

What's Past is Prologue: Health Care Fraud Enforcement and What's Ahead for 2015

Recent Cases Will Likely Change the Settlement
Calculus for Hospitals Facing Investigations

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In 2014, the Department of Justice (DOJ) obtained \$2.3 billion in health care fraud recoveries. More than 10 percent of that, or \$333 million, came from hospitals. The year opened with one of the most significant recent developments in the intersection of the False Claims Act (FCA) and the Stark law and with Halifax Health's \$85 million settlement with the DOJ, and the government's enforcement efforts gained momentum from there. In this article, we recap some significant developments with regard to the government enforcement actions as they relate to hospitals and associated providers as well as forecast what future developments we may see as 2015 unfolds. While by no means exhaustive, we hope this article provides an informative description of recent actions in this important area for hospitals and associated providers.

PATIENT "STATUS" CASES WERE A CONTINUED FOCUS FOR THE GOVERNMENT

The DOJ and Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS) have, for some time, focused their investigation and enforcement efforts on allegedly improper inpatient stays of Medicare and Medicaid beneficiaries. These efforts have been concentrated on so called "short-stays," which are inpatient stays of two days or less, and oftentimes relate to specific diagnoses such as chest pain, transient ischemic attacks, and syncope.

Until recently, many FCA settlements in this area related to single facilities. The most notable of these early cases involved the \$26 million settlement reached with St. Joseph's Hospital of Atlanta in 2007, which was captioned *United States ex rel. Ramsey v. Saint Joseph's Hospital of Atlanta*, Civ. Action File 1:04-cv-3353-TCB (N.D. Ga.). In the past several years, perhaps following

consolidation in the industry, the DOJ has focused investigatory resources on larger regional and national systems. For example, in 2013 Shands Teaching Hospitals and Clinics, a multi-facility non-profit system based in Florida, reached a \$26 million settlement with the DOJ, OIG, and State of Florida over allegedly improper short-stay inpatient admissions. The case was captioned *United States of America and the State of Florida ex rel. Myers v. Shands Healthcare et al.*, Civil Action No. 3:08-cv-441-J-16HTS (M.D. Fla). In 2014, this trend continued.

The largest of these cases to date, and one of the largest hospital-related FCA settlements in recent memory, involved Community Health Systems (CHS). CHS entered into a settlement with the DOJ, OIG, and numerous states concerning allegations that CHS improperly admitted certain Medicare beneficiaries who should have either been treated and discharged or treated as observation status patients for whom Medicare reimbursement would have been lower. The settlement also resolved allegations of improper physician relationships and certain short-stay admissions following cardiac procedures at a CHS facility in Laredo, Texas. The DOJ's investigation commenced following the filing of one or more *qui tam* FCA actions naming CHS. The first of these was filed in 2009 and eventually totaled seven separate actions, all of which were resolved in the settlement.¹ In addition, as part of the settlement CHS entered into an expansive corporate integrity agreement (CIA) with the OIG that covers all of CHS' facilities.

Notably, at least one of these *qui tam* actions, captioned *United States ex rel. Doghramji et al. v. Community Health Systems Inc., et al.*, Case No. 3-11-cv-00442 (M.D. Tenn.), contained a significant amount of data analysis of inpatient admissions from CHS' emergency rooms. Although this data analysis was focused on admissions, it was similar to an analysis made public by Tenet as part of a lawsuit it filed seeking to prevent CHS' attempted takeover of the

company. In that analysis, Tenet claimed CHS deliberately admitted more patients to its hospitals instead of classifying them for observation status, which is billed at lower rates. Tenet highlighted CHS' use of its own patient admissions manual, which was featured prominently in several of the *qui tam* complaints. While the government has made no public statements with respect to whether and how it made use of this data analysis, as discussed in more detail below, the rise of publicly available data and its use by the government and the relator in investigating and prosecuting FCA actions has significant implications for hospitals.

Following closely on the heels of the CHS settlement, in October 2014, the DOJ announced a settlement with Dignity Health, formerly known as Catholic Healthcare West, a San Francisco-based tax-exempt health system that has 39 hospitals in three states and is among the five largest hospital systems in the nation. The settlement resulted from a *qui tam* action captioned *United States ex rel. Hawkins v. Catholic Healthcare West, et al.*, CV C 09-5604 JCS (N.D. Cal.). The DOJ claimed that between 2006 and 2010 Dignity Health admitted Medicare and TRICARE patients under inpatient status when necessary medical care could have been provided in a less costly outpatient or observation setting. Dignity's settlement with the DOJ focused on certain "common medical diagnoses." While these diagnoses are not specified in the DOJ's public announcement, it is clear that at least in this case, the government focused on more specific conduct beyond simply targeting all stays of a specific length.

Along with the FCA settlement, Dignity also entered into a CIA with the OIG. This CIA is similar in scope to the one entered into with CHS. The insistence of CIAs in these short-stay status cases demonstrates that OIG takes this conduct seriously, and hospitals attempting to resolve these cases can expect that the OIG will likely insist on a CIA as part of the overall resolution,

especially when they include large hospitals and health systems.

The other significant development in these short-stay status cases was the DOJ's decision to intervene in the consolidated *qui tam* actions against Health Management Associates (HMA), which is now owned by CHS.² The multi-district litigation is captioned *In Re: Health Management Associates, Inc. Qui Tam Litigation*, No. 1:14-mc-00339 (D.D.C.). Taken with the size of the CHS and Dignity settlements, DOJ's decision to intervene in these actions demonstrates that the government is committed to prosecuting these actions, especially.

Similar in nature to the actions filed against CHS, these lawsuits against HMA allege, among other things, that HMA through its then president and chief executive officer (CEO), engaged in a corporation-wide scheme to improperly admit as inpatients for outpatient procedures or placed in observation status and admitted patients for certain surgical procedures. Notably, in the press release announcing its intervention, the DOJ chose to highlight allegations that HMA's management exerted significant pressure and even paid kickbacks in the form of bonuses or the awarding of contracts to physician staffing companies and individual physicians staffing HMA's emergency rooms.

These cases have been stayed. As of this writing, the government has not yet filed a complaint in intervention, so it is unknown what allegations it will make if, and when, it files its complaint in intervention. Nonetheless, the fact that the DOJ chose to highlight these allegations in its press release suggests they may be a potential focus. At a time when many hospitals and hospital operating companies are acquiring physician practices and seeking to centralize service delivery through subcontracting arrangements in their emergency departments, this focus is notable. In addition to the short-stay issues, the cases highlight the fact that hospital operators need to be mindful of the anti-kickback statute when

managing these relationships and should be aware that pressure placed on providers and certain types of incentive payments could be construed as kickbacks for the purposes of the FCA.

These developments in short-stay status cases come at a time when many hospitals are trying to navigate the confusion surrounding CMS' two-midnight rule, which revised long-standing guidance to hospitals and physicians over when an inpatient admission was deemed reasonable and necessary for purposes of Medicare reimbursement. Although any recent FCA developments concerning patient status surely deal with CMS' prior regulations, the proliferation of these cases nonetheless demonstrates that patient status will continue to be a focus of government regulation and enforcement efforts.

2014 STARK REVIEW

Last year, the government showed a continued willingness to intervene in and to litigate FCA cases based on violations of the Stark law following its success in obtaining a 2013 judgment in excess of \$270 million in the *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.* case, C.A. No. 3:05-cv-02858-MBS (D.S.C.), which is currently on appeal in the Fourth Circuit. First and foremost among such cases was the *U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, et al.* case, No. 6:09-cv-01002-GAP-TBS (M.D. Fl.), in which the DOJ ultimately settled with Florida-based Halifax Hospital and Halifax Staffing on March 11, 2014, for \$85 million.

In *Halifax*, the *qui tam* relator was the director of Physician Services at Halifax Medical Center, who alleged, among other things, that Halifax violated the Stark law by entering into compensation agreements with six medical oncologists that provided incentive bonuses that improperly included the value of prescription drugs and tests that those physicians ordered. The relator also alleged that Halifax knowingly violated the Stark law by paying three

neurosurgeons more than fair market value for the services they provided. The government ultimately intervened and filed a complaint regarding these allegations, contending that “by knowingly submitting claims for reimbursement based on referrals generated by physicians who received compensation based on these terms [which violated Stark], Defendants violated the False Claims Act.”

After originally filing a notice of “no-decision” as to whether it would intervene in the *Halifax* case in 2010, the DOJ continued to investigate. In October 2011, the Court permitted the DOJ to intervene. This case is one example of the government’s active monitoring and participation in the development of case law regarding FCA cases brought upon the basis of alleged Stark violations. In November 2013, the Court partially granted the government’s motion for summary judgment, finding that defendants’ Stark violation had been established but holding that Halifax’s knowledge, and the damages resulting from its conduct, should be determined at trial. Shortly before trial, the government settled these allegations for \$85 million, \$400 million less than what it potentially could have recovered with the treble damages and penalties provisions under the FCA had it been successful at trial.

Toumey and Halifax also illustrate the magnitude of exposure hospitals face in FCA cases based upon Stark law violations. Because the government claims damages for the entire amount of any reimbursement obtained as a result of a false claim submitted in violation of the Stark law, potential recoveries by the government pursuant to these cases are so high that there exists an inordinate pressure for defendants to settle rather than risk that type of exposure at trial. Further, as is common, the relator proceeded with litigating allegations which were declined by the government. She ultimately recovered an additional settlement of \$1 million for the United States, of which she retained an elevated share under the

FCA *qui tam* provisions for non-intervened claims.

Following *Halifax*, the government also obtained a significant recovery for similar allegations after litigating with interrelated clinics and a physician group in the Southern District of Alabama, settling the case for \$24.5 million on July 21, 2014. In that case, captioned *U.S. ex rel. Heesch v. Diagnostic Physicians Group, et al.*, No. 1:11-cv-00364-KD-B (S.D. Ala.), the relator was a physician formerly employed by the defendant, Diagnostic Physicians Group (DPG). He filed a *qui tam* action alleging that the defendants violated the FCA by submitting claims which violated the Stark law. Like in *Halifax*, the government partially intervened regarding certain of the relator’s Stark allegations, namely that the defendant clinics had agreements with DPG to pay the group a percentage of Medicare reimbursements for tests and procedures referred by its physicians.

The government alleged that these arrangements violated Stark and did not fall under a recognized Stark exception; therefore, all claims submitted pursuant to these arrangements violated the FCA. Notably, as evidence that DPG had “knowledge” that the arrangements violated Stark law, like it did in *Toumey*, the government cited legal opinions previously obtained by the defendants regarding the Stark implications of their contractual arrangements, which the government contended were implemented on paper but not in practice.

Similar to *Halifax*, the case ultimately settled shortly before trial for substantially less than the government could have recovered had it shown liability and prevailed on the damages theory that the entire amounts received for claims submitted in violation of the Stark law constituted damages under the FCA. Nonetheless, this settlement serves as an important reminder about legal advice. Legal opinions that are sought or offered concerning physician relationships can have far reaching consequences and may be used to meet the

scienter requirement of the FCA. Providers that receive opinions that call physician relationships in to question ignore them at their peril or obtain multiple opinions on the same issue.

Also notable among Stark recoveries within the past year were FCA settlements based on self-disclosures of arrangements potentially violating the Stark law. Though DOJ press releases relating to Stark law settlements describe them in similar terms to those based on *qui tam* actions, the government did note its appreciation of hospitals' willingness to come forward and disclose violative arrangements. For example, on December 31, 2013, the DOJ settled with Montana-based hospital St. James Healthcare and its parent company, Colorado-based Sisters of Charity of Leavenworth Health System, regarding allegations that they provided improper financial incentives to physicians and physician groups involved in a joint venture with St. James to own and operate a medical office building on its campus. This arrangement increased the value of the physician's shares and resulted in lease rates below fair market value for those physicians renting space in the building and other related rates and arrangements below fair market value.

This conduct was voluntarily disclosed to the government, resulting in a settlement for which St. James and Sisters of Charity paid \$3.85 million to resolve potential liability stemming from these issues. Likewise, on March 13, 2014, the DOJ settled with Ohio-based Memorial Hospital as a result of its self-disclosure of arrangements that potentially violated the Stark law. The \$8.5 million settlement involved allegations that Memorial's arrangements with two physicians violated the Stark law. Both self-disclosure-based settlements were for significantly less amounts than those that would have been obtained after months of litigation, presumably due to lower multipliers (1.5 times single damages) applied to settlements based on self-disclosures.

CONTINUED FOCUS ON CARDIAC PROCEDURES

Cardiac procedures, particularly cardiac stenting, performed in the hospital setting have long been a focus of the DOJ and OIG. This is in large measure driven by the volume of these procedures as well as their cost, especially when compared with less intensive therapies. Indeed, a number of studies have shown that stents can be overused, and their use varies widely from region to region and from cardiologist to cardiologist. This has not escaped the notice of the DOJ or OIG.

The DOJ has taken the position that coronary arteries require a 70 percent or greater blockage in order to justify the placement of a cardiac stent. In 2013, this position gained additional support when the Fourth Circuit Court of Appeals upheld the conviction of Dr. John McLean, a Maryland Cardiologist, who was convicted of altering medical records to meet the 70 percent threshold in the *United States v. John R. McLean* case, No. 11-5130 (4th Cir. 2013). The prosecution presented evidence that the threshold was "generally accepted in the medical community." Dr. McLean, in turn, argued that guideline was unconstitutionally vague and presented expert testimony that until as recently as 2006 a 50 percent blockage was sufficient to justify placement of a stent in conjunction with evidence of heart stress.

The Fourth Circuit focused on the fact that Dr. McLean had altered patient records to make it appear as if he had met the 70 percent threshold. The court reasoned that this was evidence that Dr. McLean knew he was engaging in fraud when he performed the procedures and sought reimbursement. The Fourth Circuit's reasoning in *McLean* tracked the Fifth Circuit's decision in another stenting case against Dr. Mehmood Patel, a cardiologist in Lafayette, La. who made similar arguments. As in these cases, until recently, much of the enforcement activity in this area focused on the actions of individual cardiologists and typically

resulted in criminal charges. In 2014, this changed markedly with several large settlements against hospitals.

ST. JOSEPH'S HEALTH SYSTEM

St. Joseph's Health System, Inc. owns and operates hospitals across Kentucky, including St. Joseph's Hospital in Loudon, Kentucky. In January 2014, St. Joseph's entered into a \$16.5 million FCA settlement with the DOJ. In its public statements, the DOJ alleged that doctors working at St. Joseph's performed numerous invasive cardiac procedures, including coronary stents, pacemakers, coronary artery bypass surgeries, and diagnostic catheterizations on Medicare and Medicaid patients who did not need them. The doctors who allegedly performed these procedures were affiliated with Cumberland Clinic, a cardiology practice owned by two cardiologists.

In addition to claiming that St. Joseph's was aware of these unnecessary procedures and allowed them to continue, the DOJ also alleged that St. Joseph's violated the Stark law and anti-kickback statute by entering into sham management agreements that financially benefited the owners of the Cumberland Clinic and induced them to direct more of their patients to the hospital. In October 2014, Cumberland Clinic and its owners entered into a separate \$360,000 settlement agreement with the DOJ to resolve their liability.

The investigation of St. Joseph's related to the filing of a whistleblower lawsuit by three Lexington area cardiologists pursuant to the *qui tam* provisions of the False Claims Act, which was captioned *United States ex rel. Jones, Hollingsworth and Rukavina v. Saint Joseph Health System et al.*, no. 11-cv-81-GFVT (E.D. Ky.). As such, while various news outlets have reported about the high rates of cardiac procedures at St. Joseph's, it appears that the investigation commenced following complaints by whistleblowers who were themselves cardiologists. As part of the settlement, the three doctors recovered over \$2.4 million

from the \$16.5 million collected from St. Joseph's. Interestingly, prior to the settlement, St. Joseph's voluntarily disclosed to the government that one of its cardiologists, Dr. Sandesh Patil, had performed medically unnecessary coronary stents. Dr. Patil previously pleaded guilty in June 2013 and was sentenced to 30 months prison in addition to losing his license and being excluded from the Medicare and Medicaid programs.

KING'S DAUGHTERS

In May, Ashland Hospital Corporation in Ashland, Kentucky, also known as King's Daughters Medical Center, reached a \$40.9 million settlement with the DOJ. The DOJ alleged that from 2006 to 2011, cardiologists at King's Daughters billed Medicare and Medicaid for numerous unnecessary cardiac stents and cardiac catheterization. In addition, the DOJ alleged that the physicians performing these procedures falsified medical records in order to justify these unnecessary procedures. While not spelled out specifically in its public pronouncements, given the DOJ's position on other cardiac stenting cases, this statement suggests the DOJ believed that cardiologists altered records in an attempt to show that arteries were 70 percent or more blocked. The settlement also resolved allegations that King's Daughters violated the Stark law by paying certain cardiologists unreasonably high salaries in excess of fair market value.

This investigation had been ongoing since at least 2011 and involved the top four billers at the hospital. While King's Daughters appears to have escaped any criminal liability itself, the criminal investigation against at least one of the physicians who performed these procedures, Dr. Paulus, is continuing. These cases are a clear focus area for the DOJ. In prepared remarks in June 2014, the Assistant Attorney General Stuart Delery highlighted the King's Daughters' settlement and emphasized the DOJ's commitment to

such cases, particularly in situations where patient harm could occur.

FALLOUT

The St. Joseph's and King's Daughters investigations have important lessons for hospital providers. First, the government is increasingly looking to recoup allegedly improper payments in addition to filing criminal charges against culpable individuals. Hospitals tend to have deeper pockets than physicians or individual physician practices that tend to become a primary enforcement target. Where hospitals are involved, the government will look to establish the requisite element of scienter under the FCA — either direct knowledge of false claims or a reckless disregard or willful blindness for their falsity — against the hospital. If it can, it will seek to recoup payments to hospitals for these procedures.

Second, hospitals need to be aware of their relationships with clinics and other physician practices. This is important for two reasons. First, as is seen in both these settlements, if inappropriately structured, there can be underlying Stark law or anti-kickback violations. FCA actions predicated on a violation of the Stark law or the anti-kickback statute can quickly accelerate any damages, rendering all the care provided pursuant to the allegedly violative arrangement or the alleged kickback subject to the treble damages and penalty provisions of the FCA.

Second, as was the case with St. Joseph's, allegations of improper treatment often circulate within the medical community, particularly in smaller markets. This can occur when patients, faced with significant medical decisions, seek second options, oftentimes from competitors. With the rise of whistleblower lawsuits, providers can expect that if known, such conduct could result in a *qui tam* lawsuit from other providers. If hospitals become aware of such concerns, either through medical staff complaints or other practitioners in the community, they should pay particularly close attention to them.

Third, and perhaps most importantly, hospitals need to be aware of secondary legal action that may result from the settlement of FCA allegations. While these settlements may have resolved government investigations and avoided a significant amount of regulatory uncertainty with regard to business operations, they did nothing to avoid — and may have increased — the potential for ancillary litigation, including medical malpractice cases and investor lawsuits. This is particularly true in cases where, as here, the government alleges that medically inappropriate or unnecessary care was delivered. FCA settlements in these areas can open the door to private plaintiffs pleading causes of action in fraud, conspiracy, and consumer protection act violations, among others. Such claims may be more expansive and not subject to the same damage caps and pleading requirements of traditional medical malpractice suits.

Indeed, following both the settlement in King's Daughters and St. Joseph's, hundreds of former patients sued both facilities in alleging not just medical malpractice but a host of other claims including fraud and conspiracy. It is yet to be seen what costs may be incurred by either facility should these lawsuits be resolved short of trial. Nonetheless, significant reputational harm has already occurred. King's Daughters stated that negative publicity from the investigation was one of the factors that has depressed patient volume at the medical center. In a call with bondholders last year, the hospital said it has seen a 48.3 percent decrease in cardiac catheterizations, which was also due to the loss of two high-volume cardiologists, and recently laid off 150 employees of its 3,800 employee base.

The experience of King's Daughters and St. Joseph's in this regard will likely change the settlement calculus for hospitals that are faced with investigations of this nature. While self-disclosure or quick settlements of government investigations can allow providers to continue with their operations,

potential tail end liability can have serious adverse reputational harm that can go well beyond that caused by the government investigation or settlement.

LOOKING AHEAD TO 2015

2015 is likely to be another significant year for the FCA, particularly as it relates to hospitals and associated providers. Some of the same trends that became apparent in 2014 are likely to continue, but hospitals and associated providers can expect FCA cases and government investigations in different areas as well. Because of the multi-year lifecycle of FCA investigations and *qui tam* actions, those that become public or settle this year were likely filed or commenced one or two years prior. The following are just some of the areas where we can expect continued high levels of enforcement activity.

CONTINUED EMPHASIS AND UNCERTAINTY ON SHORT-STAY STATUS CASES

Medicare, Medicaid, and other government health care programs continue to feel the effect of cost pressures, particularly in the acute care setting. In turn, hospitals and associated providers can expect to see a continued emphasis on ensuring that government beneficiaries are treated in the least costly setting in which they can receive the necessary level of care. Given the size and publicity of some of the recent FCA settlements in this area, providers can expect that would-be whistleblowers and their counsel will continue to aggressively investigate and file *qui tam* FCA actions surrounding patient status and short-stay cases.

As discussed above, one of the larger likely developments will be in the closely watched intervened *qui tam* actions against the legacy HMA facilities in the D.C. District Court. Currently stayed by the court, these actions cannot remain stayed forever, and 2015 will likely either see their resolution or active litigation. To date, the DOJ has not litigated a large-scale short-stay status

case. Litigation of such cases would likely provide more information about the DOJ's view of these cases and the defenses to them.

Potentially overshadowing the ongoing HMA litigation and adding uncertainty to the future of short-stay status cases will be continued developments in CMS' two-midnight rule. Providers have expressed tremendous dissatisfaction with the rule itself and CMS' attempts to clarify confusion surrounding it. This dissatisfaction, in part, drove congressional action to suspend enforcement of the rule by CMS' recovery audit contractors. While that suspension is set to end in March 2015, it coincides with the expected reduction in Medicare physician payments. As such, there is a possibility that Congress may address both issues at the same time.

While the two-midnight rule applies to claims made following its enactment, many of CMS' public statements discussing the need for clarification of what constitutes an inpatient admission and the two-midnight rule's presumptive admissions standards may effect ongoing investigations and litigation of short-stay status cases brought under CMS' prior inpatient admission guidelines. Moreover, while CMS and the OIG are unlikely to take major enforcement actions on this still developing rule, they are reviewing small samples of short-stay inpatient claims in order to examine compliance with the new rule. Hospitals and associated providers would be well served to stay abreast of developments in this area as well as examining their own utilization as clinical decision makers gain more experience with the two-midnight rule.

CONTINUED EMPHASIS ON INDIVIDUAL LIABILITY

The DOJ has come under pressure in recent years following high-profile settlements to explain why individuals who may have had criminal liability were not prosecuted. Increasingly, the DOJ has

responded to this criticism by investigating and prosecuting individuals who may share some liability for actions. The results of this can be seen in some of the cardiac stenting cases addressed here, where the cardiologists who performed these procedures are either under investigation or have been successfully criminally prosecuted. Nonetheless, the DOJ has not had universal success in holding individuals liable in connection with high-profile FCA investigations.

In 2014, federal prosecutors were unable to secure a conviction in the high profile prosecution of Joshua Putter, a former division vice president of Naples-based HMA, which the DOJ argued contained false information and was intended to obstruct and terminate an internal compliance investigation. The case was captioned *United States of America v. Joshua S. Putter*, Case No. 2:13-cr-141-FtM-29CM (M.D. Fl.).

While the DOJ will continue the aggressive investigation of allegations of criminal wrongdoing, with regard to established and reputable providers, ancillary criminal litigation stemming from FCA investigations will likely continue to focus on clear-cut cases of wrongdoing by specific individuals or providers. The higher skilled those providers, and the more defined the case law and regulations — such as the DOJ's established and supported position that a stent requires a 70 percent occlusion — the higher the likelihood that the DOJ will examine the case for potential for criminal liability.

In addition, in 2014, the DOJ's Criminal Section announced that it will begin reviewing all FCA *qui tam* actions for potential criminal liability. As many commentators have suggested, this additional scrutiny by criminal prosecutors will likely result in an uptick of criminal health care fraud investigations and enforcement. While some additional criminal enforcement may fall on companies, the Department will still face the same issues that historically have made charging a business difficult.

The larger the provider entity and the more needed the care they provide in the community, the less likely the DOJ will be to bring criminal charges that could shut down the provider. As such, the bulk of this additional criminal scrutiny is likely to fall on individuals, whether in management or clinical positions. An example of this can be seen in a guilty plea entered by an Atlanta-area hospital CEO in August in connection with allegations that he paid kickbacks in exchange for Medicaid referrals. The case was captioned *United States of America v. Gary W. Lang*, No. 1:14-CR-274 (N.D. Ga.). Because of this increased scrutiny, hospitals and associated providers need to keep in mind that it is no longer a matter of whether a criminal prosecutor has examined the allegations in an FCA case. They have, and they may well be conducting a separate parallel criminal investigation of their own. This fact, however, will make CIAs more commonplace in settlements.

“DATA” WILL CONTINUE TO DRIVE ENFORCEMENT

The use of billing and utilization data has reshaped the way the DOJ and OIG decide who and what to investigate in an FCA case. In 2015, we can expect to continue to see data play a significant role in investigations by the government as well as increasingly factor in the manner in which relators prepare and plead FCA actions under the Act's *qui tam* provisions.

The government is becoming increasingly sophisticated in the manner in which it utilizes data to identify abnormal billing patterns, identify trends, and root out health care fraud. The combined DOJ and OIG Strike Force teams, created as part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, continue to use advanced data analysis techniques to identify high-billing levels in health care fraud hot spots to target known and emerging fraud schemes as well as chronic fraud by criminals masquerading as health care providers. While

these efforts are often focused on the more wanton fraud, waste, and abuse, they can, and have been, utilized effectively against established providers. In addition, more effort and attention is being paid to the speed at which data can be analyzed, with real time data analysis, such as through CMS' Program Integrity Command Center, playing a greater role in investigations.

In addition to the use of data by the government, 2015 will likely see the increased use of data by whistleblowers and their attorneys. Some hospital-related FCA cases discussed in this article have already seen significant use of data analysis on the part of relators and their counsel. For example, in one of the related *qui tam* actions against CHS that was resolved as part of the settlement agreement, the relator made use of the Medicare Inpatient and Outpatient Limited Dataset Standard Analytical Files – a limited-use publicly available file – for 2003 through 2009. Using these files, the relator performed what amounts to an outlier analysis, by identifying admissions occurring from emergency rooms of all acute care hospitals nationwide and then comparing admissions from CHS' emergency rooms to the national average they developed. The relator pointed to its determination that there was a higher rate of admissions at CHS emergency rooms to argue that CHS was improperly admitting patients. While this type of sophisticated data analysis is not the norm, it will only grow in use by experienced relators and counsel who have the resources to bring to bear.

In addition to these types of specific data analyses, the increase in publicly available data through CMS' Open Payments³ program will likely drive additional FCA filings. CMS' first release of Open Payments' data occurred in September 2014, and the next release is set for June 2015. In addition to this Sunshine Act data, in April 2014, CMS also released Medicare Provider Utilization and Payment Data for Physician and Other Suppliers.⁴ This

doctor-specific payment data, which was strongly resisted by the American Medical Association, and others, was much more widely reported than the release of the Sunshine Act data.

It is unclear whether the public availability of these additional data sets will drive an increase in FCA cases; however, it will certainly provide additional information to relators and their counsel who are contemplating or investigating possible FCA *qui tam* actions. The public nature of this information combined with the FCA's public disclosure bar, however, may present hurdles to relators who seek to base *qui tam* actions on publicly available data alone. Nonetheless, hospitals and associated providers should review public data both for accuracy and to determine if they are an outlier in any area, particularly for procedures which already have the attention of the DOJ and relator's bar.

STARK WILL CONTINUE TO BE AN AREA OF FOCUS

While the ups and downs of the *United States ex rel. Drakeford v. Tuomey Healthcare* could take up this article and more, 2015 will see yet another chapter written when the Fourth Circuit renders its decision following oral argument in October 2014. Whatever the Fourth Circuit decides in *Toumey*, its effects will likely be far reaching and will provide additional clarity for providers, the government, and relators in FCA cases premised on Stark law violations. The government's success in cases like *Toumey*, *Halifax*, *Diagnostic Physicians Group*, and others means that hospitals can expect to see similar enforcement actions in 2015 because of the potentially high-dollar value of such cases with damages implicating the entire amount of reimbursement paid for each false claim. Relators have incentives to bring these cases in hopes that the government will intervene, and the government, with a keen interest in the development of the

case law in this complicated area, will likely monitor — and possibly participate — in a higher percentage of these cases than it otherwise would.

ADDITIONAL QUI TAM CASES AND MORE DECLINED CASES BEING LITIGATED BY RELATORS

The DOJ has for many years noted the uptick in the filing of FCA cases under the Act's *qui tam* provisions, and 2014 was no different. While there have been increased hiring and funding for the DOJ section and U.S. Attorney's offices that are tasked with investigating and responding to these filings, the increased resources have not kept pace with the increased filings by relators. While the DOJ continues to intervene in most meritorious cases, it can only be assumed that the lack of available manpower coupled with the uptick in new filings will result in additional declinations of FCA cases. Under the FCA the relator then has the option to litigate the case and, if successful, receive a heightened bounty of up to 30 percent of the proceeds. In recent years, relators have met with success in some of these declined cases.

For example, in June 2014, in the case that was captioned *United States ex rel. Gale v. Omnicare, Inc.*, (No. 1:10-cv-00127 (N.D. Oh.)), Omnicare, Inc. settled an FCA matter for \$124 million in a case in which the United States declined to intervene. In September 2014, relators in a declined case against Merck & Co. scored a major victory when Court denied Merck's motion to dismiss in *U.S. ex rel Krahling et al v. Merck & Co.*, (No. 2:10-cv-04374 (E.D. Pa.)). These successes have been noted by the relator's bar, and all health care providers, including hospitals and associated providers, should expect that relators will look much harder at declined cases and may seek to litigate them.

CONCLUSION

2014 marked the fifth consecutive fiscal year in which the DOJ recovered more than \$2 billion in cases involving false claims

against federal health care programs. Fraud enforcement may well be the single issue in Washington that has true bipartisan support, and increased enforcement resources for the DOJ are a clear indication that the emphasis on fraud and abuse will not be ending in 2015.

Based on high-profile enforcement successes in 2014 with short-stay status cases, individual liability and Stark violations, it is safe to project that the DOJ will continue its health care enforcement efforts in these key areas. In addition, health care providers should be mindful of emerging enforcement trends involving the use of big data and advanced analysis techniques and the increase in the litigation of declined *qui tam* cases by relators. The National Archives Building in Washington, D.C. is inscribed with the words "What is Past is Prologue." For health care providers, however, the inscription would be equally apt at the DOJ building.

Endnotes:

1. The False Claims Act has a *qui tam* provision (31 U.S.C. § 3730) that allows a private citizen, also known as a relator, to bring an action under the FCA in the name of the United States. Once filed, the action remains under seal for at least 60 days (which, in practice, is often extended - sometimes for many years) to allow the government an opportunity to investigate the allegations and decide if it wants to intervene and take over the action or decline and allow the relator to proceed if he or she so wishes.
2. In July 2012, CHS announced its intent to buy HMA for \$3.9 billion in cash and the assumption of \$3.7 billion of debt. The acquisition of HMA's 71 hospitals gave CHS 206 hospitals across 29 states, making it the largest for-profit hospital chain and one of the biggest hospital systems overall.
3. Open Payments is a program run by CMS that collects information about financial relationships between doctors, hospitals, and health care manufacturing companies. An overview of this program is available at www.cms.gov/OpenPayments/Downloads/Fact-Sheet-Published-Data.pdf.
4. Medicare's Provider and Utilization Payment Data for Physician and Other Suppliers contains information on services and procedures provided to Medicare beneficiaries by physicians and other health care professionals. While this data file has a wealth of information on payment and utilization for Medicare Part B services, the dataset has

a number of limitations, including that the data may not be representative of a physician's entire practice as it only includes information on Medicare fee-for-service beneficiaries. More information on

this program is available at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html.

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