measuring range of a marker to detect lower levels or adding a new marker to a panel of markers—or a test's intended use, such as changing the intended use of a Hemoglobin A1c test from monitoring glucose control in someone who already has diabetes to using that test to diagnose diabetes." When such a change can increase the risks posed by the testing or affect test performance or intended use, the FDA argues it should be exercising oversight concerning such modifications.

FDA's Next Steps

Shuren's written statement reported that the FDA "has completed its review of the public comments on the draft guidance documents that it received through an open public

FDA Report Asserts Case Studies Support Need for More Oversight of LDTs

The U.S. Food and Drug Administration (FDA) released a 30-plus page report detailing case studies it says demonstrate the need for the FDA to abandon its policy of enforcement discretion and exercise more robust oversight of laboratory developed tests (LDTs).

An *FDA Voice* blog article announcing the release of the report describes the report as an illustration of "the real and potential harms to patients and to the public health from certain laboratory developed test (LDTs)." The report covers 20 case studies that the FDA asserts demonstrate the risks of false positives and false negatives from certain LDTs. *FDA Voice* blog author, Peter Lurie M.D., M.P.H., FDA's Associate Commissioner for Public Health Strategy and Analysis claims the lack of FDA oversight of LDTs has led to "staggering" costs and indicates the report estimates the "public health cost for five of the 20 cited tests."

The FDA report, titled *The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies* is available on the FDA website. It categorizes the case studies according to the problems raised: false positives, false negatives, lack of relevance to the tested disease, tests linked to disproved scientific concepts, tests undermine drug approval or treatment selection, and unvalidated tests. The cases were gathered, according to the FDA, from "publicly available information in medical journals, media reports and FDA Warning letters."

The report detailed 20 different LDTs that while compliant with CLIA regulations, did not require approval of the FDA. A couple of the tests have been withdrawn or not brought to market, but most are currently available commercially. According to the FDA report, they "illustrate, in the absence of compliance with FDA requirements, that these products may have caused or have caused actual harm to patients. In some cases, due to false-positive tests, patients were told they have conditions they do not really have, causing unnecessary distress and resulting in unneeded treatment. In other cases, the LDTs were prone to false-negative results, in which patients' life-threatening diseases went undetected. As a result, patients failed to receive effective treatments."

Among the tests disputed by the FDA include assays to determine the risk for ovarian cancer; a test for whooping cough; tests to help guide treatment of patients with breast cancer, prostate cancer and melanoma; non-invasive prenatal testing; and vitamin D deficiency testing, among others.

The American Clinical Laboratory Association was immediately dismissive of the report. "These so-called case studies are not representative of the thousands of LDTs utilized on a daily basis by providers to positively impact patient care," the ACLA said in a statement.

docket and a two-day public meeting, as well as feedback received from several webinars FDA held with stakeholders to discuss concerns and address questions." He outlined the following steps that the FDA is now taking:

- Coordinating with CMS on laboratory oversight and FDA plans to develop draft guidance regarding quality system requirements for LDTs, "to provide clarity for laboratories on how they can leverage compliance with CLIA requirements to satisfy those applicable FDA guidelines";
- Working with CMS and accrediting bodies and CLIA-exempt state laboratory programs, "to identify any potential overlaps between CMS and FDA activities" and look for ways to increase efficiency; and
- "Ongoing meetings with stakeholders, including laboratories, patients, traditional IVD manufacturers, and medical practitioners."

In response to questioning from the committee, Shuren indicated that the FDA intends to finalize its regulatory framework in 2016.

CMS Backs Up FDA

Patrick Conway, CMS' deputy administrator for innovation and quality and chief medical officer, also provided testimony, explaining the roles of CMS, the FDA and the Centers for Disease Control and Prevention under CLIA. His written statement to the committee clarified that CLIA "merely regulates how and by whom the test is conducted and reported out, rather than the scientific principles behind or the clinical validity of the test system itself." He added that CMS defers to FDA to determine clinical validity of a test.

Conway explained that "CLIA does not regulate the scientific principles behind or the clinical validity of any test—that is, the ability of the test to identify, measure, or predict the presence or absence of a clinically relevant condition or predisposition in a patient."

Further he added: "CMS does not have a scientific staff capable of determining whether a test is difficult to successfully carry out or likely to prove detrimental to a patient if carried out improperly. This expertise resides within the FDA, which assesses clinical validity in the context of premarket reviews and other activities aligned with their regulatory efforts under the Food, Drug, and Cosmetic Act."

Takeaway: The FDA and CMS are presenting a united front concerning the need for FDA oversight of LDTs and 2016 promises to bring changes for laboratories offering LDTs. G2

Use of "Contingent" Workers Under Scrutiny: Carefully Classify Your Workers

Many labs use "contingent" workers, such as temporary personnel, freelancers, and other independent contractors to round out their staffing. While not unlawful per se, these arrangements are fraught with compliance risks that labs need to be aware of.

Contingent work on the rise

The contingent workforce has been increasing since the 2007-2008 recession because it provides employers with the flexibility to use workers on a more as-needed basis, and that is often easier than securing full-time, more permanent help. One recent study by supply management company Arden Partners found that nearly 35 percent of today's total workforce is comprised of non-employee workers and that in 2015 the industry has reached a "tipping point."

Employers have also embraced contingent workers because it's cheaper. A Government Accountability Office (GAO) report issued in May 2015 found that while millions of workers are not in a traditional employer-employee relationship, most of them in these non-standard relationships do not have job protections, such as health insurance, retirement benefits and safeguards under laws such as the Family Medical Leave Act, because the employers aren't required to provide them to non-employees. Employers also can avoid paying taxes on these workers, according to attorney Hannesson Murphy with Barnes & Thornburg in Indianapolis.

The problem arises when a marketer for a lab is not a bona fide employee of the lab.

"It's the same bang for the buck and fewer regulations," he explains.

Marketing pitfalls raise AKS specter

However, labs need to be particularly careful when using workers to market the lab who are independent contractors instead of employees. Marketing services, including any type of promotion or advertising of health care providers, raise special concerns under the Anti-Kickback Statute (AKS), warns attorney Danielle Sloane, with Bass Berry & Simms in Nashville, speaking at the G2 Lab Institute's meeting held in October in Washington, DC. If a marketed product or service may be reimbursed in whole or in part by a federal health care program, then by definition remuneration paid to marketing personnel to promote, arrange for or recommend products and services is intended to induce referrals of items or services covered by the AKS.

The problem arises when a marketer for a lab is not a bona fide employee of the lab, says Sloane. Sales representatives are typically paid on an incentive or commission basis. The AKS provides a safe harbor against AKS liability if a marketer is an employee of the provider he or she is promoting; real employees, which are subject to the employer's control and supervision are less likely to engage in abusive or suspect activities in violation of the AKS and can be paid on an incentive or commission basis, says Sloane. However, marketers who are independent contractors don't qualify for the employment safe harbor.

To complicate matters, marketers who are independent contractors typically also don't meet the conditions of the AKS' personal services and management safe harbor if they're paid

at all on a variable basis—whether by commission, bonus, per referral, or other means—since one of the requirements of this safe harbor is that the aggregate compensation is set in advance.

While fitting into a safe harbor is not a guarantee that a lab would avoid AKS scrutiny, it is much less likely that the arrangement would be found in violation of the AKS, which can impose criminal and civil penalties, imprisonment of up to five years, violations of the False Claims Act and exclusion from the federal health care programs.

"The stakes are enormous for employers that misclassify employees as independent contractors."

—Philip Eschels, Attorney, Bingham Greenebaum Doll

The Department of Health and Human Services' Office of Inspector General (OIG) has long expressed concern with marketing arrangements involving independent contractors, and has issued several advisory opinions against it. The Department of Justice has also found providers and their independent contractor marketing arrangements violative in a number of cases. Since OIG/DOJ enforcement continues to ramp up, this is an area of increasing concern.

Misclassification of employees as independent contractors

Another compliance issue for employers using contingent workers is the increased challenge by regulators and private individuals against the misclassification of workers as independent contractors who from a legal standpoint should be characterized as employees. Making the wrong decision about classification of an employee can expose an employer to liability on several different fronts.

State law

State law affords various protections to employees, such as workers' compensation, minimum wage, overtime, and unemployment benefits. An employer that inappropriately characterizes an individual as an independent contractor rather than an employee exposes itself to liability under these laws, warns attorney Philip Eschels, with Bingham Greenebaum Doll in Louisville, Kentucky, noting that the problem is "extremely widespread."

"The stakes are enormous for employers that misclassify employees as independent contractors," he explains.

Enforcing these laws has become a higher priority for state governments in recent years because the increased use of people deemed contingent workers rather than employees means that the states are receiving lower tax revenue, since the employer isn't paying payroll tax and making unemployment contributions. As a result, state regulators have become more aggressive in sleuthing whether workers at entities of all types and sizes are actually independent or have been misclassified, according to attorney John Pueschel with Womble Carlyle Sandridge & Rice in Winston Salem, North Carolina.

"This issue is front and center in employment law now," he warns.

Federal law

The federal government is also cracking down on misclassification of employees as independent contractors on the grounds that it lowers federal tax revenues, exploits workers and undermines the economy.

Department of Labor actions

In July, the Department of Labor (DOL)— perhaps in light of the GAO's report—issued new interpretive guidance that clarifies that "most workers are employees" under the Fair Labor Standards Act (see *G2 Compliance Advisor*, Aug. 2015, p. 5). The guidance says the Act uses a "to suffer or permit to work" standard and that employers should use an "economic realities" test to determine how to classify a worker, applying six factors:

> ***"The DOL is making misclassification of employees an enforcement priority."***
>
> **—Philip Eschels, Attorney, Bingham Greenebaum Doll**

- Is the work being performed integral to the employer's business
- Whether the relationship between the employer and worker is permanent or indefinite
- How does the worker's relative investment compare to the employers' investment
- Whether the worker's managerial skill affects the worker's opportunity for profit or loss
- Does the work performed require special skill and initiative
- The nature and degree of the employer's control over the work being performed.

To bolster enforcement efforts, the DOL also launched a program to collaborate with states and has entered into memoranda of understanding with a number of them to share information about employer misclassification misconduct with each other and coordinate enforcement. To date 27 states have signed such memoranda, most recently Vermont, which signed on in September. (For a link to the full list, see the DOL's website.) That means that an employer not in compliance in those states can expect to be audited by multiple state and federal agencies, warns Pueschel. The website also lists a myriad of state/federal enforcement actions regularly being taken around the country against employers found misclassifying workers.

"The DOL is making misclassification of employees an enforcement priority," says Eschels.

IRS updates its guidance

In August, the Internal Revenue Service (IRS) released a new fact sheet on employee misclassification as independent contractors, pointing out that the determination depends on the degree of control and independence the individual has, focusing on behavioral control, financial control and the type of relationship between the employer and the individual (see Page 10). The updated guidance, with 11 factors, streamlines the IRS' prior misclassification guidance, which used a 20-factor test.

"The government will do as much as it can to change the practice [of using independent contractors] improperly," Eschels says.

Other federal laws impacted

In addition to the Fair Labor Standards Act, employee misclassification can subject employers to penalties under other federal law, such as the Occupational Health and Safety Act and the Family Medical Leave Act. Moreover, as of January 1, 2016, employers who misclassify employees as independent contractors may run afoul of the Affordable Care Act (ACA), since by then a required percentage of workers will need to have health insurance that meets ACA

standards, which raises the stakes even higher, warns Eschels. Many employers have re-characterized employees as independent in order to avoid the ACA's health insurance obligations.

> *"Employers need to be alert to changes in the law and avoid being overconfident about business practices that have been followed for years."*
>
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Individuals joining the fray

The heightened focus on misclassification has caused a domino effect in the private sector, with more individual workers filing private lawsuits against employers on behalf of themselves or as class action lawsuits to attempt to obtain back pay and other benefits of employee status. These private lawsuits have in recent months involved Uber, Lowes Home Centers and FedEx, among others, which cost time and resources to defend, even if the classification was correct. The current trend in these cases is that judges are requiring them to go to trial on the issue of employee status and not allow summary judgement, says Eschels.

They also garner media attention, which increases awareness about misclassification, and snowballs into more lawsuits and complaints filed with the government, warns Eschels, who has been seeing an increasing number of government investigations spurred by such private actions. "It takes just a phone call to file a complaint," he explains. A private lawsuit can also trigger a government investigation once regulators get wind of the potential violation. In addition, once an employer has been audited by regulators for employee misclassification, the government often returns within six to twelve months to check on that employer because it's now on the government's radar, says Eschels.

"If the government knows an employer is a bad apple, it's more likely to go after lower hanging fruit," he explains.

Liability comes with hefty price tag

The legal and financial exposure if an employer is found misclassifying employees as independent contractors can be significant. Not only would the employer owe back taxes and penalties, but also liability for violating state workers' compensation, unemployment insurance and wage and hour laws, such as overtime and benefits, like 401 K participation, says Pueschel. It can also result in penalties under the federal laws.

Unfortunately, it's not always clear whether a worker should be classified as an employee or independent contractor. "There's [often] no black or white in this. You have to look to the totality of circumstances," says Pueschel. For instance, while a lab's long-term phlebotomist perhaps should be considered an employee, it may be harder to determine how to classify a lab's off and on IT wiz or a short term billing clerk. However, that is not an excuse to avoid addressing the issue. While the two federal tests, as well as factors relied on by state agencies and even courts may vary somewhat, they are all pretty similar, says Murphy. Others agree.

"Employers need to be alert to changes in the law and avoid being overconfident about business practices that have been followed for years," says Eschels. "Be honest and don't take a 'head in the sand' approach. Enforcement is real and it's a major risk," he warns.

Takeaway: Labs should carefully examine their workforce to ensure that any contingent worker who is being treated as an independent contractor properly fits the definition and, if engaged in marketing the lab, is not running afoul of the AKS.

OIG Releases 2016 Work Plan, Again Targeting Laboratory Billing, *from page 1*

Once again, the OIG also promises to review Medicare payments for clinical diagnostic laboratory tests, including the top 25 clinical diagnostic laboratory tests by Medicare expenditures. This item was added in the OIG's mid-year update to the 2015 Work Plan and is required by the Protecting Access to Medicare Act. The OIG says it has found in the past that Medicare "pays more than other insurers for certain high-volume and high-expenditure laboratory tests." In September, the OIG issued its baseline analysis of the top 25 lab tests according to review of 2014 data. That report indicated that $7 billion was paid to 63,000 labs under Medicare Part B in 2014 for 451 million lab tests performed for 27 million Medicare beneficiaries. Medicare paid $4.2 billion in payments for the top 25 lab tests. Over half of Medicare beneficiaries receive at least one lab test in 2014; the average was 17 tests per beneficiary. One percent of beneficiaries received 95 or more tests. Lab tests generated approximately 3 percent of total Medicare Part B payments and the majority of Medicare payments for the top 25 laboratory tests went to independent labs.

The newest laboratory-related item in the OIG Work Plan indicates the OIG is focusing on the propriety of payments to histocompatibility laboratories, which reported $131 million in reimbursable costs on recent cost reports (covering March 31, 2013 through Sept. 30, 2014).

For all three projects specifically mentioning laboratories, the Work Plan predicts review reports will be issued in fiscal year 2016.

Other projects included in the OIG Work Plan that could impact laboratories directly or indirectly include:

- Enhanced enrollment screening process—the OIG is concerned about the implementation of enhanced enrollment screening procedures which are intended to use site visits, fingerprinting, and background checks to prevent fraud and abuse.
- EHRs in ACOs—the OIG will be checking to see if Accountable Care Organization (ACO) participants are using electronic health records (EHRs) to share health information and increase coordination, identify best practices and barriers concerning interoperability.
- Security of computerized devices—the OIG expressed concern about "whether FDA's oversight of hospitals' networked medical devices is sufficient to effectively protect associated electronic protected health information (ePHI) and ensure beneficiary safety." *G2 Compliance Advisor* recently highlighted similar threats to and heightened government enforcement of privacy and security (see *G2 Compliance Advisor*, Oct. 2015, p. 1).
- ACO performance—A new item indicates ACO participation in the Medicare Shared Savings Program will be reviewed with regard to savings achieved and performance measures for the first three years. Examples of ACOs that performed well will be reported as well as difficulties encountered in ACOs. A report is anticipated in 2017.
- ICD-10—A new item also indicates the OIG will examine how well the new ICD-10 codes were implemented, including guidance offered to providers and impact on claims processing. Note that CMS recently added a Frequently Asked Question to its website that indicated CMS won't require that an ordering provider "rewrite the original order with the appropriate ICD-10 code for lab, radiology services

or any other services"–so for orders written prior to Oct. 1, 2015, an ICD-9 code might have been used on the order and it will not have to be rewritten. If the order is for a repetitive service that will be continued after Oct.1, 2015 providers can "use the General Equivalence Mappings (GEMS) posted on the 2016 ICD-10-CM and GEMS web page to translate the ICD-9-CM codes on the original order into ICD-10-CM diagnosis codes."

Takeaway: Laboratories continue to remain a concern for the OIG with regard to appropriateness of Medicare billings, particularly for independent clinical laboratories. G2

Ask 11 Questions to Determine Employee/Independent Contractor Status

The IRS has issued guidance explaining how to classify a worker as employee or independent contractor (see page 5). According to the IRS, "all information that provides evidence of the degree of control and the degree of independence must be considered." Additional information and examples may be found at https://www.irs.gov/pub/irs-pdf/p15a.pdf but the "[f]acts that provide evidence of the degree of control and independence fall into three categories: behavioral control, financial control, and the type of relationship of the parties." There are 11 main factors the IRS considers and based on those factors we've created a checklist you can use to review the classification of your workers:

Behavioral control. Facts that show whether the business has a right to direct and control how the worker does the task for which the worker is hired are behavioral control factors. Ask the following two questions to determine behavioral control:

1. What instructions are given to the worker? An employer may be deemed to have sufficient behavioral control for a worker to be considered an employee even if no instructions are given but the employer has the right to control "how the work results are achieved." All of the following are IRS examples of types of instructions about how to do work.

a. When and where to do the work.
b. What tools or equipment to use.
c. What workers to hire or to assist with the work.
d. Where to purchase supplies & services.
e. What work must be performed by a specified individual.
f. What order or sequence to follow.

2. What training is provided to the worker? A worker is more likely to be deemed an employee if he or she is "trained to perform services in a particular manner." That's because "independent contractors ordinarily use their own methods," according to the IRS.

Financial control. Facts that show whether the business has a right to control the business aspects of the worker's job include how much risk or cost the worker incurs and how they are paid and whether the worker also performs services for others. Ask these five questions to determine financial control:

3. Does the worker incur unreimbursed business expenses? "Independent contractors are more likely to have unreimbursed expenses than are employees," says the IRS guidance. If the worker has fixed costs that he incurs regularly regardless of whether work is performed, that is a factor favoring independence rather than employment. Note, however, that even employees can incur unreimbursed expenses so the mere presence of unreimbursed business expenses doesn't guarantee independence.

4. Has the worker made any investment in resources needed to perform the services? The IRS instructs: "An independent contractor often has a significant investment in the facilities or tools he or she uses in performing services for someone else." But keep in mind that such investment isn't always needed for the job performed—so independent contractor status can exist without it. It's still a factor that, when present, supports a finding of independence.

5. Does the worker market his or her services? An independent contractor is generally free to seek out business opportunities and makes his or her services available to the relevant market—advertising, maintaining a visible presence or otherwise making an effort to promote his or her services to others.

6. How does the business pay the worker? "An employee is generally guaranteed a regular wage amount for an hourly, weekly, or other period of time" even if it's supplemented by a commission payment, according to IRS guidance. On the other hand, independent contractors are usually paid a flat fee or a fee based on time and materials used to perform the service.

7. Can the worker realize a profit or loss? Similar to the payment issue is profit and loss—the worker's risk. An independent contractor can make a profit or loss but an employee is usually guaranteed to profit from the arrangement.

Type of relationship. The IRS cites four factors as evidence regarding the parties' type of relationship. Ask these four questions to help determine the type of relationship:

8. Is there a written contract? Labeling an individual a contractor doesn't make it so; but what the contract says can help determine if the parties intended to establish an employment or independent contractor relationship.

9. Does the business provide the worker with employee-type benefits? When a worker receives benefits such as insurance, a pension plan, vacation pay, or sick pay it generally indicates an employment relationship.

10. How long will the relationship last? "If you engage a worker with the expectation that the relationship will continue indefinitely, rather than for a specific project or period, this is generally considered evidence that your intent was to create an employer-employee relationship," says the IRS.

11. Are the worker's services a key aspect of the regular business of the company? If so, it is more likely that the business will have the right to direct and control the worker's activities and there is an employment relationship.

G2 Compliance Corner

Consider Certification for Compliance Officers and Staff

Laboratories should encourage or even require their compliance professionals to obtain compliance certification. As the Health Care Compliance Association (HCCA) reported in its recent compliance compensation survey report (see page 1), most compliance professionals hold some type of certification. Such certification correlates to higher compensation for those certified compared to chief compliance officers and compliance staff without certification. Certification also ensures your compliance officer and staff will have compliance-specific training and, because certification programs often require completion of continuing education to maintain certification, it can ensure your compliance professionals stay up-to-date on compliance issues. So it makes sense for your laboratory to require applicants for hire in your compliance department have relevant compliance certification and encourage existing staff to pursue compliance certification.

The relevant certifications can vary based on the tasks assigned but there are general compliance certification programs that address compliance broadly. More than 50 percent of chief compliance officers responding to HCCA's survey held the certification Certified in Healthcare Compliance and at least a third of all levels of compliance staff responding (55 percent for directors, 47 percent for managers and 34 percent for assistants/specialists) held that certification.

More specialized certifications cited in HCCA's report included Certified in Healthcare Privacy Compliance, Certified Compliance and Ethics Professional, Certified in Healthcare Research Compliance, Certified Public Accountant, Certified Fraud Examiner, Certified Internal Auditor, Certified Information Privacy Professional, Health Ethics Trust Certified Compliance Professional, Certified Compliance Executive (CCE), and Accredited Healthcare Fraud Investigator.

In a future issue of *G2 Compliance Advisor*, we'll provide more information about the types of certification available and how to obtain them.

News at a Glance

HCA Settles Allegations of Unnecessary Testing/Double Billing for $2 Million. HCA Holdings, Inc. (formerly called Hospital Corporation of America) has settled health care fraud allegations relating to diagnostic testing for $2 million—including payment of damages and penalties. The claims stem from a whistleblower or qui tam lawsuit brought by an HCA employee under the False Claims Act against HCA and affiliated entities. The United States Attorney's Office for the District of South Carolina with the State of Florida asserted that HCA hospitals submitted claims for unnecessary tests and double billed for other tests. Specifically, the government alleged HCA claims were improperly submitted:

- For "direct count low density lipids (LDL) when the tests were not ordered and/or not medically necessary."
- For standalone non-stress testing when claims were submitted for fetal biophysical profiles with non-stress tests.

The U.S. Attorneys Office reports that the whistleblower in the case will receive $400,000—20 percent of the settlement as provided under the False Claims Act.

FDA Challenges Four DTC Genetic Tests. The U.S. Food and Drug Administration recently issued four untitled letters regarding direct-to-consumer (DTC) genetic tests, asserting that the agency was unable to identify any FDA clearance for enumerated tests and requesting the recipients provide either a clearance number or the reasons they believe that FDA clearance is not required for those tests. DTC startup DNA4Life received a letter from the FDA questioning the company's marketing of an unapproved genetic test that predicts response to 120 commonly prescribed medications based on analysis of 12 genes tied to drug metabolism. The FDA asserted the test is being marketed as an unapproved medical device. A similar letter was issued to DNA-Cardiocheck, Inc. noting that its direct-to-consumer test, DNA-CardioCheck, which tests for DNA genetic markers relating to cardiovascular disease, deep-vein thrombosis and stroke, is a device for which no FDA clearance has been sought. Interleukin Genetics Inc. was also queried about three separate genetic tests which detect predisposition for increased risk of heart attack and diabetes and other obesity related conditions. Finally, the FDA also issued a letter to Harmonyx regarding its direct-to-consumer genetic tests for antiplatelets, statins, ADHD and pain, which test whether medications will be safe and effective for specific patients.

Latest False Claims Act Settlement Involves 457 Hospitals in 43 States. The Department of Justice recently announced the latest major settlement of False Claims Act allegations, involving hundreds of providers. This time 70 settlements with 457 hospitals across 43 states has yielded over $250 million. The allegations related to implanted cardiac devices that the government claimed violated Medicare billing rules. The government alleged that between 2003 and 2010, implantable cardioverter defibrillators were implanted in Medicare beneficiaries during 40- and 90- day waiting periods following heart attacks and bypass/angioplasty, respectively. A National Coverage Determination generally bars implantation of ICDs during those waiting periods. The DOJ statement announcing the settlement cited an "extensive investigation" involving thousands of patient records and a panel of leading cardiologists. The settlement arises out of qui tam cases brought against most of the hospitals, filed in Florida federal court. The DOJ reports that still more hospitals and health systems remain under investigation.

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