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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

FCA Trends Health Care Providers Should Expect In 2013

Law360, New York (January 22, 2013, 12:49 PM ET) -- From the perspective of False Claims Act results, 2012 was a decidedly mixed year for health care providers. The bad news was quite bad — increased FCA scrutiny by the U.S. Department of Justice led to $3 billion of health care-related FCA judgments and settlements (60 percent of the total 2012 amount for all industries). Yet there was still some good news: In many of the FCA cases in which courts reached the merits, health care providers won, including successful results at the trial and appellate levels.

If 2013 trends follow the path of 2012, health care providers will continue to face — and endure the expense of defending — increasing numbers of FCA claims. But they may take some (perhaps cold) comfort knowing that judicial skepticism toward the most aggressive FCA prosecutions may be growing and with it the likelihood of providers' ultimate success in those cases.

The mixed results of 2012 are seen clearly in the following key FCA cases decided last year. While the first five represent generally positive developments for health care providers, the latter six demonstrate the steep challenges providers continue to face.

United States of America ex rel. Julie Williams v. Renal Care Group Inc. et al., 696 F.3d 518 (6th Cir. 2012)

In perhaps the most emphatic provider victory of 2012, the Sixth Circuit reversed the trial court's summary judgment in favor of the government and the resulting $82 million damages award. In Renal Care Group, several health care providers had created separate subsidiaries (with their own supplier numbers) to gather Medicare reimbursement of dialysis supplies at the higher rate for independent companies (so-called "Method II"), rather than the lower rate for the companies that also ran dialysis facilities.

In analyzing the two main counts, the Sixth Circuit rejected the government's theories and overturned the trial court's rulings. In count one, the court examined whether the claims were in fact false and whether defendants had the requisite knowledge. With respect to falsity, the court rejected the government's focus on defendants' attempt to seek better reimbursement rates as evidence of falsity, commenting that "[w]hy a business ought to be punished solely for seeking to maximize profits escapes us."

With respect to knowledge, the court found that the FCA's reckless disregard standard only applied to a defendant who "buried his head in the sand," a standard not met here. Among the factors undermining reckless disregard were that Renal Care Group (1) sought legal counsel; (2) allowed its legal counsel to seek clarification on the rules from Centers for Medicare and Medicaid Studies officials; (3) had documentation confirming that CMS officials agreed that the arrangement was legal; (4) was aware of large dialysis providers that had wholly owned subsidiaries filing for Method II reimbursements; (5) had its position confirmed by industry publications that openly encouraged the use of Method II reimbursements to increase profit; (6) kept the higher-reimbursement entity separately incorporated with its own Medicare supplier number; and (7) gave evidence that CMS and the Office of Inspector General knew of the ownership structure.

In count two, the government contended that defendants were subject to FCA liability by not complying with the durable medical equipment standards set forth in 42 U.S.C. § 1395m and the accompanying regulations. The Sixth Circuit again rejected that argument and vacated the summary judgment. In declining to use the standards for durable medical equipment suppliers as a basis for FCA liability, the court observed that "the regulations set forth in the United States' complaint are conditions of participation, the violation of which do not lead to [FCA] liability," and, more broadly, that the FCA "is not a vehicle to police technical compliance with complex federal regulations."

After reversing the trial court and granting summary judgment for defendants on counts one and two, the court reversed and remanded the judgments on the remaining counts.

U.S. ex rel. Drakeford v. Tuomey Healthcare System Inc., 675 F.3d 394 (4th Cir. 2012)

In Tuomey, the government brought several FCA claims and equitable claims premised on Stark Law violations. A jury returned a verdict finding no FCA violation, but it answered affirmatively a special interrogatory regarding whether Tuomey violated the Stark Law. The district court later set aside the verdict on the FCA claims and ordered a new trial.

At the same time, however, it entered a judgment on the equitable claims based on the jury's finding in the special interrogatory, which entitled the government to recover over $44 million. On appeal, the Fourth Circuit vacated the judgment, concluding that Toumey's Seventh Amendment right to a jury trial was violated when the district court premised its judgment on a jury verdict that it had already set aside. The court then went on to address two Stark Law issues likely to recur on remand.

First, the court considered whether the facility component of services performed by the physicians (for which Tuomey billed a facility fee to Medicare) constituted a referral under Stark. Drawing on past Health Care Financing Administration commentary, the court concluded that the personal services exception did not apply to the facility component of the services and therefore the facility component could constitute a referral.

Second, the Fourth Circuit considered whether the contracts with the physicians implicated Stark's "volume or value" standard. The court ultimately concluded that, as a legal matter, contracts that require a physician to refer patients to a particular provider as a condition of compensation do not violate Stark, as long as certain conditions are met, including that the physician's compensation must not take into account the volume or value of anticipated referrals. The question left for the jury on remand was whether the contracts on their face took into account the volume or value of anticipated referrals.

United States of America ex rel. Thomas F. Jamison v. McKesson Corporation et al., No. 08-214, (N.D. Miss. Sept. 28, 2012)

In Jamison, following a bench trial, the district court found that no violation of the anti-kickback statute ("AKS"), and therefore no violation of the FCA, had occurred. The government contended that because the defendants had violated the AKS, all claims that they submitted became false. But after a trial complete with extensive factual findings, the court found that various medical supply companies and nursing home entities had not committed AKS violations.

In its primary finding that the requisite remuneration or inducement did not pass from one set of defendants to the other, the court stated that "it is not enough to covet the business of another, there must actually be some bad intent to violate the law." The defendants had joint ventures with one another to handle various services involved in seeking reimbursement for nursing home supplies. But the government could not prove that the defendants offered each other the services below fair market value, actual costs, or for a discount. The trial court also confirmed that occasionally careless estimates of costs do not support the requisite knowing and willful standards under the AKS.
U.S. ex rel. Davis v. Dist. of Columbia, 679 F.3d 832 (D.C. Cir. 2012)

In Davis, the relator alleged that the District of Columbia and its schools violated the FCA by submitting a Medicaid reimbursement claim without maintaining adequate supporting documentation. The district provided certain medical and transportation services to special education students, which were reimbursed by Medicaid. A public auditor's report later revealed that the district did not maintain adequate records to document these services, as required by federal regulations. Relators alleged that this failure to maintain documentation rendered the underlying claims false.

The D.C. Circuit disagreed and affirmed the district court. In doing so, the court noted that this was "a rare case in which there is no allegation that what the government received was worth less than what it believed it had purchased" and that, even if defendants had failed to keep the documentation, no actual damage existed because all parties agreed that the services paid for were provided. As the court colorfully analogized, "a server's failure to bring a receipt after dinner causes no harm when you know you've been properly charged." The same held true in this case; the "government got what it paid for and there are no damages."

U.S. ex rel. Black v. Health & Hosp. Corp. of Marion County (4th Cir. Aug. 17, 2012)

In Black, the Fourth Circuit affirmed the dismissal of the relator's claims against an Indiana county hospital, finding the claims were precluded by the public-disclosure bar in 31 U.S.C. § 3730(e)(4). The public disclosure in Black was caused by regulatory activity: CMS issued a proposed rule, held public hearings, and engaged with the U.S. Government Accountability Office in a "lengthy and systematic review of the state Medicaid financing programs," mentioning Indiana in particular. After affirming that a public disclosure had occurred, the court further concluded that the relator had failed to establish himself as an original source.

The court therefore affirmed dismissal. While the circumstances leading to dismissal in Black were somewhat case-specific, the Fourth Circuit's decision nonetheless highlights that regulatory activity — including the extensive fraud-and-abuse announcements by CMS, which are often further disseminated by various news sources — can create a public disclosure for purposes of the FCA, particularly when those announcements pinpoint specific types of health care providers.

Sanders v. Allison Engine Company Inc. (6th Cir. 2012)

In Allison Engine, the Sixth Circuit addressed certain portions of the Fraud Enforcement and Recovery Act of 2009 amendments to the FCA that created liability for false records or statements material to false claims. The court found those amendments applied to FCA civil actions pending on or before June 7, 2008. Although that decision will have a diminishing effect as the cases pending on or before that triggering date conclude, one aspect of Allison Engine will affect health care providers going forward: the Sixth Circuit's finding that the FCA is not a punitive statute. This finding should affect arguments that broadly drafted statutes and regulations — often found in the health care sector — should be strictly construed without reference to the regulatory and subregulatory guidance often underlying the statute.

United States ex rel. Matheny v. Medco Health Solutions Inc. et al., 671 F.3d 1217 (11th Cir. 2012)

In Matheny, the Eleventh Circuit confirmed that breach of a corporate integrity agreement ("CIA") can create FCA liability. CIA agreements are well-known tools to allow a provider continued participation in government programs. The Eleventh Circuit's decision, which reversed the trial court's dismissal, highlights that FCA obligations arise from not only statutes and regulations but also agreements. The Matheny relators (all employees) proceeded without the government and alleged that the defendants certified compliance with the CIA despite trying to conceal overpayments that the defendants were obligated to return to the government.

The overpayments resulted, as alleged, from duplicate billing and other billing errors. Although this decision made for straightforward materiality analysis because the government relied on defendants to report accurately the value of government property, CIA agreements also contain other obligations that may or may not affect the government's decision to pay, and each context remains important.

United States ex rel. Schweizer v. Oce N.V., 677 F.3d 1228 (D.C. Cir. 2012)

In Schweizer, the government initially declined to intervene in this qui tam case but remained in settlement discussions with the defendant. Later, the government, the defendant, and one of the two relators settled the case. The government then intervened and moved to dismiss. The other relator, who had not been involved in the settlement discussions, appealed, arguing that the court had to determine if the settlement was fair, adequate, and reasonable. The court agreed with that relator, concluded that the trial court must determine the settlement's fairness, and remanded for such a determination. The court's conclusion may have implications for parties negotiating a qui tam settlement because it appears to give the relator more bargaining power through the ability to force judicial scrutiny.

Little v. Shell Exploration & Production Co., 690 F.3d 282 (5th Cir. 2012).

In Shell, the Fifth Circuit, joining the Eleventh and Tenth Circuits, found that a federal government employee has standing to act as a relator bringing an FCA action. Given the common interactions between federal employees and health care providers, the court's decision expands potential FCA exposure to providers. Nonetheless, the Fifth Circuit's analysis did limit the practical effect of its decision.

The court noted that, if on remand the district court concludes that the qui tam was based on publicly disclosed allegations, the relators could not be considered original sources, as is required in public-disclosure cases. In reaching that conclusion, the court reasoned that, to qualify as an original source, the relators must have voluntarily provided the information to the government. But relators could not meet that voluntariness standard because they were employed specifically to disclose fraud, which is "sufficient to render [the] disclosures nonvoluntary." While that limitation bodes well for providers, an argument invoking the public disclosure bar and original source status will still likely require more factual development and expense than one invoking standing.

U.S. ex rel. Baklid-Kunz v. Halifax Hosp. Medical Center, No. 09–1002, (M.D. Fla. 2012) and United States of America, ex. rel. Jerre Frazier v. IASIS Healthcare Corporation, 05-766 (D. Ariz. January 10, 2012).

Finally, two decisions illustrate courts' and practitioners' struggles in construing traditional notions of the attorney-client privilege in the context of compliance programs, which can result in communications for mixed legal and business purposes. Baklid-Kunz suggests the privilege is not widely available, while Frazier expressed a contrary view.

In Baklid-Kunz, the magistrate judge created differing standards for determining privilege, dependent on whether communications from corporate clients went to outside counsel or in-house counsel. The decision's bright-line reasoning found that emails to both a company lawyer and a nonlawyer suggested both business and legal purposes, not legal advice solely.

Specifically, the court refused to protect a log of compliance complaints — even though the legal department supervised the compliance department and the legal department instructed the compliance department to keep the log. This decision underscores for health care providers that communication with in-house counsel should be carefully managed and that earlier use of outside counsel may help preserve a privilege.

In Frazier, the district court analyzed what kind of compliance documents are privileged and what remedies a health care company has if a member of the compliance staff becomes a relator. The court found that certain documents — audits at the legal department's behest of physician contracts — were created as a predicate to obtaining advice regarding legal issues, not just later compliance reviews. Interestingly, the defendant had kept the legal and compliance departments separate. The relator, the former chief compliance officer, retained these documents. Relator's counsel had to pay the defendant's attorney fees incurred in trying to retrieve the documents.

--By Ty Howard and Cameron Ellis, Bradley Arant Boult Cummings LLP

Ty Howard is a partner in Bradley Arant's Nashville, Tenn., office. Cameron Ellis is an associate in the firm's Birmingham, Ala., office.

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