G2 Compliance Report

For Hospitals, Laboratories and Physician Practices

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Sequester May Hurt Long-Term, Short-Term Anti-Fraud Efforts

Current fraud cases could take longer to resolve and fewer individuals may be willing to work for the federal government in fraud-fighting roles as a result of sequester cuts focused on Medicare and Medicaid program integrity that could harm both short-term and long-term fraud-fighting efforts, say experts.

The sequester, which was signed by President Obama March 1, will cut $57 million from the Health Care Fraud and Abuse Control (HCFAC) account by the end of the fiscal year in September, as well as $3 million from the Department of Health and Human Services Office of Inspector General (HHS OIG), according to a report from the Office of Management and Budget (OMB).

The HCFAC account coordinates law enforcement activity related to health care fraud and abuse on the federal, state, and local levels.

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Patent Claims Against LabCorp Allowed to Proceed

A patent infringement case filed by Verinata Health against Ariosa Diagnostics and LabCorp will be allowed to proceed.

A federal district court Feb. 20 denied a motion by LabCorp to dismiss contributory and induced infringement claims concerning patents related to prenatal genetic abnormality detection (*Verinata Health Inc. v. Ariosa Diagnostics Inc.*, N.D. Cal., No. 3:12-cv-05501-SI.

The U.S. District Court for the Northern District of California did grant LabCorp's motion to dismiss direct infringement claims by Verinata Health Inc. and Stanford University. The court also granted the plaintiffs leave to amend the complaint and indicated that with the amendment, the direct infringement claim would be "plausible, non-speculative, and sufficient."

According to the complaint, Verinata owns U.S. Patent No. 8,318,430 ("Methods of fetal abnormality detection," issued Nov. 17, 2012) and has an exclusive license from Stanford for U.S. Patent No. 8,296,076 ("Noninvasive diagnosis of fetal aneuploidy by sequencing," issued Oct. 22, 2012).

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Sequester May Hurt Anti-Fraud Efforts, *from page 1*

Demoralized Employees

Lewis Morris, an attorney with Adelman, Sheff & Smith LLC in Annapolis, Md., told BNA, G2 Intelligence's parent company, that the sequestration will trigger furloughs, demoralize employees, and divert attention from critical missions.

Morris, who previously served as chief counsel to HHS OIG, said he was worried that "many talented individuals who might have made a contribution to public service will decide to forgo a career in the government."

Although he acknowledged that federal employees will continue to work hard during the sequester, Morris said "cases may take longer to resolve, guidance and other discretionary projects may be postponed—and that hurts the integrity of the programs and the providers that play by the rules."

Brian Roark, an attorney with Bass Berry & Sims PLC, Nashville, Tenn., said the biggest potential impact of the sequester would be the "disruption of momentum in the government's health care fraud enforcement initiatives, especially civil enforcement whose personnel are considered nonessential."

He said that even if the sequester does not lead to reductions in the overall number of attorneys or agents focused on health care fraud enforcement, "extended furloughs generally increase attrition, with lawyers and agents leaving government service for the private sector, which likely could disrupt the momentum of civil enforcement activities."

Reduced Resources

In addition to causing delays in resolving anti-fraud cases, the sequester may diminish available program integrity resources, Kirk Nahra, an attorney with Wiley Rein, Washington, said.

He said the government's anti-fraud programs require substantial resources, provided by both internal government employees and outside contractors.

"By reducing the anti-fraud effort, the government will actually spend more on fraudulent claims, with an overall net negative effect on the government budget," Nahra said, as fewer cases of health care fraud will be investigated.

Louis Saccoccio, chief executive officer of the National Health Care Anti-Fraud Association (NHCAA), said that the immediate impact of the sequester would be felt in the training and education of federal agents at the Federal Bureau of Investigation and OIG who are involved in fighting fraud.

> ***"By reducing the anti-fraud effort, the government will actually spend more on fraudulent claims, with an overall net negative effect on the government budget."***
>
> ***—Kirk Nahra, Esq. Wiley Rein***

"Both agencies already are cutting back on planned attendance at training conferences by their agents," he said.

Saccoccio also said the NHCAA offers a range of education and training events open to public and private fraud investigators, and "we expect to see a very significant decline in attendance by federal employees this year."

Peter Budetti, director of the Center for Program Integrity at the Centers for Medicare and Medicaid Services (CMS), addressed the sequester during an appearance Feb.

27 before the House Energy and Commerce Subcommittee on Health. He said any reduction in resources resulting from the sequester would have a negative impact on program integrity efforts.

Rep. Bill Cassidy (R-La.) said he was incredulous that CMS would allow the sequester to impact program integrity efforts and attributed that to "poor management" at CMS. He urged the agency to find alternate cuts.

"Will the sequester cut a program that saves $7.90 for every $1 spent? What kind of management would do that?" Cassidy asked, referring to the return on investment rate provided in the fiscal year 2012 HCFAC report.

The OMB report is at *www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/fy13ombjcsequestrationreport.pdf.*

New Trial Ordered for Man Who Claims Quest Disclosed His HIV-Positive Status

The Missouri Supreme Court has ordered a retrial for a man who sued Quest Diagnostics, claiming the lab disclosed his HIV-positive status to the church where he worked, according to a report in the *St. Louis Post-Dispatch*.

The plaintiff, identified in court records only as John Doe 1631, went to Quest Labs in the Central West End, Mo., for blood work in July 2006. He had been living with HIV since 1999.

According to court records, the man's doctor faxed a form ordering blood work to him at the Wayman AME Church in St. Louis. The man then took the form, with the fax number written on the top, to the lab. Lab workers then sent the blood results to the church by mistake, assuming that's why the fax number was written on the order form.

The results came while Doe was on vacation and sat for about a week in view of church members and employees, according to the *Post-Dispatch*. The results referenced HIV in three places but did not make his positive status explicit.

A St. Louis Circuit Court jury sided with Quest in 2010, and the Eastern District Court of Appeals upheld the case last year. But on appeal, the man's attorney, Ken Chackes, argued that jurors were improperly instructed to consider whether Doe had given Quest "written authorization" to release the results by providing the form with the fax number on top.

The unanimous ruling, authored by Missouri Supreme Court Judge Laura Denvir Stith, agrees that the jury instruction was prejudicial to Doe's case. The court also ruled that Circuit Court Judge Dennis Schaumann properly granted a directed verdict to the lab's parent company, Quest Diagnostics, which argued that it should not be held liable for the actions of a subsidiary. Chackes had argued that the two should be treated as one and the same.

According to court records, Doe was fired from the church six months after the fax incident. The pastor said that he had already known of Doe's HIV-positive status and that the dismissal was for financial reasons. But Chackes argued that nobody else knew before the results were left in the open on the fax machine. He said his client received threatening phone calls at his home, with profane language warning Doe to stay away from the caller's children, says the *Post-Dispatch*. Doe is seeking unspecified punitive damages and compensation for emotional distress.

Bill Would Exempt Pathologists From 'Meaningful Use,' Penalties

A bill introduced March 21 by Rep. Tom Price (R-Ga.) would exempt pathologists from participating in the Medicare and Medicaid Electronic Health Record (EHR) incentive programs.

The Health Information Technology Reform Act (H.R. 1309) would prevent pathologists from being eligible for "meaningful use" incentives but would also protect them from Medicare payment penalties—scheduled to begin in 2015—for not meeting the program's criteria.

The bill reflects long-standing concerns from pathologists that the meaningful use program for eligible professionals is focused almost entirely on office-based physicians and generally does not apply to their pathology practices. The bill also notes that most pathologists already use laboratory and pathology information systems to maintain patient information and exchange laboratory and pathology test data with EHRs and other systems.

However, the "lack of alignment" between pathology practices and their existing information systems and the meaningful use regulations "make it nearly impossible" for pathologists to meet the programs' requirements, according to the bill.

"Through their role in appropriate test selection and personalized medicine, and with access to the patient's electronic health record, pathologists can play a key role in furthering Congress' goals of reducing costs and improving health care quality," Price wrote in the bill.

But pathologists should not be subject to payment penalties under the EHR program for failing to meet standards that do not apply to their practices or their typical interactions with patients, according to the bill.

Comments to ONC

In a January letter to the Office of the National Coordinator's Health IT Policy Committee commenting on recommendations for Stage 3 of the meaningful use program, the College of American Pathologists (CAP) criticized the advisory group for not addressing the issue of specialists more directly.

The HIT Policy Committee had sought comments on a slew of recommendations for the next phase of the incentive program. Those recommendations will be used to advise ONC and the Centers for Medicare and Medicaid Services. CMS is responsible for meaningful use program rules.

"The CAP understands that CMS and ONC wrote MU rules largely to incent office-based providers, particularly primary care physicians and hospitals, to adopt certified EHRs," the pathologists' group wrote. "Therefore, it is not surprising that the majority of the Stage 1 and Stages 2 objectives are outside the scope of pathology practice. The draft Stage 3 recommendations perpetuate this practice. We are disappointed that the HITPC continues to fail to recognize important and fundamental differences among specialties."

CAP also acknowledged that most pathologists automatically qualify for the significant hardship exemption under the meaningful use rules, which protect them from Medicare payment adjustments after the penalty phase kicks in. But the group said permanent relief—not temporary regulatory relief—was needed.

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

Donations of Electronic Health Records Technology: Is It Still Safe to Take Advantage of the Federal Safe Harbor?

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The safe harbor issued by the Department of Health and Human Services Office of Inspector General under the Medicare and Medicaid anti-kickback law and the exception issued by the Centers for Medicare and Medicaid Services under the Stark physician self-referral law that permit certain donations of electronic health record (EHR) software or information technology and training services will terminate on Dec. 31, 2013. Generally, under the EHR safe harbor and exception, pathology providers, laboratories, and other permitted donors can subsidize the cost of compliant EHR technology for referring physicians at up to 85 percent of the cost of such technology, provided that all of the criteria of the safe harbor and the exception are met.

As the federal safe harbor and exception for EHR donations do not pre-empt or displace state anti-kickback law and regulations, all providers must comply with both federal and state statutes and regulations. Therefore, it is particularly important to review the formal guidance that has been issued in New York, New Jersey, Pennsylvania, Tennessee, Missouri, Washington, and West Virginia regarding EHR donations.

State Law Analysis

Tennessee

On March 4, 2013, the Tennessee attorney general issued an opinion severely restricting many if not most EHR donations in Tennessee. Specifically, the Tennessee attorney general relied on Tenn. Code Ann. 68-29-129(7), which is part of the Tennessee Medical Laboratory Act, and prohibits any person from soliciting the referral of specimens to such person's (or to any other) medical laboratory or from contracting to perform medical laboratory examination of specimens "in a manner that offers or implies an offer of rebates to a person or persons submitting specimens, other fee-splitting inducements, participation in any fee-splitting arrangements, or other unearned remuneration." The Tennessee attorney general opined that this "anti-kickback" provision prohibits any explicit or *implicit* financial incentive to solicit a contract to perform medical laboratory examinations of specimens. Thus, even the implication of an offer by a medical laboratory of a rebate, fee-splitting inducement, fee-splitting arrangement, or "other unearned remuneration" to a person submitting specimens is prohibited.

Accordingly, the Tennessee attorney general ruled that a licensed medical laboratory is prohibited from making any monetary donation to a physician to cover the cost of software designed to manage the physician's EHRs when the physician's office that receives the donation either continues an existing referral arrangement with the donating laboratory or subsequently initiates an arrangement for referral of specimens to the donating laboratory for analysis.

Washington

On Nov. 20, 2012, the Washington attorney general issued a similar opinion restricting many if not most EHR donations in Washington. Specifically, the Washington

attorney general ruled that a donation by a laboratory to a referring physician of 85 percent of the software cost of the physician's EHR, when the physician either has a continued referral arrangement with the laboratory or subsequently initiates a referral relationship with the laboratory, violates Section 19.68.010 of the Washington Anti-Rebate Statute (RCW 19.68.010). This state law generally makes it unlawful to request, receive, or allow, directly or indirectly, a rebate, refund, commission, unearned discount, or profit by means of a credit or other valuable consideration in connection with the referral of patients.

Specifically, the Washington attorney general ruled that a donation by a laboratory to a referring physician of 85 percent of the software cost of the physician's EHR, when the physician either has a continued referral arrangement with the laboratory or subsequently initiates a referral relationship with the laboratory, violates Section 19.68.010 of the Washington Anti-Rebate Statute (RCW 19.68.010).

West Virginia

On July 9, 2012, the West Virginia Board of Medicine issued a similar opinion. Specifically, the West Virginia Board of Medicine stated that if a physician receives a monetary donation to cover 85 percent of the cost of the physician's EHR when the recipient physician either continues a referral arrangement with the laboratory, or subsequently initiates an arrangement for the referral of specimens to the donating laboratory for analysis, these actions would be in violation of West Virginia Code 30-3-14(c)(6). This West Virginia law defines the grounds for professional discipline of physicians and podiatrists, and these grounds include requesting, receiving, or paying directly or indirectly a payment, rebate, refund, commission, credit, or other form of profit or valuable consideration for the referral of patients to any person or entity in connection with providing medical or other health care services or clinical laboratory services, supplies of any kind, drugs, medication or any other medical goods, services, or devices used in connection with medical or other health care services.

Pennsylvania

On Aug. 18, 2011, the Pennsylvania Department of Health issued an opinion regarding the application of Section 5.71 of the Pennsylvania Administrative Code to the donation of EHR software costs by a laboratory to a physician who refers specimens to that laboratory. Section 5.71 states that "No employee or representative of a laboratory, either personally or through an agent, may solicit referral of specimens to his or any other laboratory in a manner which offers or implies an offer of rebates to persons submitting specimens or other feesplitting inducements. . . . No person involved in the submission of specimens may receive payment or other inducement by the laboratory or its representative."

The department determined that this state law could be violated if the donation in question is made by the laboratory to the physician in order for the laboratory to obtain more business from the physician in question. If the donation is made without this expectation, real or implied, then the prohibition contained in Section 5.71 does not apply. If, however, the donation is made with the explicit or implicit expectation or understanding of increased referrals, the donation could be a violation of Section 5.71. The department warned that if the Bureau of Laboratories discovers an increase in specimen referrals between the physician recipient and the donating laboratory and it appears that the increase is a result of the donation made by the clinical laboratory, then Section 5.71 would be implicated and the department would take appropriate action.

Missouri

On June 14, 2011, the Missouri attorney general issued an opinion finding that a laboratory's donation of 85 percent of the costs of a physician's EHR software costs,

when afterward the physician either initiates or increases the referral of certain work to that laboratory, constitutes a kickback in violation of Missouri Revised Statutes Section 191.905. This state statute states in relevant part:

> 2. No person shall knowingly solicit or receive any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for:
>
> (1) Referring another person to a health care provider for the furnishing or arranging for the furnishing of any health care; or
>
> (2) Purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any health care.
>
> 3. No person shall knowingly offer or pay any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person to refer another person to a health care provider for the furnishing or arranging for the furnishing of any health care.

New Jersey

On July 19, 2010, the New Jersey Department of Health and Senior Services issued a new regulation, N.J.A.C. 8:44-2.14(a)(5), which states, "A clinical laboratory that operates a collection station in a physician's office, also known as in-office phlebotomy, shall be limited to collecting specimens from patients of the medical practice in which the collection station is located, and shall comply with the following provisions: Except as necessary for the reporting of test results, the laboratory shall not provide office supplies, equipment, waste disposal services, test kits for the physician's own use, electronic medical records systems or other goods or services to the physician."

If a laboratory donates an EHR system to a physician office with which the laboratory has a referral arrangement and the physician's laboratory referral pattern shifts significantly in favor of the donating laboratory, the department would consider the donation an incentive to the physician to refer specimens in violation of N.J.S.A. 45:9-42.42 unless the shift can be demonstrated to be beyond the control of the physician.

On March 16, 2011, the director of the Clinical Laboratory Improvement Service issued guidance stating that the rule does not prohibit all EHR donations but only those under certain circumstances. The operation of an on-site histologic processing facility at a physician's offices does not preclude the laboratory from donating an EHR system when the laboratory does not operate a collection station in the physician office and the donation complies with the federal safe harbor. A laboratory with no referral arrangement with a physician can donate an EHR system, assuming the donation is also in compliance with the federal safe harbor. However, if such donation is determined to be contingent upon the referral of specimens as evidenced by a significant shift in prior referral patterns, the laboratory may be determined to be in violation of N.J.S.A. 45:9-42.42.

If a laboratory donates an EHR system to a physician office with which the laboratory has a referral arrangement and the physician's laboratory referral pattern shifts significantly in favor of the donating laboratory, the department would consider the donation an incentive to the physician to refer specimens in violation of N.J.S.A. 45:9-42.42 unless the shift can be demonstrated to be beyond the control of the physician.

New York

On Sept. 27, 2010, the New York Department of Health issued a mandate prohibiting the donation of EHR systems to physician referral sources. In an open letter to laboratory owners and operators, the department provided guidance regarding the parameters under which laboratories are permitted to provide software and hardware to physicians in order to facilitate test ordering and the transfer and storage of laboratory-generated data. Specifically, laboratories are permitted to:

1. Interface their laboratory information system to the client's existing EHR to enable seamless laboratory test ordering and laboratory test reporting, and facilitate other laboratory-related functions (see item 2 below), and may assume, as a cost of doing business, the cost of such a limited interface;

2. Provide to a practitioner computer hardware, software, and information technology training and supplies that are restricted to laboratory-related functions that enable the practitioner to (i) order tests from the laboratory, including access to a directory of services (i.e., specimen type, collection container, and test information); (ii) receive, access, print, and store test results received from the laboratory, including storing cumulative results for individual patients; (iii) transmit data necessary for the laboratory to prepare requisitions and generate bills, invoices, or claims for reimbursement; and (iv) transfer laboratory data received from the laboratory to any computer system maintained by the practitioner;

3. Provide computer hardware and software as noted above that also contains functionality that permits a practitioner to make referrals to other laboratories and/or provides access to other laboratories' Internet portals; and

4. Provide to a regional health information organization (RHIO) or health information exchange (HIE) computer equipment and supplies, information technology, and software in accordance with the requirements in bullet 2 above. Laboratories may not contribute to the RHIO's or HIE's acquisition costs for EHR components, including software interfaces, or a practitioner's costs of participation unless in accordance with the requirements in bullet 2 above.

Anti-Kickback Safe Harbor and Stark Exception

For those laboratories that wish to consider a donation before the expiration of the anti-kickback safe harbor and Stark exception for EHR donations, here are some important considerations to keep in mind:

What can be donated?

The donation must consist of interoperable EHR software and the directly related technical and training services that are necessary and used predominantly to receive, transmit, and maintain electronic health records of the medical practice's or physician's patients. Hardware, such as computers and routers, are not allowable donations. An EHR system is broadly defined as "a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions."

Any donation of EHR software must be capable of electronic prescribing, either through an e-prescribing component or module or through the ability to integrate with a physician's existing e-prescribing system. Interoperability is specifically defined as "the ability [of the EHR software] to communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose of the data are

preserved and unaltered." Software may be deemed interoperable if a certifying body recognized by the secretary of the Department of Health and Human Services has certified the software no more than 12 months prior to the date it is provided to the physician, such as the Certification Commission for Health Information Technology (*www.cchit.org*).

Further, the donated systems may not include software that is used primarily for personal or business unrelated to the physician's medical practice, e.g., scheduling, billing, or claims software packages that do not have EHR components. Staffing of physicians' offices cannot be included in the donation.

A donation is not permitted if the prospective recipient already possesses equivalent technology, which means that a physician who already has an EHR system cannot later ask a laboratory to make a donation toward the system.

What are the criteria that may be used to select recipients?

Donors of EHRs may not take into account, directly or indirectly, the volume or value of physician referrals or other business generated between the parties when determining which physicians are eligible to receive donated items and services, or the nature of those items and services. Donations cannot be conditioned upon the commencement or continuation of referrals from the recipient.

There are a number of criteria that are deemed to meet these requirements:

- The total number of prescriptions written by the physician (but not the total number of laboratory or pathology services ordered by the physician);
- The size of the physician's medical practice, e.g., total number of patients, encounters, or relative value units;
- The physician's overall use of automated information technology in his or her medical practice;
- The total number of hours the physician practices medicine or surgery;
- Whether the physician is a member of the donor's medical staff; and
- The level of uncompensated care provided by the physician.

What arrangements or agreements need to be made between donor and recipient?

The arrangement must be set forth in a written agreement that specifies in detail the items and services that are being donated and the donor's costs, and that covers all of the items and services that are to be provided by the donor. Before the physician receives the donated items, the physician must pay 15 percent of the cost of the EHR costs that are eligible for donation. The donor is prohibited from financing the physician's portion of the costs.

Conclusion

If a donation is made that does not comply fully with the applicable Stark exception and anti-kickback safe harbor, as well as any applicable state laws, both the recipient and the donor, including individuals who are involved in the donation negotiations, could be subject to civil and criminal penalties under these fraud and abuse laws. These penalties can include civil monetary fines, exclusion from the Medicare and Medicaid programs, and up to five years in prison. The physicians could also be at risk of discipline by their state medical boards. As a result, compliance is critical.

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Patent Claims Against LabCorp Allowed to Proceed, *from page 1*

Verinata and Stanford stated in the complaint that in early 2012, Verinata began offering the verifi prenatal test that analyzes cell-free DNA from a pregnant woman to determine whether the fetus is at risk of having an abnormal number of chromosomes. They also alleged that in or around May 2012, Ariosa Diagnostics and LabCorp began offering the Harmony Prenatal Test, a noninvasive test for Down syndrome, that Verinata and Stanford alleged infringed the '076 and '430 patents.

Verinata and Stanford jointly asserted the following claims against the defendants regarding the '076 patent, and Verinata alone asserted those claims against the defendants regarding the '430 patent: direct infringement, induced infringement, and contributory infringement. Ariosa and LabCorp moved to dismiss the claims asserted against LabCorp.

In an opinion authored by Judge Susan Illston, the court noted that allegations regarding LabCorp's involvement rested on three things: a May 7, 2012, press release that stated the Harmony Test "will be offered through LabCorp and will be available at its 1,000+ patient service centers," literature on Ariosa's Web site that described the test, and statements that "Defendants have [performed] and continued to perform the [Harmony Test] on samples of maternal blood."

Direct Infringement Dismissed—for Now

The defendants moved to dismiss the complaint, arguing that the plaintiffs had failed to adequately allege LabCorp's infringement. They also moved to dismiss the plaintiffs' request for enhanced damages. Because the plaintiffs agreed to withdraw that request, the court granted the defendants' motion to dismiss that element of the complaint.

The court agreed with the plaintiffs that the defendants' unsubstantiated claims regarding the actual role LabCorp played in preparing and running the Harmony Test should not be considered in a motion to dismiss.

According to the argument that the plaintiffs failed to adequately plead direct infringement under 35 U.S.C. §271(a), the first amended complaint alleged that the defendants were "practicing" the patent but did not allege directly that LabCorp "makes, uses or sells" the patented invention, as required by Fed. R. Civ. P. 84, Form 18. The court agreed with the plaintiffs that the defendants' unsubstantiated claims regarding the actual role LabCorp played in preparing and running the Harmony Test should not be considered in a motion to dismiss.

"However," Illston wrote, "the Amended Complaint does not expressly allege that LabCorp 'makes' or 'uses' the Harmony Test. Therefore, the Court grants defendants' motion to dismiss, but allows plaintiffs leave to amend to clearly allege that LabCorp is directly liable under the 'make' and 'use' prongs of §271(a). If amended, the revised allegations, when combined with inferences from language contained in Ariosa's press release, would be plausible, non-speculative and sufficient."

The court also found that the plaintiffs should be allowed to amend their complaint to expressly allege that LabCorp sold and/or offered to sell the Harmony Test in violation of Section 271(a). G2

HHS OIG Releases Updated Guidelines On Evaluating State False Claims Laws

The Department of Health and Human Services Office of Inspector General (OIG) March 15 issued updated guidelines for evaluating state false claims act legislation to reflect amendments made to the federal False Claims Act (FCA) in 2009 and 2010.

The updated guidelines, which are effective March 15, apply amendments to FCA made by the Fraud Enforcement and Recovery Act, the Affordable Care Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act to OIG's evaluation process of state FCA legislation under Section 1909 of the Social Security Act.

"These three acts, among other things, amended the bases for liability in the FCA, expanded the rights of qui tam relators, and added an express requirement that civil penalties include adjustments under the Federal Civil Penalties Inflation Adjustment Act of 1990," OIG said.

The original guidelines for evaluating state FCA laws were released in August 2006.

Financial Incentive for States

Under Section 1909, if OIG determines a state has a qualifying FCA law, the state's share of any Medicaid recoveries made under their FCA will be increased by 10 percentage points. "For example, if the State's Medicaid share is 50 percent, the State would be entitled to 60 percent of the amount of the recovery, while the Federal Government would be entitled to 40 percent," OIG said.

The updated guidelines, which are effective March 15, apply amendments to FCA made by the Fraud Enforcement and Recovery Act, the Affordable Care Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act to OIG's evaluation process of state FCA legislation under Section 1909 of the Social Security Act.

To qualify for the 10 percent incentive, OIG must determine that the state's FCA:

- Establishes liability for false or fraudulent claims (the updated guidelines include definitions for "claim," "obligation," and "material");
- Contains provisions that are at least as effective in rewarding qui tam actions as those in the federal FCA;
- Contains a requirement for filing an action under seal for 60 days with review by the state attorney general; and
- Contains a civil monetary penalty that is not smaller than the CMP authorized by the federal FCA (under the previous guidelines, the CMP had to be at least $5,000 to $10,000 per false claim, while the CMP is now $5,500 to $11,000 per false claim, due to adjustment by the Federal Civil Penalties Inflation Adjustment Act).

States that had their FCA laws approved by OIG prior to the three amendments to the federal FCA were given a two-year grace period, with expiration dates included in individual letters sent to the affected states, OIG said.

"After the expiration of its 2-year grace period, a State will no longer qualify for the incentive unless its law: (1) is amended and resubmitted to OIG for review and (2) either is approved by OIG or is pending review by OIG," OIG said.

The updated OIG guidelines are at *https://oig.hhs.gov/fraud/docs/falseclaimsact/guidelines-sfca.pdf*. The original OIG guidelines are at *http://www.gpo.gov/fdsys/pkg/FR-2006-08-21/pdf/E6-13749.pdf*.

News-At-A-Glance

WHO SHOULD COMPLIANCE OFFICER REPORT TO? An overwhelming majority (80 percent) of compliance officers opposed having their compliance department report to their organization's corporate counsel, according to a survey from the Health Care Compliance Association and the Society of Corporate Compliance and Ethics released March 7. The survey, *Should Compliance Report to the General Counsel?*, also found that 88 percent of compliance officers opposed having the organization's corporate counsel serve as the chief compliance officer. The online survey was conducted in January and February and included responses from more than 800 compliance officers representing private and public companies as well as nonprofit organizations. Forty-nine percent of respondents were from health care organizations. A central reason for the opposition to reporting to the corporate counsel, and having a corporate counsel serve as chief compliance officer, was a fear over potential conflicts of interest, the survey said. For example, one respondent said there was a potential conflict of interest between the role of compliance officers, which involves uncovering an organization's weaknesses, and the role of the chief counsel, which involves defending an organization from legal attacks.

EHR AND UPCODING CONCERNS: The Centers for Medicare and Medicaid Services (CMS) remains committed to ensuring Medicare providers adopt electronic health records (EHRs), despite an increase in claims upcoding that may be related to the systems, acting CMS Administrator Marilyn Tavenner told hospital executives March 5. Speaking at a Federation of American Hospitals conference, Tavenner said CMS will spend more time this year educating providers about the use of EHRs and will conduct "small, targeted audits" to ensure electronic billing is being "done properly." Tavenner said there has been an increase in upcoding in physician offices and hospital emergency rooms, possibly related to the use of EHRs. The increased use by providers of EHRs may be helping CMS uncover more instances of upcoding than in the past, and/or the design of the system may somehow be contributing to the increase in upcoding, Tavenner said.