G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

FDA Cracking Down on DTC Genetic Tests

In a sign that it is cracking down on companies that sell genetic tests directly to consumers, the Food and Drug Administration (FDA) in early June issued formal letters to five companies informing them that their tests are medical devices and may require premarket approval.

The letters, dated June 10 and posted online, were sent to genetic testing firms 23andMe, decode Genetics, Illumina, Nagivenics, and Knome Inc. The letters state that the tests manufactured by these companies are medical devices subject to FDA regulation. The letters also note that none of the companies has received premarket approval from the FDA, which is necessary for a company to commercially distribute medical devices.

The FDA letters follow closely on the heels of an announcement by Pathway Genomics (San Diego) that it planned to sell an over-the-counter genetic test kit at Walgreens drugstores. That plan is now on hold (GCR, *June 2010, p. 1*). In addition, personal genomics company 23andMe announced recently that it mixed up results on genetic tests of as many as 96 customers.

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Legal Issues in Laboratory Outreach

Though outreach laboratories function as part of a hospital or health system and thus are distinct in many ways from independent laboratories, in terms of compliance and fraud and abuse, the issues are much the same regardless of setting.

Speaking at Washington G-2 Reports' Lab Outreach conference, held June 2-4 in Baltimore, Craig Holden, an attorney and chief operating officer at Ober/Kaler, reviewed key legal and compliance issues that apply to hospital outreach labs.

First, Holden noted, it's important to understand the distinction—from Medicare's perspective—between an outreach test and an outpatient test. According to the Medicare Benefit Policy Manual, "Where a tissue sample, blood sample, or specimen is taken by personnel that are neither employed nor arranged for by the hospital and is sent to the hospital for performance of tests, the tests are not outpatient hospital services."

This is important because Medicare "rebundling" rules require

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Kimberly Scott, Senior Editor,
kscott@ioma.com

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FDA Cracking Down, *from page 1*

Both incidents have called attention to oversight—or lack thereof—by the federal government, with critics saying this provides further evidence supporting the need for greater federal regulatory scrutiny of genetic testing. Not only has the FDA begun looking more closely at genetic testing, but Congress also has launched an investigation into direct-to-consumer genetic tests.

> ***'The policy is no different than for any other test . Those tests that are being offered directly to the consumer in which the company sends out a collection device . . . need to be cleared or approved' by the FDA.***
>
> ***— Alberto Gutierrez, FDA***

In an interview with *G-2 Compliance Report*, Alberto Gutierrez, Ph.D., director of the FDA Office of In Vitro Diagnostics, says the FDA is merely enforcing an existing policy. Any company planning to sell a genetic test directly to consumers must first consult with the agency and, depending on what the test is and the claim made, may need to submit a premarket approval application, he says. Laboratory-developed tests may need approval if they are marketed directly to consumers, but they don't if they are ordered through physicians, he explains.

"The policy is no different than for any other test," he says. "Those tests that are being offered directly to the consumer in which the company sends out a collection device . . . need to be cleared or approved" by the FDA.

Mix-up at 23andMe

23andMe announced its mix-up in early June, blaming LabCorp, with which it contracts, for the error. In its announcement, 23andMe said, "Upon learning of the mix-ups, we immediately identified all customers potentially affected, notified them of the problem and removed the data from their accounts. The lab is now concurrently conducting an investigation and reprocessing the samples of the affected customers."

The company added that it is currently putting additional procedures in place that will add an extra layer of safeguards to help ensure that similar incidents do not occur in the future. "We are deliberating on a process that would include removing manual steps at the lab, completely automating the sample analyses, and implementing further checks of the data before it gets loaded into customer accounts," said the company.

While some have pointed to the mix-up as just the latest example of the dangers of DTC genetic testing, Dan Vorhaus, an attorney with the law firm of Robinson, Bradshaw and Hinston (Charlotte, N.C.) and editor of the online *Genomics Law Report* (*www.genomicslawreport.com*), says that while there may be a number of reasons why DTC genetic testing may soon find itself subject to increased regulatory oversight, 23andMe's error should not be one of them.

"In fact, the sample swap, while unfortunately timed, actually presents a compelling argument in favor of the direct-to-consumer model for genetic testing," writes Vorhaus. He notes that the FDA currently exercises "enforcement discretion" in regulating all but a select subset of lab-developed tests (which most genetic tests are).

The FDA is not, however, tasked with overseeing the analytic validity of genetic tests, notes Vorhaus. That job falls to the Centers for Medicare and Medicaid Services (CMS), which enforces the Clinical Laboratory Improvement Amend-

At press time, the FDA announced it will hold a public meeting July 19-20, 2010, to discuss how the agency will oversee laboratory-developed tests. The agency says it will then move forward in drafting an oversight framework. See the next issue of G-2 Compliance Report *for more on the outcome of the meeting.*

ments of 1988 (CLIA). Under CLIA, labs that perform human testing, including genetic testing, are regulated through a certification process, which requires labs to demonstrate the analytical validity of their tests.

In its 2008 report, *The U.S. System of Oversight of Genetic Testing*, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) expressed concern that CLIA's proficiency testing (PT) requirements may not adequately ensure the analytical validity of genetic tests.

Would establishing PT guidelines for genetic testing have helped 23andMe and LabCorp spot the error before returning erroneous results to customers? "Possibly," speculates Vorhaus. "There is no way to say for sure since those PT guidelines do not exist. Even if they did, many CLIA-certified laboratories also participate in voluntary accreditation programs that already go beyond the likely PT requirements for genetic testing. Ultimately, however, even the most robust regulations, whether CLIA or otherwise, are incapable of eliminating all mistakes."

Consumer Involvement Key

Both Vorhaus and Daniel MacArthur at Genetic Future say that while improved regulation may be one way to reduce the incidence of genetic testing errors, it is unrealistic to expect regulation to eliminate such mistakes entirely, which means that complementary strategies must also be pursued. Judging from the response to 23andMe's sample swap, the presence of an engaged community of genetic testing consumers appears to be one such strategy. It was 23andMe's active user community that alerted the company to the mix-up.

"At least in this particular example, the inevitability of genetic testing errors argues in favor of more consumer access—not less—to allow individuals to continue to play an active role in finding and correcting such mistakes," Vorhaus writes. "There is no question that 23andMe made a mistake and must take appropriate measures to help prevent similar errors from occurring in the future. But while the timing of the incident is unfortunate, it seems that the response to this mistake—particularly from 23andMe's community of users—is more indicative of DTC genetic testing's promise than its perils."

Lab Group Seeks Exemption From PHI Requirement

New accounting of disclosure requirements for personal health information (PHI) should not apply to clinical laboratories, says the American Clinical Laboratory Association (ACLA), which argues that a laboratory information system (LIS) does not constitute an electronic health record (EHR).

Currently, the Health Insurance Portability and Accountability Act (HIPAA) privacy rule requires covered entities to make available to an individual upon request an accounting of certain disclosures of the individual's PHI over the past six years. The privacy rule excludes from this requirement disclosures made by covered entities relating to treatment, payment, and health care operations.

Under the Health Information Technology for Economic and Clinical Health (HITECH) Act, passed in 2009, this exemption no longer applies to disclosures through an EHR. As such, individuals will be permitted to request an accounting of disclosures of their PHI relating to treatment, payment, and health care operations so long as the covered entity uses or maintains such PHI in an EHR.

"The threshold question regarding whether this requirement is applicable to a covered entity, therefore, is whether the covered entity discloses PHI through an EHR as defined under the HITECH Act," writes ACLA President Alan Mertz in a letter to Georgina Verdugo, director of the Office for Civil Rights (OCR) in the Department of Health and Human Services. "[W]e strongly believe that is not the case for disclosures from a clinical laboratory's information system."

The HITECH Act defines an EHR as "an electronic health record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff." By this definition alone, an LIS is not an EHR, says Mertz in comments submitted May 18 to Verdugo. While an LIS is an integral part of the laboratory's infrastructure, it is not intended to be consulted by a patient's health care clinicians and is not used by the laboratory to make health care decisions regarding the treatment of a patient.

"First, unlike an EHR, an LIS is an electronic solution for receiving, processing, and storing information used solely by the clinical laboratory in the performance of laboratory testing, for billing purposes, and for other information gathering activities as required by our customers," writes Mertz.

"While the definition of an EHR is seemingly broad in its inclusion of an 'electronic record of health-related information,' we do not believe Congress intended the definition of an EHR to include an LIS based on the most critical component of this definition. Specifically, an LIS not created, gathered, managed, and consulted by *authorized health care clinicians and staff*."

Significant Burden

If HHS determines that an LIS should be considered an EHR, this would place a significant burden on clinical laboratories, says Mertz, arguing that the volume of disclosures of PHI by clinical laboratories for treatment, payment, and health care operations is staggering.

ACLA member labs perform well over 1 billion tests per year, he notes. Each of these tests produces a test result, which becomes a disclosure of PHI to the ordering provider for treatment purposes. Moreover, other covered entities are increasingly demanding test results or related PHI for their own legitimate health care operations purposes. As a result, each patient encounter generates multiple disclosures of PHI for treatment, payment, and health care operations purposes on a daily basis.

For many labs, that translates into multiple billions of disclosures of PHI every year that will be subject to an accounting if their LIS systems are determined to be EHRs, explains Mertz. "Due to the sheer volume of transactions in which clinical laboratories are engaged, the complexity of their systems, and the ongoing efforts to achieve other major compliance initiatives mandated by HHS during the same timeframe (e.g., implementation of ICD-10), the burden of complying with this requirement for clinical laboratories would be severe."

Mertz also argues that the privacy rule should be amended to permit covered entities to charge a reasonable fee for each request for an accounting of disclosures of an individual's PHI.

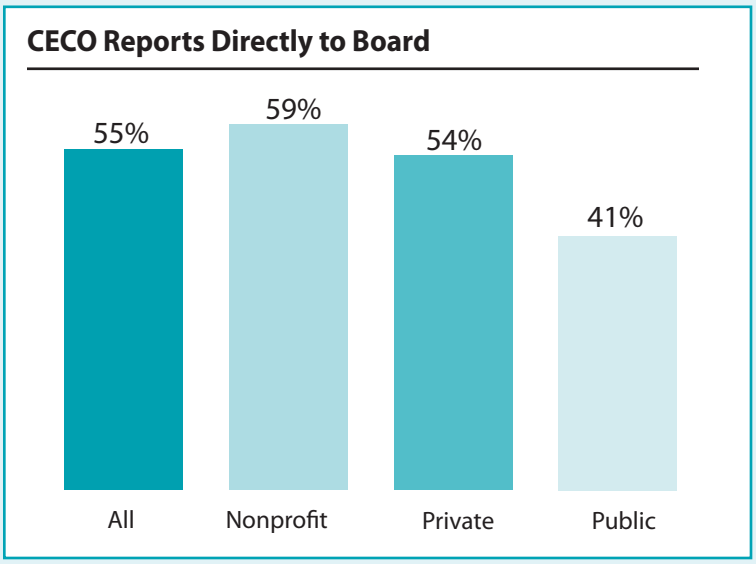
In the event that clinical laboratories are subject to the new disclosure requirement, Mertz believes that OCR should use its discretion to delay the compliance date to the latest dates permitted by the HITECH Act. Therefore, covered entities that acquire an EHR after Jan. 1, 2009, should have until Dec. 31, 2013, to comply with the new requirements, and covered entities that acquired an EHR on or before Jan. 1, 2009, should have until Dec. 31, 2016.

COMPLIANCE PERSPECTIVES

Direct Compliance Reporting to Board More Likely in Health Care Industry, Survey Finds

More Progress Still to Be Made

More than half of all health care industry chief ethics and compliance officers (CECOs), or 58 percent, reported having a direct reporting relationship with their board of directors, a higher rate than that of all other industries, according to report by the Society of Corporate Compliance and Ethics and the Health Care Compliance Association (HCCA).



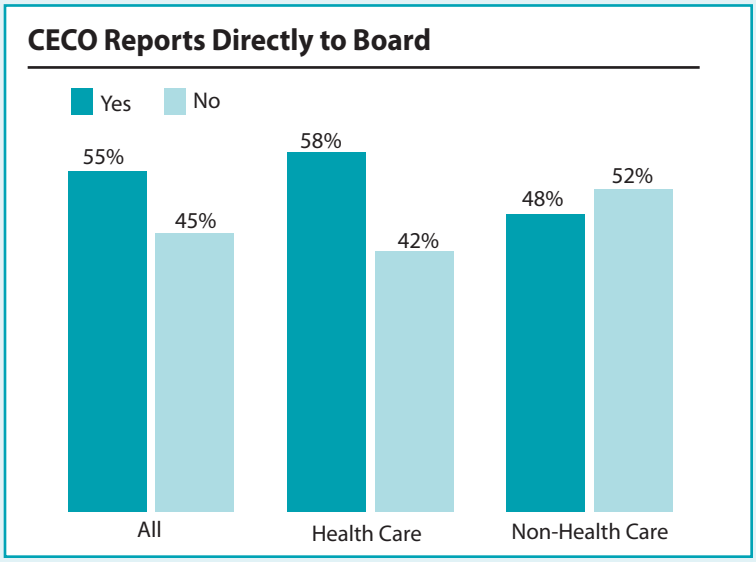
By contrast, the report said, only 48 percent of CECOs across all other industries reported having a direct board relationship.

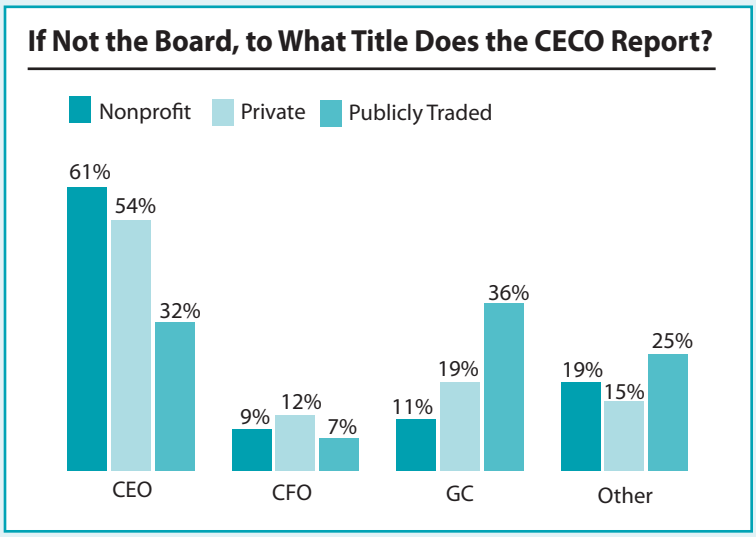
"In the health care industry, compliance officers are far more responsible and far more accountable," says HCCA Chief Executive Officer Roy Snell. "More health care compliance officers have their jobs properly defined, whereas in financial services, for example, the job is very narrowly defined."

The survey collected 481 responses, with roughly three-quarters coming from the health care industry. It also looked at compliance reporting across a spectrum of private, publicly traded, and nonprofit companies and found that publicly traded companies were the least likely to have a direct reporting arrangement to the board, with only 41 percent of respondents saying they had a direct relationship.

Nonprofits were the most likely to have a direct compliance relationship with the board, at 59 percent, followed by private companies at 54 percent.

In situations where CECOs did not report directly to the board, public companies also were the least likely to have a compliance reporting relationship with the chief executive officer, with only 32 percent of public company CECOs reporting such a relationship. Nonprofits in a similar situation had 61 percent of their CECOs reporting directly to the CEO, and private companies had 54 percent.





However, even if CECOs do not report to the board, there appears to be a regular interaction with it. Across all respondents, 65 percent reported that the CECO has four or more regularly scheduled meetings with the board. The overall responses were consistent across for-profit and nonprofit companies. Industry, though, was a factor, with 69 percent of health care respondents reporting having four or more meetings a year but just 53 percent of respondents outside health care having that many.

In terms of total meetings—regularly scheduled and not—between the CECO and board, industry is less important than profit orientation. Overall, 36 percent of respondents reported that five or more meetings take place with the board annually. For nonprofit entities, the percent was 40 percent, but for publicly traded companies the figure was just 26 percent.

Meetings in executive session were relatively uncommon. Regular board interactions far outnumbered those in executive session. Just 22 percent reported meeting in executive session four or more times a year while 46 percent reported that they have no meetings in executive session in the course of a typical year.

When it comes to getting their reports in front of the board without screening and editing, publicly traded companies again fall short, with just 35 percent saying that reports by the CECO to the board are always screened and substantially edited by the general counsel or some other executive. Such was the case for just 15 percent of respondents from privately held companies and 12 percent from nonprofits.

"Despite all the talk of integrated Governance Risk and Compliance (GCR) programs, despite [Sarbanes-Oxley] requirements for stronger internal controls, compliance remains farther down the pecking order at publicly traded companies than it is at either privately held or nonprofit organizations," notes the executive summary. "The data . . . reveals that boards and even CEOs have less contact with CECOs than recent legislation would suggest is necessary. This could pose a significant risk for

companies as they seek to implement compliance programs that have the ability to meet both the common and legal meaning of the term 'effective.'"

More to Be Done

While the health care industry is doing a good job with compliance, there is more progress to be made, the report concluded. Many companies do not have effective compliance reporting arrangements and may face larger penalties if any wrongdoing is uncovered than if they had workable relationships in place.

Specifically, the report said that the U.S. Sentencing Commission "recently sent changes to Congress which would enable organizations to get credit for having an effective compliance program, despite wrongdoing by senior leadership, if the individual with operational responsibility for compliance in the organization has direct reporting authority to the board level."

Snell says there are "two key steps" that need to be taken. "First, boards need to build awareness that they could be facing massive regulatory problems," he said. "Secondly, they need to realize that the solution to the problems is having an independent, transparent, unconflicted compliance program that looks, finds, and fixes the problem."

He said it is important that the compliance officer update the board on at least a quarterly basis. "The compliance officer needs to tell the board about the functions of the compliance program, as well as their role in the program," Snell said. The report, *The Relationship Between the Board of Directors and the Compliance and Ethics Officer*, is available at *www.hcca-info.org*.

Conclusions and Implications

- **Organizations, both public and private, will have a great deal more to do to ensure that they can take full advantage of potential fine reductions under the U.S. Sentencing Guidelines.** The proposed changes to the guidelines require a direct relationship with the board if a company is to receive credit for having an effective compliance program even if there was wrongdoing by senior management. Clearly, many companies do not meet those obligations and, troublingly, the publicly traded companies are the least likely to meet them at present. Without significant changes in practices, the companies most at risk for large fines are likely to have the least effective defense.

- **Despite all the efforts to promote better governance, it does not appear that there is yet a fully developed connection between governance and compliance.** Many compliance officers don't report either to the board of directors or even the CEO. The general counsel (GC) is still charged with responsibility in a large number of organizations despite the recent Pfizer settlement, which ordered that the CECO specifically not report to the GC. More, with compliance reports heavily vetted in many cases, it is difficult to know how true a picture of the compliance program many board members see.

- **The satisfaction of CECOs with their frequency of contact with the board is both heartening and puzzling.** It is encouraging to see the CECOs don't feel as if they are not seeing the board enough. But, in hindsight, it would likely have been worthwhile assessing the satisfaction levels with the quality of those contacts.

Craig Holden, Esq.

Legal Issues in Laboratory Outreach, *from page 1*

a hospital that refers a test for a Medicare hospital outpatient to a reference laboratory to bill Medicare for the test. Under Medicare direct billing rules, Medicare pays only the entity that actually performed or supervised a clinical laboratory test except:

- Lab-to-lab referrals if the laboratory billing for the referred test actually performs 70 percent of the test requests annually;
- Lab-to-lab referrals if the laboratory performing the test is under specified common ownership with the billing laboratory; and
- Tests provided under an arrangement with a hospital, critical-access hospital, or skilled nursing facility.

All labs, whether independent or outreach, are subject to the compliance program guidance for clinical laboratories issued by the Health and Human Services Office of Inspector General (OIG) in 1998. According to the guidance:

- Labs are required to take "all reasonable steps" to ensure that they are not submitting claims for services that are not "covered, reasonable, and necessary";
- Physicians must be made aware that Medicare will not pay for tests unless they meet Medicare coverage requirements and are reasonable and necessary;
- Requisition forms must "promote the conscious ordering of tests by physicians";
- Requisitions should advise physicians that Medicare does not cover routine screening tests; and
- Custom profiles are discouraged through use of notices mentioning false claims and physician acknowledgements.

Claims for Reimbursement

Fraud and abuse issues for clinical laboratories typically fall under two primary areas: claims for reimbursement and relationships with referral sources. The False Claims Act (FCA) prohibits filing, or causing to be filed, "false or fraudulent" claims, as well as using false statements to "conceal, avoid or decrease" a government obligation, explains Holden. The FCA does not require "intent to defraud." Instead, filing claims with "reckless disregard" of their truth or falsity is sufficient.

FCA liability is three times damages, plus $5,500 to $11,000 per claim. For a defense contractor with $100,000 in damages, the total penalty—assuming 12 claims—could be $432,000 ($100,000 x 3 + 12 x $11,000). "This would seem somewhat reasonable," notes Holden. But for a health care provider with $100,000 in damages and 2,000 claims, the total liability could be as high as $22.3 million ($100,000 x 3 + 2,000 x $11,000).

"I don't think anyone would call that fair," says Holden, who adds that because the financial stakes are so high, health care providers need to be especially careful about filing false claims.

The Fraud Enforcement and Recovery Act of 2009 (FERA) modified the FCA so that it is now illegal to "knowingly conceal . . . or knowingly and improperly avoid . . . or decrease . . . an obligation to pay or transmit money or property to the government." Essentially this change eliminated the old statutory language's need to make a "false statement of record." Mere knowledge of a false claim is now apparently enough for a fine to be levied, according to Holden.

Another important change with regard to overpayments by the federal programs was implemented as part of the Patient Protection and Affordable Care Act of 2010 (PPACA). Section 6402 of that law now requires reporting and repayment of overpayments within 60 days of *identification* (or the due date of the next cost report, if applicable). Violations of this provision are actionable under the FCA.

Cincinnati Health Alliance Agrees to Pay $108 Million in FCA Anti-Kickback Settlement

The Health Alliance of Greater Cincinnati (HAGC) and a former member hospital have agreed to pay $108 million to resolve claims they violated the anti-kickback statute and the False Claims Act by paying physicians for referring cardiac patients to the hospital, the Department of Justice (DOJ) announced May 21 (*United States ex rel. Fry v. Health Alliance of Greater Cincinnati Inc.*).

In a pay-to-play scheme, the United States alleged that the Christ Hospital, a 555-bed acute-care hospital in Mount Auburn, Ohio, limited the opportunity to work at the Heart Station, an outpatient cardiology testing unit that provides noninvasive heart procedures, to those cardiologists who referred cardiac business to the hospital, the DOJ press release said.

The United States further alleged that cardiologists whose referrals contributed at least 2 percent of the hospital's yearly gross revenues were rewarded with a corresponding percentage of time at the Heart Station. Thus, they had the opportunity to generate additional income by billing for the patients they treated at the unit and for any follow-up procedures that the patients required.

In addition, the government asserted that the hospital's use of Heart Station panel time to induce lucrative cardiac referrals violated the federal anti-kickback statute, which prohibits a hospital from offering or paying, or a physician from soliciting or receiving, anything of value in return for patient referrals, the release said. The United States also alleged that the claims the Christ Hospital submitted to Medicare and Medicaid as a result of this illegal kickback scheme constituted a violation of the False Claims Act.

Because the Christ Hospital declined to enter into a corporate integrity agreement acceptable to the Department of Health and Human Services Office of Inspector General (OIG), the OIG did not provide a release of its administrative exclusion authorities and is further evaluating the matter, the DOJ release said.

Relationships With Referral Sources

The two primary laws governing relationships with referral sources are the anti-kickback statute and the Stark law, which prohibits self-referrals. Penalties under the anti-kickback statute include criminal fines and imprisonment, civil money penalties of $50,000 plus three times the amount of the remuneration, and exclusion from federal health programs.

Prior to enactment of PPACA, prosecutors had to prove intent to commit a violation under the anti-kickback statute. However, PPACA lessened the burden of proof, stating that "with respect to the violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."

Remuneration under the anti-kickback statute does not necessarily have to be monetary, notes Holden. The Department of Justice, for example, intervened in a qui tam lawsuit alleging that a hospital rewarded cardiologists with favorable scheduling times for their own patients while physicians who were not good referrers were denied time in violation of the anti-kickback statute. This case recently settled for $108 million (*see box*).

Sanctions under the Stark self-referral prohibition include denial of payment, refund of amounts collected as a result of improper billing, CMPs of $15,000 per item or service plus two times the amount claimed, CMPs of $100,000 for "circumvention schemes," exclusion from federal

health care programs, and FCA liability.

Recent changes to Stark include a provision in FERA that makes knowing retention of overpayment a false claim. PPACA also creates a clear obligation to refund overpayments, creates a Stark self-disclosure process, and requires compliance programs for virtually all providers and suppliers, except physicians.

The changes mean "huge new FCA exposure for health care providers," says Holden. In addition, mandatory compliance programs will result in discoveries of more and more of Stark violations, he says, noting that smaller and less sophisticated providers will be disproportionately impacted.

For more on legal issues in laboratory outreach, see the September issue of G-2 Compliance Report.

Providers Can Expect More Stark Law Litigation Cases From DOJ, Attorney Says

No Stark law cases are too small or too large for the attention of the Department of Justice (DOJ), and providers can expect an aggressive DOJ litigation policy designed to seek massive damages, T. Reed Stephens, an attorney with the Washington office of McDermott Will & Emery, said June 8.

Stephens, speaking during the law firm's webinar, Compliance, Violations and Self-Disclosure: Managing New Risks under the Health Reform Law, also said that technical violations, as opposed to outright fraud, would still trigger litigation and advised providers to start reviewing physician agreements and various self-disclosure options available. The webinar was the second part in a series from McDermott. Part one focused on Stark compliance programs, among other issues.

Ankur Goel, an attorney also in McDermott's Washington office, said that providers have three options when it comes to handling a possible Stark law violation, including taking prospective corrective action, making a refund of Medicare payments received pursuant to claims that violated the Stark law, and making a disclosure of a violation.

'Prospective Corrective Action'

"Prospective corrective action is the first thing you need to do if you discover a violation," Goel said. "It's important to take action through the lens of how it will be included in a disclosure."

One way to take action is to terminate the affected physician relationship, Goel said. The relationship can also be modified to remove any potential future violations, he said, and providers should consider the possibility of training and discipline for violations.

Providers also can make refunds to the government of funds that resulted from prohibited referrals, Goel said. In this case, he said, providers should be aware that the refund is based on the value of Medicare reimbursements, not the dollar value of the physician compensation. There has not been a long history of providers making these refunds, he said.

The third option, Goel said, is providing a disclosure report to one of the enforcement agencies, such as the Department of Health and Human Services

Office of Inspector General, DOJ, the U.S. attorney's office, or the Centers for Medicare and Medicaid Services. Disclosures typically do not include repayments, he said.

Providers have several reasons for considering filing a disclosure, Goel said, including seeking a better financial resolution than a refund would provide and avoiding future qui tam or False Claims Act cases. Goel said that disclosures should prevent any FCA claims based on allegations that providers improperly avoided obligations to repay the government.

Regence BlueCross Investigating Billing Fraud

Regence BlueCross BlueShield is investigating medical billing fraud involving a multilevel vitamin marketing operation in several western states, according to a Regence anti-fraud specialist.

In recent weeks, Regence members in four western states have reported that their benefits have not matched the services that they ostensibly had received, said Alex Johnson, assistant director of the special investigative unit at Regence BlueCross BlueShield of Oregon.

The company, headquartered in Portland, has 2.5 million members in Oregon, Washington, Idaho, and Utah. Johnson is at Regence's Utah branch, and the vitamin operation was first uncovered in Utah. Specifically, an online ad sponsored by a California nutritional company promised that nutritional supplements are reimbursed up to 100 percent through health insurance plans. Some Regence members paid a fee to be part of this scheme.

The members then ordered supplements, and they entered their health insurance information into a Web-based form when the members placed their orders. The members sent receipts to the company which, in turn, billed the insurance company. Later, the members received their supplements, and they also received reimbursement checks from Regence, as promised. The members then sent a portion of the reimbursement checks on to the company, as well, Johnson said.

Customer Complaints

However, some members called Regence officials and said that the explanation of benefits from the reimbursement checks did not match the claims. The claims on behalf of the company were coded for legitimate covered services—such as consultations, laboratory, and X-ray services—but the members did not receive any such services.

For its part, the company essentially advised consumers to disregard any notes on their health plan's coding for services, alleging that the company was attempting to pay less than it should under the plan.

The bottom line, Johnson said, is that Regence paid benefits to members who did not receive any legitimate services whatsoever. Like most health insurers, Regence does not cover vitamins or nutritional supplements. As a result, he said, those members need to return their reimbursement checks.

In April, Regence sent out a nationwide alert to all Blue Cross and Blue Shield plans about this scam because some members may believe that vitamins are fully paid under their health insurance plan.

News-At-A-Glance

HHS, DOJ CALL FOR STATE FRAUD EDUCATION: Attorney General Eric Holder and Health and Human Services (HHS) Secretary Kathleen Sebelius June 8 called on all state attorneys general to create outreach programs this summer to educate seniors on Medicare fraud prevention and protection. "The more we can educate the American people about fraud prevention, the better chance we have to protect taxpayer dollars and the Medicare trust fund," Holder and Sebelius said in a letter to the state AGs. State education and outreach efforts can build on a number of existing initiatives from HHS and Department of Justice (DOJ), as well as on new tools provided by the Patient Protection and Affordable Care Act (Pub. L. No. 111-148), the letter said. For example, HHS and DOJ will hold a number of regional fraud prevention summits across the country, beginning with one in Miami on July 16. In addition, all 93 offices of the U.S. attorney have been asked to plan regular health care fraud task force meetings, with initial meetings scheduled to begin Aug. 16, the letter said.

OIG CLEARS PATIENT ASSISTANCE PROGRAM: A recent advisory opinion from the Department of Health and Human Services Office of Inspector General (OIG) said there was no violation of the anti-kickback statute regarding a donor-funded patient assistance program (PAP) that provided financial assistance to the underinsured for their prescription drug copayments. The OIG analyzed the nonprofit PAP to determine if it violated the Social Security Act's provision prohibiting inducements to beneficiaries, as well as whether it violated the federal anti-kickback statute. The OIG determined that the PAP was properly structured to insulate beneficiary identities from donors, making it unlikely that a donor's contributions could influence a beneficiary's choice of provider, supplier, or health insurance plan. In addition, OIG found that grants were awarded based on objective criteria, such as financial need or medical condition, which also prevented any connection between donor and beneficiary. Based on these findings, the OIG said that no donor contributions could be seen as payments to beneficiaries to arrange referrals. The advisory opinion is at *http://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10-06.pdf.*

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