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For Clinical and AP Laboratories and Pathology Practices

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CareFusion Settles False Claims, Kickback Charges

CareFusion will pay $40.1 million under a settlement agreement with the United States and 31 individual states to resolve a whistleblower lawsuit alleging violations of state and federal False Claims Acts and anti-kickback laws to help promote off-label use of one of its products, according to a Jan. 9 announcement by the Department of Justice (DOJ).

According to the 106-page second amended complaint filed in the case, qui tam relator Cynthia Kirk, M.D., a former vice president of regulatory affairs for CareFusion in its infection prevention unit, alleges that she informed senior executives on several occasions of her belief that the company was violating both federal and state laws through its marketing and off-label promotion of the product ChloraPrep but was rebuffed and ultimately terminated when she would not relent. The defendants in the case are CareFusion Corp., based in San Diego, Calif. and Cardinal Health Inc., based in Dublin, Ohio. CareFusion was spun off from Cardinal Health in 2009.

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Government Intervenes in Eight Lawsuits Against National Hospital Chain

Unnecessary inpatient admissions and paying kickbacks to physicians to induce those admissions and to order unnecessary diagnostic tests are among the allegations in eight whistleblower cases filed against Health Management Associates (HMA), a hospital chain that operates 71 hospitals in 15 states.

The lawsuits were announced Jan. 13 by the Department of Justice, which said the government will intervene in all eight cases. The announcement includes examples from some of the lawsuits, one of which alleges that HMA's former CEO, Gary Newsome, "directed HMA's corporate practice of pressuring emergency department physicians and hospital administrators to raise inpatient admission rates, regardless of medical necessity." Emergency room physicians were allegedly pressured by HMA corporate officers, or offered kickbacks in the form of rewards for meeting HMA benchmarks, to admit patients who could have been placed in observation, treated as outpatients, or discharged.

The lawsuits cover the entire gamut of anti-kickback and physician self-referral (Stark) violations and allege sham management agreements

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CareFusion Settles False Claims, Kickback Charges, *from page 1*

According to the complaint, Kirk is identified as the original source of the facts and information concerning the activities of the defendants. The allegations in the complaint are "based entirely on her direct, independent knowledge, personal observations and documents in her possession and also on information and belief." The settlement between CareFusion and the government resolves these allegations with no admission of liability by CareFusion.

The original complaint was filed in September 2010, followed by an amended complaint in October 2010 and a second amended complaint filed July 5, 2011. Kirk's allegations, as detailed in the complaints, provide a glimpse of a compliance professional working within her company to try to resolve what she perceived as compliance problems and actual violations of federal and state laws. Kirk carefully recorded dates, locations, and names of individuals involved in meetings and conversations with other executives at CareFusion, all of which provide support for her allegations in the whistleblower complaint.

According to the documents, Kirk alleges that within one week of her employment as the vice president of regulatory affairs, she began raising concerns to executives of the company about off-label marketing and promotion of ChloraPrep for the prevention of infections, a use for which it was not approved by the Food and Drug Administration (FDA). She also raised concerns over the use a study known as the "ChloraPrep Study" because she believed it did not meet requirements for a valid study and because it promoted the off-label use of ChloraPrep. The study was a key element used by the sales and marketing department to boost the sales of ChloraPrep.

According to the documents, Kirk alleges that within one week of her employment as the vice president of regulatory affairs, she began raising concerns to executives of the company about off-label marketing and promotion of ChloraPrep for the prevention of infections, a use for which it was not approved by the Food and Drug Administration (FDA).

ChloraPrep is an antiseptic product used to clean the skin of a patient before surgery or an injection. According to a DOJ announcement about the settlement agreement between CareFusion and the government, CareFusion marketed the product for the use of prevention and reduction of infections. According to the government, it also marketed ChloraPrep for other uses for which there was no FDA approval and made unsubstantiated claims about the appropriate use of ChloraPrep.

The DOJ says the settlement agreement also resolves allegations that one of CareFusion's predecessors paid $11.6 million in kickbacks to Charles Denham, M.D., for the purpose of inducing him to recommend, promote, and arrange for the purchase of ChloraPrep by health care providers. Denham was the co-chair of the Safe Practices Committee at the National Quality Forum, a nonprofit organization that reviews, endorses, and recommends standardized health care performance measures and practices.

Documentation of the Allegations

In the complaints, Kirk details meetings and conversations with her supervisor and other executives of the company where she was allegedly told that regulatory functions are a service and that there isn't a regulatory problem until the business unit says there is. After raising concerns about the continued aggressive off-label promotion practices at CareFusion, Kirk was told that "competitor off-label promotional activities justified the way ChloraPrep had been promoted historically and the way CareFusion should continue to promote ChloraPrep in the future." A senior vice president told Kirk "the risk of FDA action was 'extremely minimal' based on the regulatory history of ChloraPrep's product category." She allegedly was told that the off-label practices were too profitable to abandon.

The ChloraPrep Study

In 2009, CareFusion paid millions of dollars to sponsor an investigational study to demonstrate the safety and effectiveness of ChloraPrep in reducing and preventing infections. Known as the ChloraPrep Study, the results of the study were used by CareFusion to promote off-label use of the product. According to the court documents, the study was not valid because "Defendant CareFusion failed to meet statutory obligations of a sponsor in all respects in the conduct of the study." CareFusion allegedly also did not secure required contracts with the investigator, Rabih Darouiche. The study's authors included Cindy Crosby, vice president of medical affairs, who has no advanced degrees and also performs sales functions for CareFusion.

Seven patients died during the study, but the deaths were not reported by the investigator Darouiche to the sponsor and not reported by the sponsor to the FDA as required by regulation (21 CFR 312.64). According to the court documents, the compliance officer never reviewed or evaluated grants or contracts for the fair market value of the payments to Darouiche.

Lessons for Labs

Laboratory compliance officers sometimes find themselves in a similar situation where they may be perceived as a hindrance to business concerns at their laboratory. This case can provide some guidance for them because the relator in the case exhausted all internal avenues to try to resolve the issues and get the company to correct actions she believed were in violations of laws and regulations, even in the face of resistance by senior executives. All compliance officers can learn from Kirk's experience.

Takeaway: Compliance professionals need to be persistent when they believe laws are being violated and they may face the risk of being terminated as a result and should carefully document all meetings and conversations concerning the issue at hand.

Hospitals Must Bundle Certain Lab Tests Into OPPS Payment

Effective Jan. 1, hospitals and their laboratories will be reimbursed in a bundled payment for certain laboratory tests performed on hospital outpatients under the Hospital Outpatient Prospective Payment System (HOPPS) rather than billing them separately and directly to Medicare as was previously allowed.

According to Centers for Medicare and Medicaid Services (CMS) Transmittal R2845CP (Change Request 8572), issued Dec. 27, 2013, beginning in January 2014, payment for most laboratory tests provided in hospital outpatient settings will be reimbursed under the HOPPS and should be reported on a 13X type of bill and billed by the hospital rather than the laboratory. There may be important implications for laboratory outreach programs in cases where the outreach laboratory is competing with other independent laboratories in its marketplace and is using the hospital laboratory as a collection site for some of the specimens for the outreach program. There may also be a reduction in reimbursements because of the bundled payments, even though CMS says it has included the cost of lab services when determining the amount of the bundled payments.

According to Centers for Medicare and Medicaid Services (CMS) Transmittal R2845CP (Change Request 8572), issued Dec. 27, 2013, beginning in January 2014, payment for most laboratory tests provided in hospital outpatient settings will be reimbursed under the HOPPS and should be reported on a 13X type of bill and billed by the hospital rather than the laboratory.

The transmittal implements provisions contained in a final rule with comment published in the *Federal Register* on Dec. 10, 2013: "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Pro-

grams." The transmittal provides some specific billing information and other clarifying information. For instance, it helps clarify the criteria for determining a patient's status as an inpatient, outpatient, or nonpatient. Under the new policy, the 14X bill type is to be used for nonpatients as before the change but now will also be used for certain other patient encounters that create exceptions to the bundling payment.

It is these exceptions to the rule that help outreach laboratories in one sense because they allow separate billing for the nonpatients served by the outreach program, but it is these exceptions that create an increased risk for hospitals and laboratories. Prior to these changes, both outpatient and nonpatient testing were reimbursed under the Clinical Laboratory Fee Schedule (CLFS). Since this change in policy, most outpatient tests will be reimbursed under the HOPPS while nonpatient and certain other tests meeting the new criteria, including molecular pathology tests, will remain separately billable and paid under the CLFS.

Criteria for Determining Patient Status

The critical decision for the purpose of ensuring proper billing under these new rules is determining which patients qualify to be separately billable and should be billed using the 14X type of bill. The criteria includes tests that are considered integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting. In an attempt to simplify and clarify what this definition means, CMS provided the following in the transmittal to describe which lab services may be billed separately:

The critical decision for the purpose of ensuring proper billing under these new rules is determining which patients qualify to be separately billable and should be billed using the 14X type of bill.

- Any test performed on a nonpatient of the hospital. The current definition of nonpatient says any beneficiary that is neither an inpatient nor an outpatient but has a specimen presented for testing and the beneficiary is not physically present at the hospital.
- When the only services that a beneficiary receives are laboratory services. The patient does not receive any other outpatient services during the same encounter.
- If the patient receives other outpatient services during the same encounter besides laboratory services, but the laboratory services are clinically unrelated to the reason for the outpatient encounter and are ordered by a different provider, bill on a 14X bill type.

Molecular pathology tests are excluded from the bundling rule and are always paid under the CLFS regardless of the patient status. These tests are recognized by their specific Current Procedural Terminology codes and are listed in the transmittal as codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479. There may be reasons a hospital may want to bill these as nonpatients rather than outpatients, particularly when direct billing by the test provider of a referred test is preferred because of below-cost reimbursement by Medicare.

CMS expects hospitals and hospital laboratories to determine the proper bill type to use to ensure proper billing. The transmittal indicates that edits may not be in place initially so denials may not occur if the tests are not billed correctly. Each hospital may find different solutions to detect improper claims but it is likely that this will be a point of emphasis by government auditors in 2014.

Takeaway: Hospitals and their laboratories must monitor and track testing on their patients to ensure compliance with these policy changes and should conduct audits of claims early in 2014 to detect any improper billing and take appropriate actions, including returning any overpayments.

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COMPLIANCE PERSPECTIVES

Clinical Laboratories Now Outside Electronic Health Records Safe Harbor and Stark Exceptions

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Stakeholders in the clinical laboratory industry have frequently expressed concern about potentially suspect donations of electronic health records software, information technology, and training services (EHRs) to physicians, with blame cast on all the players—labs, the physicians, and the EHR vendors. The federal government, following the lead of various states, recently tried to address this problem by eliminating laboratories as a category of protected donors of EHRs under pertinent safe harbors and exceptions to the federal anti-kickback statute (AKS) and the federal physician self-referral (Stark) law.[1] This revision to the law is expected to change the competitive landscape for laboratories and reduce fraud and abuse.

This change is effective March 27, 2014. Laboratories should act now to unwind arrangements no longer protected by the EHR safe harbor/exception and review their risk profile to ensure compliance with applicable law.

Labs No Longer Protected Donors of EHRs

On Dec. 27, 2013, the U.S. Department of Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) jointly released final rules removing laboratories as protected donors of EHRs to physicians, effective March 27, 2014 (the 2013 final rules).[2] The two agencies have historically sought to maintain consistency between the provisions of the AKS safe harbor and the Stark exception, subject to the differences in the underlying laws, and again attempted to do so here.

Stakeholders have historically identified alleged bad behavior by various parties with respect to the donation of EHRs by laboratories to physicians.

The revised regulations under the 2013 final rules create a national standard carving "laboratory companies" out of the otherwise broad definition of protected donors of EHRs:

The AKS EHR Safe Harbor: "An individual or entity, *other than a laboratory company*, that provides services covered by a Federal health care program and submits claims or requests of payment, either directly or through reassignment, to the Federal health care program."[3]

The Stark Law EHR Exception: "The items and services are provided to a physician by an entity (as defined at 411.351) *that is not a laboratory company*."[4]

1. *78 Fed. Reg. 78751 (Dec. 27, 2013); 78 Fed. Reg. 79202 (Dec. 27, 2013).*
2. *The final rules waive the 30-day delay in effective date generally applicable to final rulemakings solely with respect to extension of the "sunset" provision of the final rules. In order to prevent expiration of the EHR AKS safe harbor and Stark law exception, the OIG and CMS have extended the sunset from December 31, 2013, to December 31, 2021, effective immediately. All other provisions of the final rules take effect on March 27, 2014.*
3. *See 42 CFR §1001.952(y)(1)(i) (emphasis added).*
4. *See 42 CFR §411.357(w)(1) (emphasis added).*

The agencies explain that "laboratory companies" include laboratories that provide clinical laboratory services and those that provide anatomic pathology services, but generally do not include hospitals with laboratory departments. However, if a hospital-affiliated or hospital-owned company with its own supplier number provides laboratory services that are billed under the billing number assigned to the company (and not to the hospital), then the laboratory is considered a "laboratory company" for purposes of the safe harbor/exception and does not qualify as a protected donor.[5]

Reasoning Behind Removal of Labs as Protected Donors

Stakeholders have historically identified alleged bad behavior by various parties with respect to the donation of EHRs by laboratories to physicians. This list of complaints included concerns that laboratories conditioned EHR donations on the receipt of referrals and targeted physician recipients based on the volume or value of potential referrals. Other improper practices alleged include the charging of high fees by vendors to other laboratory companies to interface with the technology donated by a given laboratory and the blocking of other companies from buying the EHRs for donation to their own clients. In complaints lodged against physicians, laboratories argued that physicians threatened to withhold referrals and redirect business absent EHR donations and chose EHRs based on the largest donations offered.

This long list of complaints reached the ears of the government. In its August 2006 final rule initially establishing the EHR safe harbor under the AKS, the OIG created a broad definition of protected donors but expressed concern about including laboratories due to past instances of abusive referral payments and a belief that laboratories may not have a comparable stake in advancing the goal of intraoperable EHRs for patients.[6] Despite this articulated concern in the 2006 final rule, the complaints continued and led to the removal of laboratories as donors in these latest final rules.

In complaints lodged against physicians, laboratories argued that physicians threatened to withhold referrals and redirect business absent EHR donations and chose EHRs based on the largest donations offered.

The agencies justify their exclusion of laboratories as the best means to find a balance between promoting the adoption of intraoperable EHRs and reducing fraud and abuse given the circumstances of which it had become aware:

> We believe this decision is consistent with and furthers the goal of promoting the adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that the safe harbor will be misused by donors to secure referral. We also believe that our decision will address potential abuse identified by some of the commenters involving potential recipients conditioning referrals for laboratory services on the receipt of, or redirecting referrals for laboratory services following, donations from laboratory companies. [7]

The government also acknowledges that its new national standard, applicable regardless of location, aligns with the actions of various states, including Missouri, New Jersey, and New York, that have already precluded or restricted laboratories from donating EHRs in order to eliminate suspected fraud and abuse. Activists at the state level supported this federal solution, as did laboratories located in such states who believed they were at a competitive disadvantage when they could not offer EHR donations.

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5. *78 Fed. Reg. at 79210.*
6. *CMS included laboratories in its 2006 final rule establishing the EHR exception to the Stark law because laboratories are suppliers of designated health services under the Stark law.*
7. *78 Fed. Reg. at 79208.*

Laboratory Interfaces Still Protected

Another important aspect of the 2013 final rules is the agencies' proclamation that limited-use laboratory interfaces fall outside the AKS and Stark law prohibitions. Laboratories typically rely on laboratory information systems (LISs) or special IT systems unique to anatomical pathology and bloodbanking, rather than EHRs, to operate and manage patient information specific to the laboratory. Critical to laboratories, then, are the interfaces that allow their LISs and related systems to interact with the EHRs of physicians and other referral sources. Laboratories generally invest considerable resources in designing, updating, and maintaining these interfaces. Under the 2006 final rules, the government appeared to include items like interfaces and patches under the rubric of the types of EHR that were protected by the EHR safe harbor/exception.[8] Some risk thus existed that elimination of laboratories as donors in the 2013 final rules also eliminated the ability of laboratories to offer interfaces.

Significantly, the government now clarifies that certain limited-use interfaces are outside the ambit of the AKS and the Stark law. Specifically, the OIG indicated that it has long distinguished between free items and services that are integral to a supplier's services (i.e., lacking independent value) from those that are not integral or that have independent value to the physician. The government concluded that free access to a limited-use interface that has no independent value to physicians would not require AKS safe harbor protection.[9]

Laboratories should determine if revision to existing EHR contribution contracts with physicians is possible or if termination is necessary prior to March 27, 2014. Parties may consider continuing EHR relationships under other safe harbors and exceptions to the extent requirements can be met. For example, EHRs that are leased at fair market value may potentially comply with safe harbors and exceptions for personal services, equipment leases, or fair market value transactions.

Similarly, CMS indicated that the donation of limited-use laboratory interfaces would fall outside of the definition of "remuneration" under the Stark law because the definition does not include "the provision of items, devices, or supplies that are used solely to: (i) collect, transport, process, or store specimens for the entity providing the item, device, or supply; or (ii) order or communicate the results of tests or procedures for such entity."[10] Accordingly, the provision of such interfaces would not result in a compensation arrangement that would implicate the Stark law's referral and billing prohibitions.

The loss of the protection of the EHR safe harbor/exception will not impact many laboratory interfaces, which are protected under other provisions of the law.

Next Steps for Labs

In light of the final rules, laboratories may wish to consider some or all of the following steps:

Unwinding or Restructuring Arrangements

Laboratories should determine if revision to existing EHR contribution contracts with physicians is possible or if termination is necessary prior to March 27, 2014. Parties may consider continuing EHR relationships under other safe harbors and exceptions to the extent requirements can be met. For example, EHRs that are leased at fair market value may potentially comply with safe harbors and exceptions for personal services, equipment leases, or fair market value transactions.

8. See, *e.g.*, *71 Fed. Reg. at 45151.*
9. *78 Fed. Reg. at 79210.*
10. *42 U.S.C. §1395nn(h)(1).*

Review Other Ongoing Commitments

Laboratories should also review any ongoing commitments with respect to maintenance, training, clinical support, or other services provided for free under the protection of the EHR safe harbor/exception. These commitments should be unwound prior to the effective date of the 2013 final rules, or laboratories should confirm that such arrangements comply with other AKS safe harbors and Stark law exceptions.

Compliance Analysis of Previous Conduct

The government, and in particular the OIG, concluded that a number of practices identified by commenters in the final rules would likely not comply with the EHR safe harbor/exception, presenting risk of an AKS or Stark law violation. For example, the OIG cautioned that any quid pro quo arrangements, whether they originate with the donor, the physician, or the vendor, and conversion arrangements involving equivalent items or services, are problematic and are not subject to safe harbor protection. Similarly, reimbursement for previously incurred expenses and donations of hardware are also not protected. Among other things, CMS also identified quid pro quo arrangements, particularly where laboratories conditioned donations of EHRs on referral by physicians, the targeting of physicians based on their volume or value of referrals, and agreements between laboratories and vendors that preclude or limit the ability of competitors to interface with donated EHRs as conduct that would not meet Stark law exceptions.

The revised EHR safe harbor and exception are expected to have a positive effect on competition. Improper use of EHR donations as a means to gain referral sources or a competitive advantage will be largely minimized and laboratories will be allowed to compete on other bases, such as the quality and timeliness of their services and the nature of the tests.

Given the enhanced fraud and abuse enforcement provisions under the Patient Protection and Affordable Care Act of 2010, laboratories may consider conducting compliance reviews of past conduct and determining their risk profile with respect to previous EHR donations. For example, if an EHR donation was not protected by the EHR Stark law exception (or any other exception) then the physician's referrals to the laboratory may be tainted, precluding the laboratory from billing for such tests. Importantly, the government did not specifically indicate in the 2013 final rules that it intended to seek out or prosecute such previous conduct for violations of the AKS or Stark law. Laboratories should remember, however, the ever-present threat that qui tam relator plaintiffs (who may be employees or competitors) may pursue claims for suspected fraud and abuse under the federal False Claims Act. Laboratories should consult counsel as appropriate.

The revised EHR safe harbor and exception are expected to have a positive effect on competition. Improper use of EHR donations as a means to gain referral sources or a competitive advantage will be largely minimized and laboratories will be allowed to compete on other bases, such as the quality and timeliness of their services and the nature of the tests. Likewise, the quality of laboratory services available to patients should improve, as a physician's decision to choose a certain laboratory can be better focused on factors such as choice of the best test for the patient, quality of services, availability of tests, and turnaround times.

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Government Intervenes in Eight Lawsuits, *from page 1*

to disguise kickback payments to physicians, less-than-fair market value lease arrangements, provision of free office space and staff, and paying inflated prices for physician owned assets. The alleged goal of these efforts was to increase referrals and admissions at HMA owned hospitals.

"Improper hospital admissions cost the government millions of dollars in unnecessary fees and subject patients to excessive treatment and needless risk, driving up the cost of health care," said Anne M. Tompkins, U.S. attorney for the Middle District of Florida, in announcing the lawsuits.

Some of the lawsuits include other parties as defendants along with HMA. For instance, a lawsuit filed in North Carolina brought by two emergency room doctors includes two hospitals owned by HMA and an emergency room practice management company, Emergency Medical Services Corp. Another lawsuit names a physician group as a defendant along with individual hospitals and HMA. The lawsuits also claim violations of state anti-kickback laws and regulations in various states.

Pro-MED Software

The North Carolina lawsuit alleged the use of software to order unnecessary tests on emergency room patients before any physician had seen the patient. Many of these tests were laboratory tests and, according to the complaint filed in the Western District of North Carolina, were unnecessary and in some cases billed multiple times. These tests were ordered based on guidelines in the software system, known as Pro-MED, that linked complaints to test orders. In many cases, according to the complaint, once emergency room physicians saw patients, they tried to change the test orders or cancel them as unnecessary. It was unclear in the complaint whether the tests actually were cancelled or were billed.

HMA Denies Allegations

In a statement released by HMA, it denies the allegations but says that it is cooperating with the Justice Department in the cases. HMA also notes that the existence of the investigations has been disclosed in previous public Securities and Exchange Commission filings. HMA says it will contest the allegations. In an interview cited in a Jan. 3 posting by the *Charlotte Observer* (*www.charlotteobserver.com*), attorney Kirk Ogrosky, a Washington-based lawyer for HMA, said, "There will always be doctors who believe that any effort to manage them is designed to interfere with their medical decision-making. The question is whether a single doctor knows better than everyone else."

In an interview cited in a Jan. 3 posting by the* Charlotte Observer *(www.charlotteobserver.com), attorney Kirk Ogrosky, a Washington-based lawyer for HMA, said, "There will always be doctors who believe that any effort to manage them is designed to interfere with their medical decision-making."

The allegations in the pending lawsuits are allegations only, and there has been no determination of liability.

These cases are in their initial stages of development and how they will proceed over time cannot be predicted. Also, the amount of any fines or other monetary penalties have not yet been established, but many observers believe it will be in the hundreds of millions of dollars. Since these are all whistleblower cases, the aggregate whistleblower payouts in any case the government wins will be dependent on the individual case and its relators.

In a related story, shareholders of HMA approved a merger with Community Health Systems (CHS) by an overwhelming majority. If the deal goes through, CHS will pay $7.6 billion to acquire HMA. The merged companies will be the largest for-profit hospital operator in terms of the number of facilities but not in revenue.

Government Gaining Experience

Federal Bureau of Investigation (FBI) Assistant Director Ron Hosko noted that the investigative agencies relied on a centralized team to provide nationwide support to the field offices. "Investigations such as these are a very high priority for the FBI because of the potential impact to the nation's health care system and to the public," he said. This kind of cooperation between departments of the federal government and it various agencies and state investigators and prosecutors is testimony to the commitment of the government to find and prosecute fraud and abuse against government programs like Medicare and Medicaid. The extensive use of whistleblower information in these cases demonstrates the value the government places on them and the help they provide in bringing these kinds of cases to light.

Each case provides lessons for government agents and helps them learn to better detect fraud and abuse when it is present. Hospitals and other health care providers should take note of this commitment and this expanding understanding of how these frauds are perpetrated. If they are involved in any activities similar to those described in these lawsuits, even if they have had legal counsel review their activities, they may want to take a closer look to ensure they are not violating any laws or regulations.

Takeaway: Because of increased government scrutiny and whistleblower activity, all health care providers should review compliance programs for effectiveness and conduct reviews of all contracts and relationships with referral sources to ensure compliance with both state and federal laws and regulations.

Physicians Choice Laboratory Files Counterclaim Against USHG

In the ongoing dispute between Physicians Choice Laboratory Services (PCLS; Rock Hill, S.C.) and US Health Group Inc. (USHG; Dallas), PCLS has filed a counterclaim to the request for a temporary restraining order (TRO) filed in October 2013.

A Dallas District Court granted part of the TRO requests filed by USHG but denied others, including a provision that PCLS could not contact USHG business partners, clients, and employees. The signed order, dated Oct. 4, 2013, replaces an earlier TRO filed by USHG, which *G2 Compliance Advisor* reported on in the December 2013 issue (page 11).

The counterclaim field by PCLS in November asserts that USHG has failed to plead sufficient facts in support of its claim for tortious interference with prospective business relations and requests that the court dismiss USHG's claim.

The four employee defendants, PCLS, and plaintiff USHG filed additional documents since the story was published that supplements the records for this ongoing case, which is now headed for trial, barring a settlement between the parties. The original story cited a TRO that USHG filed against PCLS and the four employees involved in the case, seeking an end to the activities alleged in their original pleading.

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The TRO used for the original story was an unsigned version. In the signed version, the judge has lined through two items in the TRO and amended one additional. All other sections of the TRO stood. PCLS says in a response to the TRO that it has always denied that any of its employees ever engaged in such behavior, so it did not oppose including the allegations in the amended TRO. Additional documents filed in the case include PCLS's response to the TRO and counterclaims against USHG as well as a variety of motions and depositions and responses to those filings. A

review of this case's court record and document history shows the last document filed was an unopposed motion to substitute counsel filed Jan. 17. The case (DC-13-12019) is filed in the 134th judicial district of Dallas County, Texas.

Takeaway: Physicians Choice Laboratory Services disputes allegations made by US Health Group, maintains that USHG has failed to state a cause of action, and has asked a Dallas District Court to dismiss USHG claims.

Hospital Self-Discloses Improper Financial Arrangements

A Montana hospital and its parent company agreed to a $3.85 million settlement with the government to resolve allegations that they violated the anti-kickback statute, the physician self-referral (Stark) law, and the False Claims Act by providing improper financial benefits to physicians and physician groups who made referrals to the hospital, according to the Department of Justice (DOJ).

St. James Healthcare, a hospital located in Butte, Mont., and its parent, Sisters of Charity of Leavenworth Health System, based in Denver, discovered the issues during an internal compliance review and chose to self-disclose the problem and cooperate with the government to reach the settlement agreement.

According to the DOJ announcement, St. James and Sisters of Charity allegedly paid improper financial incentives to physicians it was involved with in a joint venture concerning a medical building on the St. James campus. The improper payments took the form of below-market lease rates for the physicians renting space in the building, below-fair market lease rates for the land on which the building was constructed, and other below-fair market value arrangements for the shared facility use and maintenance.

In the announcement, U.S. Attorney for the District of Montana Michael W. Cotter said, "We are encouraged that hospitals like St. James Healthcare are taking these issues seriously by reviewing their operations and making disclosures to the government where necessary." There is no mention of a corporate integrity agreement (CIA) in the announcement, which may mean that as a result of the self-disclosure, St. James and Sisters of Charity may have avoided the cost and resource consuming requirements of a CIA.

Takeaway: There is usually a benefit of some kind as a result of self-disclosure of compliance problems and issues discovered during internal audits and reviews. Conversely, there can be negative and costly outcomes if a problem is discovered but not reported and later is revealed by a whistleblower or other external party.

Compliance Corner

In last month's issue, we addressed changes to the CPT codes used to bill for immunohistochemistry stains. A reader pointed out an error in the article in one of the scenarios presented to illustrate proper use of the new codes for non-Medicare patients. In the article, we made the following statement: "Thus, in 2014 for non-Medicare patients, same stain on multiple blocks (same specimen) on same date of service, you should code 88342 for the first separately identifiable antibody in a specimen or block and then 88343 for each additional antibody in additional blocks." The reader pointed out that the 2014 CPT description used the term *slides* instead of blocks.

The term *slides* must be interpreted in the context of the entire description, which includes "separately identifiable antibodies" per slide. Laboratories should understand that the unit of service is the separately identifiable antibodies, not simply the number of slides. When using cocktail stains where a single slide may include the ability to identify two or three separately identifiable antibodies, the lab may bill for all three of the antibodies.

We appreciate readers taking the time to comment on our articles. Please send your questions for Compliance Corner to Christopher Young, editor, at *cyoung@G2Intelligence.com*.

News-At-A-Glance

FIRST HIPAA SETTLEMENT FOR NOT HAVING POLICIES AND PROCEDURES: Adult & Pediatric Dermatology, P.C. (APDerm) of Concord, Mass., agreed to a $150,000 settlement with the Department of Health and Human Services Office for Civil Rights (OCR) to resolve potential violations of the Health Insurance Portability and Accountability Act of 1996 in a first-of-its-kind settlement for not having policies and procedures in place. APDerm allegedly did not comply with certain requirements under the Health Information Technology for Economic and Clinical Health Act because it had never conducted an accurate and thorough risk assessment as part of its security management process, did not have written policies and procedures in place, and did not train employees as required by the breach notification rule. OCR received a report that an unencrypted thumb drive was stolen from a staff member's vehicle, which contained protected health information of approximately 2,200 individuals, resulting in the investigation that revealed the compliance issues. As part of the settlement, APDerm must develop a corrective action plan, develop a risk analysis plan, and provide an implementation report to OCR.

PENNSYLVANIA HOSPITAL PAYS $2MILLION AFTER SELF-DISCLOSURE: St. Mary Medical Center (SMMC) in Langharne, Pa., self-disclosed its failure to properly administer certain physician income guarantee agreements used by the medical center as part of its efforts to recruit physicians, resulting in overpayments to some of the recruited physicians. SMMC disclosed that it filed false claims as a result of the improperly administrated agreements and agreed to pay $2,339,224.70 to resolve the matter.

NEW YORK CITY EDUCATION DEPARTMENT SETTLES FALSE CLAIMS COMPLAINT: The New York City Department of Education (DOE) allegedly submitted false claims to the Medicaid program for psychological counseling services to special education students in New York public schools. According to Loretta E. Lynch, U.S. attorney for the Eastern District of New York, Medicaid pays the DOE a flat rate of $223 for each student who receives counseling services at least twice each month. The DOE receives no payments if an individual does not receive at least two counseling sessions. The complaint alleges that the DOE knowingly billed for the services even when its own records showed that students had not received the requisite number of counseling sessions. According to a statement by Lynch, "When Medicaid shells out scarce dollars for services that are not provided, both the students in need of psychological support and the public fisc are harmed." The DOE paid $1,375,000 to settle the complaint and an additional $40,000 in attorneys' fees. The whistleblower in the case, Dana Ohlmeyer, will receive $206,250 or 15 percent of the settlement amount.

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