G2 Compliance Report

For Hospitals, Laboratories and Physician Practices

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Ohio State Medical Center Reaches Settlement Over PT Violations; Lab to Stay Open

Ohio State University's Wexner Medical Center will pay the federal government $268,000 to settle allegations that its lab violated proficiency testing laws. The agreement will allow the lab to stay open and under OSU control, according to a report in *The Columbus Dispatch*.

The settlement "is a very favorable resolution for the hospital because its laboratory can continue to provide testing and can continue to bill Medicare and Medicaid for its services," says Robert Mazer, Esq., an attorney with the law firm of Ober | Kaler in Baltimore.

The Centers for Medicare and Medicaid Services (CMS) levied sanctions this past summer after the lab sent six proficiency-test samples to the Mayo Clinic and to another OSU lab for testing. Federal law prohibits a lab from sending such samples to another lab, even within the same hospital system.

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Court Refuses to Dismiss Lab Owner's FCA Complaint Against Rival Company

A federal trial court in Ohio has refused to dismiss a False Claims Act (FCA) lawsuit by a lab owner who alleged that a competing lab performed and billed for kidney tests not ordered by treating physicians and paid kickbacks to induce physicians to refer business to it (*United States ex rel. Daugherty v. Bostwick Laboratories*, S.D. Ohio, No. 1:08-cv-00354-SAS-KLL, 12/18/12).

The U.S. District Court for the Southern District of Ohio rejected the defense argument that the lawsuit was jurisdictionally barred because the question of whether physicians are allowed to mark up the technical component of lab tests has been publicly debated for years. The public disclosure bar also is inapplicable, the court said.

The court also rejected the defense argument that the complaint should be dismissed because it failed to specify a single case where it billed a medically unnecessary fluorescence in situ hybridization (FISH) test to federal health care programs.

Defendant Bostwick Laboratories argued that any FISH test it ran without a treating physician's signature was medically necessary in

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Ohio State Medical Center Reaches Settlement, *from page 1*

The sanctions could have cost OSU millions of dollars in Medicare and Medicaid reimbursement, according to the *Dispatch* report. The penalties had been on hold during the university's appeal of the sanctions.

As part of the settlement, OSU has appointed a new clinical laboratory director. Daniel Sedmak, M.D., a professor of pathology, will replace Amy Gerwitz, M.D., who will remain an OSU employee. In addition, the lab staff will undergo additional training.

"We are grateful to CMS for its willingness to work toward a resolution that best meets the needs of our patients and the community," said Larry Anstine, CEO of OSU Hospital, in a statement.

Violations Self-Reported

According to a July 20, 2012, report in the *Dispatch*, the lab in February 2012 sent a PT sample of Lyme disease to an outside lab in violation of federal rules. A subsequent review found that five more blood-culture specimens had been improperly referred to another OSU laboratory between November 2009 and November 2011. Laboratory officials self-reported the violations, which they said were accidental.

In a June 14 letter, CMS officials told Gerwitz that the lab was out of compliance with federal rules. The lab responded with more than 100 pages of documents, but CMS on July 12 imposed sanctions on the lab, including revocation of the lab's CLIA certificate and a loss of Medicare and Medicaid reimbursement for services. The lab appealed, and sanctions were put on hold pending an appeal before an administrative law judge.

The laboratories at OSU's Wexner Medical Center perform approximately 9.6 million patient tests and 9,200 proficiency tests a year and have been fully accredited by the College of American Pathologists since 1969.

Under current federal law, labs may not send PT samples to another laboratory for testing even if they typically send patient specimens out for confirmation. Sending PT samples to another laboratory for testing may be considered PT referral and could result in the loss of the lab's CLIA certificate for at least one year. In addition, the lab director cannot direct a laboratory for two years, and the lab owner may not own or operate a lab for two years.

President Obama recently signed into law a bill passed by Congress that gives CMS leeway in enforcing sanctions on clinical laboratories for violating PT referral rules. Specifically, the Taking Essential Steps for Testing Act gives CMS enforcement discretion to make the one-year CLIA certificate revocation optional rather than mandatory and allows CMS to levy intermediate sanctions instead of the two-year prohibition against ownership or operation of a lab.

"The settlement may indicate that, in appropriate cases, CMS will accept lesser sanctions than revocation," notes Mazer from Ober|Kaler. "However, the settlement is not precedent on which another laboratory can legally rely. Additionally, it's very difficult to determine what factors CMS will consider important in determining whether to accept a sanction other than revocation based on a single settlement."

In the past, CMS was required to revoke a laboratory CLIA certificate if it found that laboratory intentionally referred PT specimens to another laboratory, says

Mazer. "A lesser penalty might be imposed only if the referral was unintentional," he explains. "However, CMS viewed a referral to be intentional if the laboratory intended for another laboratory to test its proficiency testing specimens, even if it didn't know that it was breaking the law."

Under the new law, CMS now has discretion in determining whether a PT referral was intentional or not, as well as what the appropriate sanction should be.

Free Access to Electronic Interface OK, Says OIG

The Health and Human Services Office of Inspector General (OIG) has given the green light to a proposed arrangement whereby a hospital would provide physicians with free access to an electronic interface for sending lab and diagnostic test orders to the hospital and receiving the results.

In Advisory Opinion 12-20, released Dec. 19, the OIG said the arrangement would not generate prohibited remuneration under the anti-kickback statute (42 U.S.C. §1320a-7b(a)) or lead to administrative sanctions under its exclusionary authority or provisions governing the imposition of civil money penalties.

Facts Presented to the OIG

The party that sought the OIG's opinion is a hospital operated by a county government and located in a health professional shortage area. It would provide free access to an electronic interface to community physicians and physician practices that request it. The physicians could use the interface to transmit to the hospital orders for laboratory and diagnostic services to be performed by the hospital and to receive the results of those services.

In addition, the hospital would provide, through a contractor, support services necessary to maintain the interface, including software updates. The physicians who chose to participate in the arrangement would remain responsible for all aspects (e.g., acquiring, installing, and maintaining) of their own electronic health records system, including all necessary hardware and connectivity services, that would allow them to communicate with the hospital through the interface. The hospital certified that the interface would serve no purpose other than to transmit the orders and results.

Legal Analysis

The OIG said the arrangement would not violate the anti-kickback statute because it would not provide remuneration to the participating physicians. In light of the facts presented, the OIG concluded, "interface access would be integrally related to the hospital's services, such that the free access would have no independent value to the physicians apart from the services the hospital provides. Accordingly, we conclude that the proposed arrangement would not implicate the anti-kickback statute."

If physicians were able to use the free interface for additional functions beyond transmitting test orders, then the free interface would have an independent value and could be an illegal inducement prohibited under the anti-kickback statute, the OIG cautioned.

The advisory opinion is posted at *oig.hhs.gov*. It applies only to the party requesting it and is based on information the party provided. It has no application to, and cannot be relied upon by, any other individual or entity.

Lab EMR Donations Violate Washington Anti-Rebate Statute

Washington state Attorney General Rob McKenna has ruled that the donation by a laboratory to a referring physician of 85 percent of the software cost of the physician's electronic health record (EHR) violates the state anti-rebate statute.

The Washington anti-rebate statute provides that is 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."

"The state attorneys general of Missouri and Pennsylvania also have issued opinions that question the legality of EMR donations, and regulations in New Jersey and New York also place limitations on EMR donations."

—Jane Pine Wood, Esq.

According to Jane Pine Wood, Esq., an attorney with McDonald Hopkins, the attorney general considered a donation by a laboratory to a referring physician for 85 percent of the electronic health record software expenses.

While such a donation can be structured to fall within the applicable exception under the Stark law and the applicable safe harbor under the Medicare and Medicaid anti-kickback statute, the Washington attorney general ruled that such a donation would still be in violation of [the anti-rebate statute].

"The state attorneys general of Missouri and Pennsylvania also have issued opinions that question the legality of EMR donations, and regulations in New Jersey and New York also place limitations on EMR donations. Many states have fraud and abuse laws, and these recent attorney general opinions raise the possibility that other state attorney generals could issue similar opinions," says Wood.

While both the anti-kickback and the Stark law prohibit inducements for referrals, the electronic health records safe harbor permits referring providers to receive a donation of EHR software and related training from a clinical laboratory (or other health care provider) provided certain conditions are met.

The EHR donation cannot be tied to the volume of referrals, and the recipient must pay a minimum of 15 percent of the costs. No portion of this contribution may be funded or financed by the donor or any affiliate of the donor. The safe harbor is set to expire at the end of 2013.

HIPAA Enforcement Final Rule Increases CMP Cap

The Health Insurance Portability and Accountability Act (HIPAA) enforcement final rule, released Jan. 17, incorporates increased civil monetary penalties and caps maximum annual penalties at $1.5 million, up from an existing $25,000 cap.

The final rule, released as part of an omnibus package of HIPAA final rules, "adopted a range of penalty amounts between the minimum given in one tier and the maximum given in the second tier for each violation and adopted the amount of $1.5 million as the limit for all violations" of the same HIPAA provision in a calendar year. The increased penalties apply to all covered entities, which are defined as health care providers, health plans, and health care clearinghouses.

The final rule will be published in the Jan. 25 *Federal Register* and will take effect March 26. Covered entities and business associates must be in compliance with the final rule by Sept. 23. An interim HIPAA enforcement final rule was released Oct. 30, 2009. The final rule did not make any significant changes to the interim final rule.

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

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Editor's note: This article is excerpted from Gibson and Dunn's "2012 Year-End False Claims Act Update." The full article is available at www.gibsondunn.com/publications/Pages/2012YearEnd-FalseClaimsActUpdate.aspx.

Torrid Pace of False Claims Act Recoveries Likely to Continue in 2013

For years, the Department of Justice (DOJ) has sought recoveries under the False Claims Act (FCA) with a torrid pace. In 2012, those efforts remained unabated. The federal government recovered approximately $5 billion in the last fiscal year alone from settlements and judgments in cases filed under the FCA. This record amount marks the third consecutive fiscal year in which the government recovered more than $3 billion and brings total recoveries under the FCA during the last four years up to $13.3 billion, the largest four-year total ever.

Although staggering, the monetary values of these settlements and judgments tell only part of a much bigger story: Today, FCA resolutions frequently entail significant nonmonetary components requiring companies to implement enhanced compliance practices that can compound corporate trauma and disruption. Moreover, the DOJ continues to advocate novel recovery theories—pushing the envelope past the statute's historic roots. We have pounded the drum consistently about the onslaught of FCA cases. And all available evidence shows that as the government's recoveries under the FCA continue to grow, the DOJ continues to devote more resources to investigating and enforcing the act, and plaintiffs' lawyers representing "whistleblowers" (called qui tam relators) continue to file more qui tam lawsuits.

This past year was no exception. As in prior years, the government's enforcement of the FCA—in cases brought either directly by the government or by qui tam relators—spread across the pharmaceutical, health care, defense, government procurement, mortgage, financial, and educational industries, among others. In the last fiscal year alone, for example, the government trumpeted FCA recoveries of more than $3 billion in the pharmaceutical and health care industries and, as part of the government's February 2012 record settlement with five banks over the 2008 mortgage crisis, $900 million related to alleged mortgage fraud.

FCA whistleblowers also fared well in 2012. These relators, empowered by the act to file suits on the government's behalf, can receive as much as 30 percent of any recovery obtained in the suit by the government (the exact amount depending upon whether the government intervenes in the suit). In 2012, qui tam relators earned more than $439 million in share awards. More than 60 percent of the government's recoveries in 2012 ($3.3 billion) derived from cases initiated under the FCA's qui tam provisions, and whistleblowers initiated more new matters in 2012 than in any prior year on record (647, or 82.7 percent of the 782 new matters). In all, private individuals initiated more than 8,489 qui tam actions since 1986, when statutory amendments markedly expanded whistleblowers' rights and protections and increased the percentage of their potential recoveries. Total recoveries since 1986 from whistleblower suits now exceed $24 billion.

These ever-increasing bounties, along with rapidly expanding theories of liability under the FCA, make it easy to see why the number of qui tam cases continues to increase, why qui tam cases account for most new FCA matters opened each year, and why a thriving cottage industry of plaintiffs' lawyers and qui tam resources has developed.

Although qui tam relators initiate far more FCA lawsuits than the government, and although the government declines to intervene in most, the DOJ continues to actively prosecute FCA cases. In our 2012 midyear false claims act update, we discussed how the Obama administration increased the focus on the FCA and sought large monetary and nonmonetary settlements from potential FCA defendants. The administration's "relentless focus" on eliminating fraud and waste in government programs is achieving considerable results. More than 99 percent of the $4.9 billion recovered under the FCA in fiscal year 2012 arose from cases where the government either filed the case directly or intervened in an action filed by a qui tam relator; less than 1 percent of that amount was recovered in actions in which the DOJ declined to intervene. Clearly, as we have reiterated in our earlier alerts, the government's determination whether to intervene in an FCA qui tam case represents one of the most crucial junctures in the entire proceeding.

The federal government is not alone in pursuing recoveries under the FCA; as of this writing, 29 states and the District of Columbia have adopted their own false claims laws. Several states recently strengthened their laws, and at least seven states currently have legislation pending to either enact or expand a false claims law. (A number of municipalities, including New York City, also have their own false claims laws.) As budgetary pressures at the state and local level drive state officials to weed out "waste, fraud, and abuse," we expect to see a significant increase in enforcement activity by states using both their own false claims laws and other related consumer protection laws.

FCA Enforcement Activity

For the 2012 fiscal year, the federal government secured nearly $5 billion in civil settlements and judgments under the FCA—a record amount for recoveries in a single year. The end of fiscal year 2012 also marked the end of a "record-setting four-year period," in which the federal government recovered $13.3 billion from FCA cases, an amount representing more than one-third of the total recoveries under the FCA since the 1986 amendments.

Fiscal year 2013 promises to be a banner year as well. The DOJ already has announced more than 15 FCA settlements for the first quarter of fiscal year 2013 (October through December 2012), including a $762 million civil and criminal settlement billed by the DOJ as the largest in history involving a biotechnology company and a $109 million civil settlement with a pharmaceutical company. And although the DOJ has yet to make an official announcement, yet another pharmaceutical company reported recently that it had reached an agreement-in-principle to enter a $491 million settlement (including $257 million to settle civil allegations).

Qui Tam Activity

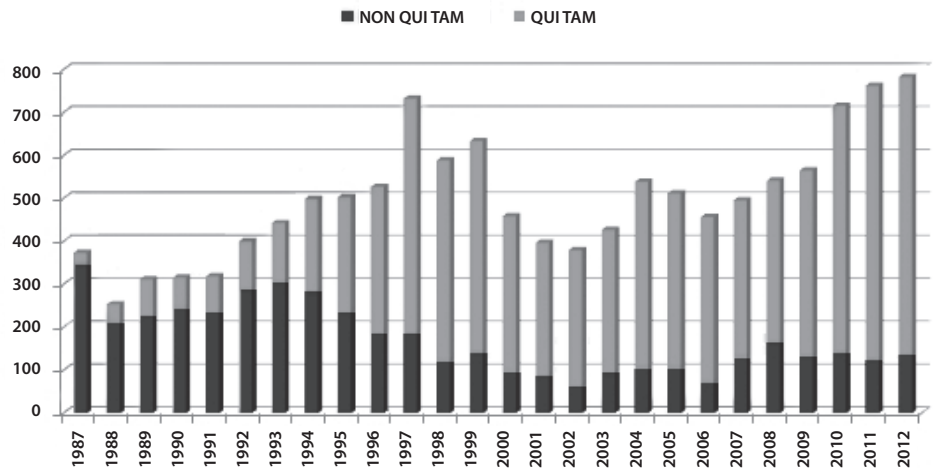
As in years past, whistleblowers were a key driver of the record-breaking 2012 recoveries under the FCA. Of the $4.9 billion in fiscal year 2012 recoveries, a record $3.3 billion—or two-thirds—was recovered in whistleblower suits. As noted above, 647—82.7 percent—of the 782 new FCA matters opened during the 2012 fiscal year were initiated by complaints filed pursuant to the FCA's qui tam provisions. This stands in contrast to fiscal year 1987, when relators initiated only 30—8 percent—of 373 new matters.

The increase is both stark and accelerating. Of the nearly 8,500 qui tam suits filed since the 1986 amendments, nearly 2,200 were filed after January 2009. These qui

tam cases have led to over $24.2 billion in government recoveries since 1986, with almost half ($10.5 billion) of that amount recovered in the last four years. Further, for these 8,500 suits, whistleblowers have been awarded nearly $4 billion, with $439 million in awards in fiscal year 2012 alone. Overall, nearly 70 percent of all FCA recoveries since 1986 can be attributed to qui tam matters, and all indicators suggest this proportion will continue to grow.

The chart below demonstrates both an increase in overall FCA activity and a distinct shift from largely government-driven investigations and enforcement to qui tam-initiated activity.

FCA New Matters, Including Referrals, Investigations, and Qui Tam Actions



Source: DOJ "Fraud Statistics—Overview" (Oct. 24, 2012)

Health Care/Pharmaceutical Industry

Most recoveries in fiscal year 2012—a record-breaking $3 billion—stemmed from settlements and judgments involving fraud allegedly committed against federal health care programs. Since January 2009, the DOJ has recovered $10.1 billion for health care fraud under the FCA. And in its most recent Semiannual Report to Congress, the Health and Human Services (HHS) Office of Inspector General (OIG) reported expected recoveries of about $6.9 billion, including $6 billion in "investigative receivables." HHS OIG also reported commencing 367 civil actions in fiscal year 2012, which includes FCA and other civil and administrative actions.

In July 2012, the administration announced a new public-private partnership, its latest effort in the fight against health care fraud. Described as "a ground-breaking partnership among the federal government, state officials, several leading private health insurance organizations, and other health care anti-fraud groups," the new partnership is an effort to "share information and best practices in order to improve detection and prevent payment of fraudulent health care billings." This new partnership will build on the work of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), which was formed in 2009 and generated more than $8.8 billion in health care fraud recoveries for the government in the first three years of its existence.

In addition to record-breaking monetary recoveries, the DOJ increased its use of nonmonetary penalties in the last year. These nonmonetary penalties were prominent in both of the large settlements mentioned above: for example, one company entered into a corporate integrity agreement (CIA) with HHS OIG, it will be subject to probation for five years, its chief executive and board of directors must make

certain certifications of compliance, and it agreed not to compensate sales representatives for off-label sales.

The DOJ is not alone in emphasizing prospective compliance, acknowledging efforts by its "agency partners . . . [to] negotiate compliance agreements in connection with their administrative remedies that establish tough structures to help prevent further instances of fraud." For example, HHS OIG requires CIAs as a condition of waiving its exclusion authority. These agreements, which have long been a regular component of negotiated FCA resolutions, now often include what HHS OIG calls "enhanced compliance provisions." One notable example is an "Executive Financial Recoupment Program," which requires the company to recoup up to three years of annual performance pay (i.e., bonus plus long-term incentives) from executives who are discovered to have participated in significant misconduct. Other enhanced provisions relate to management certifications, compliance experts and outside consultants, compensation policies, transparency in journal article authorship, and cooperation with continuing government investigations.

State agencies, too, have placed a focus on prospective relief. Using deceptive marketing and other similar laws, many states have pursued cases based on allegations similar to those underlying many FCA cases. Settlements arising out of these cases have included not only monetary relief, but also affirmative commitments regarding how the defendant companies will market and promote their products. And they are not without teeth: in December 2012, a large pharmaceutical company agreed to conduct a corrective advertising campaign and to pay $1 million to the state of Oregon after Oregon alleged that the company's receipt of two regulatory letters from the Food and Drug Administration reflected violations of its 2008 consumer protection settlement with the state.

There is every indication that health care will continue to lead FCA recoveries going forward.

Conclusion

In today's world of increased government spending and expanding breadth of the FCA, it is more important than ever that companies remain mindful of the FCA, have compliance programs in place to prevent violations of the FCA, and appropriately respond and react to allegations of FCA violations that may have occurred despite these precautions. Defending an FCA investigation, even successfully, can be extremely disruptive and expensive.

Furthermore, studies show that most whistleblowers first report their concerns internally. Companies therefore must take employee complaints seriously, establish standard procedures for raising complaints and responding to them, and educate the workforce about the FCA. Every well-designed response plan also should include a discussion with qualified outside counsel about the potential benefits and risks of self-disclosure to the government. It is important to be thoughtful and strategic about this decision and whether to avail oneself of the various voluntary self-disclosure regimes that now exist (e.g., HHS OIG). The factors leading to a determination about self-disclosure are complex and nuanced, and must be handled appropriately.

In conclusion, based on our observations from 2012, the ever-increasing and well-publicized FCA bounties, the staggering figures of fraud and abuse in government programs, and the intense demand for oversight and accountability discussed in this and our prior FCA updates, we predict that 2013 will be another dynamic and interesting year for FCA activity.

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Court Refuses to Dismiss Lab Owner's Complaint, *from page 1*

order to allow the pathologist to reach a diagnosis, which is an exception to the rule that all tests paid for by federal health care programs must be ordered by the treating physician.

At this early stage of the litigation, the court said, the only question before it was whether the complaint stated a plausible claim. Noting that it will become clearer through the discovery process whether the exception applies, the court concluded that the relator set forth sufficient factual allegations from which a court may plausibly infer that Bostwick conducted a fraudulent billing scheme.

Further, the court said, the relator sufficiently alleged that Bostwick violated the anti-kickback statute and the Stark self-referral law. Given that compliance with those statutes is a condition of payment from the government, the complaint fell within the ambit of the FCA, the court said.

Test for Bladder Cancer

According to the opinion, relator Michael Daugherty is the president of LabMD, an Atlanta-based urology and uropathology laboratory. He claimed he was personally familiar with Bostwick Lab's procedures and personnel because Bostwick provided diagnostic testing on samples submitted to his company's predecessor for two years.

The specific service at issue is the FISH test for bladder cancer. As the court explained, urologists concerned about the possibility of bladder cancer routinely order urine cytology, where a urine sample is sent to a lab and examined under a microscope to determine whether cancerous or precancerous cells are present. If the cells are present, the American Urological Association recommends a cystoscopy, a procedure in which the bladder and the urethra are examined using a thin, lighted instrument called a cytoscope.

Other Food and Drug Administration-approved noninvasive tests, such as the FISH test, are used to assist in the diagnosis and surveillance of bladder cancers. However, the FISH test is an adjunctive test, meaning that it received FDA approval for use "in conjunction with and not in lieu of current standard diagnostic procedures."

The FISH test has both a technical component and a professional component. The former refers to the preparation of the sample and the addition of the fluorescent DNA probes to the specimen, which is then incubated. The latter refers to the analysis of the sample after incubation and the interpretation of the analysis.

The relator alleged that Bostwick engaged in a scheme to defraud the government by reflexively conducting the FISH test without the ordering physician's consent and submitting the claim to Medicare and Medicaid and other federally funded programs.

The relator also alleged that in exchange for getting all of certain types of lab work from urology practices, Bostwick performed the technical component of the FISH test and then drafted a report for the professional component, which the urology practice's pathologist then signed and billed for as though they had conducted it.

Bostwick also allegedly charged certain physicians less to perform the technical component of the FISH test, so that they could then bill Medicare for a higher amount, thus profiting from the arrangement.

In order for the public disclosure bar to apply, the court observed, the transactions that form the basis of the relator's complaint must have been publicly disclosed in a criminal, civil, or administrative hearing; a congressional, administrative, or government report, hearing, audit, or investigation; or from the news media.

Bostwick argued that public disclosure occurred in April 2009, when its general counsel sent a letter to urology practices advising them of its markup program, which allowed physicians to purchase the technical component of certain tests at a below-rate charge and then bill Medicare for the full amount. In the letter, the general counsel expressed his opinion that Bostwick could do this because the anti-markup rule was inapplicable to lab tests that require physician supervision.

Bostwick also cited a June 2009 meeting in which representatives from the American Society for Clinical Pathology, the American Clinical Laboratory Association, the College of American Pathologists, and some large independent labs met with officials from the Centers for Medicare and Medicaid Services (CMS) to discuss this loophole concept and the anti-markup rule. According to Bostwick, this meeting, along with several articles discussing the loophole and the anti-markup rule, constituted public disclosure under the applicable statute.

"Such an arrangement, where Bostwick incurs all costs associated with the tests but where the physician practice gets to reap the payment from the federal health care program, is . . . clearly an arrangement whereby something of value was given in order to induce referrals, exactly the scenarios contemplated by the AKS and the Stark Laws."

—District Court

The court disagreed. The general counsel's letter to clients does not fall within the ambit of a public disclosure because it cannot legitimately be seen to be a criminal, civil, or administrative hearing; a congressional, administrative or Government Accountability Office report, hearing, audit, or investigation; or from the news media, the court said.

While the court found that the articles Bostwick cited were legitimate examples of news media, and the CMS meeting was an administrative hearing, it concluded that the disclosures made in those fora did not contain enough information to disclose the fraudulent transactions in their entirety because they did not identify Bostwick specifically and they did not discuss the incentives provided by Bostwick.

Kickbacks Alleged

The court also refused to dismiss the relator's claim that Bostwick Lab provided remuneration to physicians in order to induce them to refer business its way, in violation of the anti-kickback and Stark laws.

The court found that as part of its application to participate in the federal health care programs, Bostwick signed a supplier agreement certifying that "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the federal anti-kickback statute [AKS] and the Stark law)."

Noting that violations of the AKS and Stark laws are material as a matter of law, the court concluded that "had the government known about the referral inducement programs alleged in the amended complaint, the government may very well have rejected payment of claims tainted by those programs."

The court also concluded that the relator sufficiently alleged facts from which the court could infer that Bostwick offered or provided something of value to physician practices in exchange for referrals—the opportunity to bill for the professional component of tests that the physicians did not perform.

"Such an arrangement, where Bostwick incurs all costs associated with the tests but where the physician practice gets to reap the payment from the federal health care program, is . . . clearly an arrangement whereby something of value was given in order to induce referrals, exactly the scenarios contemplated by the AKS and the Stark Laws," the court concluded.

Finally, the court said the fraud allegations were sufficiently specific to survive dismissal under Federal Rule of Civil Procedure 9(b). While the relator did not attach actual fraudulent claims to the complaint, he gave a representative example of an impermissible reflex FISH test that identified a Florida urology practice that had not ordered or consented to a FISH test but for whom it was nonetheless done for a specific patient on a specific date.

He further alleged that a Bostwick representative admitted that it was company policy to conduct reflex FISH testing without a physician's order. The court concluded that the relator provided the requisite who, what, where, when, and how of the alleged fraud.

Pathology Groups, Medical Billing Company Settle Claims Over Improper Disposal of Records

The former owners of a medical billing practice and four pathology groups have agreed to collectively pay $140,000 to settle allegations that medical records and patient billing information for "tens of thousands of Massachusetts patients were improperly disposed of at a public dump."

Under the settlements, the defendants have agreed to pay a total of $140,000 for civil penalties, attorneys' fees, and a data protection fund to support efforts to improve the security and privacy of sensitive health and financial information in Massachusetts.

The complaint, filed in Suffolk Superior Court, alleges that Joseph and Louise Gagnon, doing business as Goldthwait Associates, violated state data security laws when they mishandled and improperly disposed of medical records containing personal information and protected health information from four Massachusetts pathology groups at the Georgetown Transfer Station. The medical records contained information for more than 67,000 residents, including names, Social Security numbers, and medical diagnoses that were not redacted or destroyed when they were dumped.

The matter came to the public's attention in July 2010 when a *Boston Globe* photographer was disposing of his own trash at the dump and observed a large mound of paper which, upon closer inspection, he determined were medical records. His discovery was first reported in the *Globe* shortly thereafter.

The other defendants involved in the settlement are Kevin Dole, M.D., former president of Chestnut Pathology Services, P.C. Milford Pathology Associates, P.C.; Milton Pathology Associates, P.C.; and Pioneer Valley Pathology Associates, P.C.

The AG's office alleges that these pathology groups violated Health Insurance Portability and Accountability Act regulations by failing to have appropriate safeguards in place to protect the personal information they provided to Goldthwait Associates and violated state data security regulations by not taking reasonable steps to select and retain a service provider that would maintain appropriate security measures.

According to the complaint, the Gagnons ran Goldthwait Associates—which primarily provided medical billing services for pathology groups—and received sensitive medical records and billing information of clients in order to send medical bills on behalf of the groups. The Gagnons retired from Goldthwait Associates and the medical billing business in 2010.

News-At-A-Glance

MEDICARE OVERPAYMENT PERIOD EXTENDED: A provision in the American Taxpayer Relief Act of 2012, the "fiscal cliff" legislation signed into law Jan. 2, extends the statute of limitations on Medicare overpayment recoveries from three years to five years. Section 638 of ATRA amends Section 1870 of the Social Security Act, which covers the acceptable time frame under which the Centers for Medicare and Medicaid Services can recover a Medicare overpayment. Before ATRA, a provider who received an overpayment was "to be deemed without fault" if the determination of an overpayment "was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid," according to the Social Security Act. Under Section 638 of ATRA, "third year" was replaced with "fifth year." The provision went into effect Jan. 2. Experts say that the statute of limitations extension negatively affects providers, both in terms of increasing provider uncertainty and increasing costs associated with defending and appealing old claims.

FRAUD PREVENTION APPEARS PROMISING: The Centers for Medicare and Medicaid Services' Fraud Prevention System (FPS) helped stop, prevent, or identify roughly $115 million in fraudulent payments during its first year of operation, according to a CMS report released Dec. 14, 2012. The congressionally mandated *Report to Congress: Fraud Prevention System First Implementation Year*—which was due Oct. 1, 2012, and was released nearly three months late—also said the FPS generated leads for 536 investigations conducted by CMS program integrity contractors, and it helped support 511 ongoing investigations. The FPS, which was launched July 1, 2011, uses predictive modeling and data analytics to review all Medicare fee-for-service claims for indications of fraud. Meanwhile, a report released Dec. 17, 2012, from the Department of Health and Human Services Office of Inspector General was critical of CMS's methodology and conclusions. The OIG said CMS "did not fully comply with the requirements for reporting actual and projected improper payments recovered and avoided in the Medicare fee-for-service program and its return on investment related to its use of predictive analytics technologies."

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