



HEALTH CARE FRAUD REPORT



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State False Claims Acts, Physician Relationships Top 2007 Fraud Issues

The anticipated proliferation of state false claims acts in 2007 is certain to broaden the scope of health care fraud cases by opening new venues for the qui tam bar to bring whistleblower cases, but, while the advent of new state laws may result in more whistleblower cases in future years, the more immediate effect could be to complicate the qui tam process with a surge in government players trying to coordinate prosecutorial efforts, industry observers and health care attorneys told BNA.

As the qui tam landscape is changing, though, other areas of health care fraud enforcement are expected to continue on the same track. Most notably, observers expect federal agencies to continue pursuing average wholesale price and off-label cases in the pharmaceutical sector, as well as continue using the anti-kickback statute as a key fraud enforcement tool, especially in investigating suspect arrangements between doctors and hospitals.

Beginning in 2007, states will be eligible to keep 10 percent more in federal recoveries for Medicaid fraud as a result of lawsuits filed under a state false claims act modeled after the federal FCA, due to a provision in the Deficit Reduction Act of 2005.

The financial incentive widely is expected to motivate state legislatures to enact new laws or beef up existing statutes, with some industry observers estimating that over half of all states will have false claims statutes on the books in the near future. However, to date, few state-based laws have been approved by the OIG as eligible for the bonus (*see related item in the Federal News section*).

The prevailing sentiment among industry experts, though, is that new state false claims acts will not nec-

essarily lead to a significant increase in whistleblower lawsuits, but will give relators and their attorneys greater leverage in bringing and litigating cases.

The federal financial incentive for enacting state false claims laws "is too good to pass up," attorney Kevin G. McAnaney, Washington, explained, although he said he was skeptical about the effectiveness of such state-based statutes.

"The laws will complicate these cases, making settlement very difficult, and increasing the defense costs for even frivolous cases," McAnaney said. "The effectiveness of the cases will not be known for five years or so at most."

Top 10 Health Care Fraud Issues in 2007

According to a survey of BNA's *Health Care Fraud Report* Advisory Board, the top 10 health care fraud issues for 2007 are:

1. State false claims acts
2. Physician-hospital arrangements
3. Compliance with Deficit Reduction Act of 2005 provisions
4. Kickbacks to doctors
5. Pharmaceutical off-label cases
6. Compliance with Part D fraud, waste, and abuse guidance
7. Medical device fraud
8. Medicaid fraud enforcement
9. Part D fraud and abuse
10. Drug pricing

More Complex, Confusing. Attorney John T. Brennan, Crowell & Moring LLP, Washington, agreed, saying whistleblower activity at the state level will generate more complexity and more confusion in prosecuting FCA cases.

"Multi-jurisdiction actions which heretofore have been under the purview of the Department of Justice may now encounter procedural and other barriers when they run into parallel, multiple state actions," Brennan said.

Stuart I. Silverman, an attorney with the District of Columbia Office of Inspector General's Medicaid Fraud Control Unit, questioned whether an increase in the number of state false claims acts would lead to significant changes at the state level, saying that any real increases in state-based false claims cases would take several years to occur.

Nevertheless, Silverman said, greater numbers of state false claims acts would allow qui tam relators the ability to "forum shop" cases for the best venue.

"Certainly, if a state [attorney general] declines to intervene in a qui tam case, then there is every incentive for a relator to look for another state that is more friendly to the lawsuit," he said, adding that some relators may seek states where attorneys general are better equipped and prepared to handle false claims cases.

"It takes significant state resources and expertise to litigate a false claims case involving health care fraud," Silverman explained. "Those state [attorney general] offices that have geared up for the effort, with more funding to seriously litigate such cases, will be more attractive to the whistleblower, and thus provide a more appealing forum to file the suit."

'Wooring' AGs. Attorney Carolyn McElroy, Pacific Pulmonary Services, Novato, Calif., similarly said that states with strong attorneys general would be "wooded" by relators, but that national cases already are filed in every state court where an FCA exists, "so the concept of forum shopping at the state level does not really apply."

Taxpayers Against Fraud staff attorney Joseph E.B. White agreed that forum shopping of cases would not become a significant concern, saying such efforts have not been an issue in existing federal-state false claims cases.

"While state FCAs will admittedly increase the relators' share of federal-state settlements, the primary enforcement engine—and the primary decision driver for the qui tam bar—will remain with proactive U.S. attorney's offices," White said. "Indeed, the most active USAO for qui tam suits is the Eastern District of Pennsylvania, a state that does not have a state FCA."

DRA Compliance

FCA provisions in DRA also raise new compliance concerns for health care companies with at least \$5 million in annual payments under a state Medicaid plan, requiring that such entities establish written policies for their employees, contractors, and agents about state and federal false claims laws as well as their procedures for detecting fraud, waste, and abuse.

Such providers also must include in their employee handbooks a discussion specific to the FCA and whistleblower protections for employees. Attorneys and consultants largely said they are waiting for specific guidance from the Centers for Medicare & Medicaid Services before advising organizations on what they should include in their employee training.

Nevertheless, White said his organization has received requests from companies for help complying with DRA, and many are "proactively" educating employees, and, in some cases, vendors and contractors.

Brennan said the DRA False Claims Act training requirements should not add "significant new burdens to most robust and well functioning compliance programs." However, several industry watchers called the DRA mandate to include information about the federal FCA in employee handbooks unnecessary and too far-reaching.

Furthermore, McElroy asserted that most health care compliance departments already address FCA matters in employee training.

Former HHS IG Richard Kusserow, now president of Strategic Management Systems Inc., Alexandria Va., said most providers "are not quite sure of exactly what is needed in their training. The law was not that specific as to content, type and length of training, evidence of effectiveness, or frequency of training. As such, the

general pattern will be to meet what they consider minimum levels.”

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He added that providers should try to integrate DRA training into their compliance training programs.

Physicians, Hospitals

The anti-kickback statute is the cornerstone of health care fraud enforcement, although hospitals and other providers that receive referrals from physicians have been the primary target of government scrutiny.

That trend could change in 2007, observers said, as law enforcers take a closer look at relationships between physicians and hospitals.

Brennan said he expects law enforcement agencies to scrutinize hospital-physician “under arrangement” relationships more closely this year.

“These relationships have had a revival recently, as hospitals struggle to find new ways to maintain win-win relationships with their medical staffs,” Brennan said. “If the physicians in these wall-to-wall management relationships are also referers to the hospital, variable compensation arrangements will need to be clearly related to incentives other than volume or volume-related variables, or kickback risks arise.”

Brennan said physicians likely would be at greater risk for prosecuting under the theory that their referral to or compensation arrangement with an entity caused the “tainted” claims to be submitted.

“Given that the physicians received ‘improper compensation’ in the first place, they may not be the most sympathetic defendants in these situations,” he said.

Competitors Bring Action. Furthermore, Brennan said “jealous competitors may fuel the flame of government action if competitive advantages are at stake.”

Kusserow also noted that several new kickback cases are being brought to the government by credible physicians with the necessary evidence to suggest illicit payments.

“Physicians and those involved in arrangements with physicians are a growing source of cases for the OIG,” Kusserow said. “These include physicians not included in a ‘good deal’ or feel they are being injured by an arrangement that cuts them out of the market.”

Health care attorneys also said they expect the government to focus more attention on physician relationships that may violate the Stark law, with McAnaney characterizing such cases and settlements as “low-profile” and “lucrative.”

Specifically, McAnaney said that he expects to see a growth in cases involving joint venture arrangements between doctors and hospitals, and anticipates hospitals will scrutinize what he called disproportionate penalties for hospitals in physician self-referral schemes.

“As long as there is so much money in the health care system, kickbacks will keep appearing in any shape, size, or flavor,” attorney Thomas S. Crane, Mintz, Levin, Cohen, Ferris, Glovsky and Popeo PC, Boston, said.

Among new issues on the horizon, Crane said are fraud and abuse concerns that could arise from CMS’s new decision to base reimbursement for certain high dollar procedures on costs. Concerns, he said, range from accuracy of reporting costs and discounts and rebates associated with the procedures to disclosing related party transactions.

Medical Devices

Federal scrutiny of medical device companies and relationships between such entities and physicians has become a growing area for law enforcers as well, and will continue to grow in the coming year, industry watchers said.

“I would not be surprised to see the government criminally prosecute a prominent physician for taking payment from device companies,” McAnaney said. “I think the government is waking up to the fact that they need to hit physicians with a two-by-four to get through to them.”

McAnaney also predicted an end to efforts to advance gainsharing initiatives through Congress, saying Rep. Fortney (Pete) Stark (D-Calif.), incoming chairman of the House Ways and Means Subcommittee on Health, is not favorable to such arrangements.

Gainsharing arrangements have been touted as a prime way to drive cost-saving collaboration between doctors and hospitals, with special attention to arrangements that pay incentives to physicians for choosing the least costly medical devices during procedures.

Kusserow explained that the best way to determine where the government will be focusing its attention in the device industry is to look at new devices introduced on the market in the past two to three year because the government has to “look back” on new devices.

“Although every new device brings the potential for fraud and abuse, CMS and OIG have no way to predict the problems,” Kusserow explained.

“They have to examine what happens to these devices once they are on the market,” he continued. “After indications for abuse and fraud are surfaced, they then develop strategies to address them.”

Medicare Part D

As the Medicare Part D program enters its second year, plans face what some industry experts said could be a rough period for compliance matters as insurers figure out ways to ensure compliance within their organizations as well as among their contractors.

Attorney Kirk Nahra, Wiley, Rein & Fielding, Washington, said that creating a plan for ensuring compliance among contractors will be a top priority for plans, and noted that CMS continues to “struggle” with the requirement that is part of the fraud, waste, abuse guidance, which took effect Jan. 1.

Key among issues, Nahra said, is how far downstream plans must police entities to comply with the requirements. Furthermore, he said, the compliance requirement poses business concerns for plans.

“There are very real commercial difficulties [for plans] with getting downstream partners to agree to many of these requirements, and practical issues with requiring downstream partners to implement obligations to many different Part D plans,” Nahra said.

CMS has announced Part D audits, which could show that plans need to be more aggressive in fraud fighting, Crane explained. Furthermore, he noted, most health care compliance officers work for providers, but Part D enforcement has been left in the hands of the plans.

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Concerning enforcement initiatives, McAnaney predicted the government will evaluate employer subsidies, looking for inappropriate calculations. In addition, he said, the government likely will evaluate plans’ risk sharing payments.

McElroy said she expects few large Part D fraud and abuse cases to emerge this year; instead, most will be smaller cases addressing problems at the beneficiary level rather than broad, national issues.

“Long term, compliance officers should be most concerned about the contractual relationships forged all along the distribution chain, and should watch for arrangements where extra dollars are being retained or bled into the administration that were intended by Congress to be passed through to Medicare and the beneficiaries,” McElroy said.

Beneficiary ‘Horror Stories.’ Much of the Part D enforcement in the coming year could be directed by congressional oversight agendas, with particular attention to beneficiary “horror stories,” Kusserow said.

“I think you can expect beneficiary horror stories about how the drug benefit has not helped them and the confusion associated with the program” at congressional hearings, he added.

Medicaid agencies also are faced with Part D compliance concerns, Silverman said. Specifically, states need reliable Part D encounter data to ensure Medicaid is not being fraudulently or errantly billed at the same time Medicare is being billed for a Part D-covered drug.

Furthermore, he said, if fraud is perpetrated against the Medicare program, then it is likely Medicaid also is being defrauded.

Silverman said he also expects to see Part D fraud enforcement in the area of identify theft and for scams to inappropriately enroll seniors in bogus plans.

Pharmaceutical Industry

Law enforcers also are expected to remain focused on other areas of the pharmaceutical industry in 2007. Despite years of big-ticket settlements with drug companies involving manipulation of average wholesale prices, such cases will continue to surface, especially those in which Medicaid rebate law is implicated, McAnaney said.

He added that off-label marketing would “continue to be the bread and butter cases” during the year.

Silverman agreed, saying off-label marketing likely will continue to be an important element in newly filed false claims act cases, as will illicit marketing schemes akin to the allegations raised against TAP Pharmaceuticals in 2001.

Medicaid Integrity Program

With the advent of the newly created Medicaid Integrity Program, announced by CMS in July 2006, and new state false claims acts, health care industry observers expect greater Medicaid enforcement efforts, though not much growth in 2007.

Silverman said it may be too soon to know what impact the CMS Medicaid Integrity Program will have in fighting health care fraud, but that he is encouraged that Congress recognized a need for the program and provided funding.

“I believe that Congress will be monitoring progress of this initiative carefully, through annual reporting,” he said.

White said there will be some rise in Medicaid fraud cases in 2007, but that growth could be more significant in three to five years as newly enacted state false claims statutes result in increased investigative and litigation resources at the state level.

Medicaid managed care plans also could be the focus of stepped up enforcement activity, Brennan said.

“As more funding flows to this sector, and as Medicaid managed care companies demonstrate they can be actually be successful, the government will naturally be interested—perhaps suspicious—as to how this can be so,” Brennan said.

False Claims Act

Health care attorneys will be anticipating a decision in a False Claims Act whistleblower case pending before the U.S. Supreme Court, *Rockwell International Corp. v. United States ex rel. Stone* (U.S., No. 05-1272, oral argument 12/5/06), which could be significant for the health care industry, Silverman said. Several of the amici briefs filed in the case noted that almost half of the False Claims Act qui tam actions filed between 1987 and 2005 addressed allegations of health care fraud, he said.

“[T]he federal government has decided to intervene in less than one third of those qui tam cases,” he added.

“Thus, there is a large number of qui tam FCA cases that are brought alleging health care fraud where the government declines intervention.”

The amici briefs challenging the U.S. Court of Appeals for the Tenth Circuit’s opinion in *Rockwell*, which included the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, and the American Health Care Association, argued that the relator had no first hand knowledge that anyone at Rockwell had made a specific false statement or claim to the government, he said.

The high court heard oral argument Dec. 5, 2006, in the FCA action in which petitioner Rockwell is challenging two determinations by the Tenth Circuit that James Stone, a former Rockwell employee, was an original source of information about a contractor’s concealment of environmental violations in the Department of Energy’s Rocky Flats facility, a nuclear disposal site.

The Tenth Circuit ruled in 2001—and reiterated in a 2004 order on limited remand—that Stone qualified as an original source of the publicly disclosed information on which his FCA claim was based because he had provided the government with information on his concerns regarding the ineffectiveness of Rockwell’s manufacture and storage of pondcrete, a form of processed toxic waste.

Hard to Call. The case is “just too hard to call,” Crane said. He said some judges are offended by the qui tam provisions and the qui tam relators, while others view the FCA provisions as effective fraud-fighting weapons.

“So this issue cuts across ideology,” Crane said. “Depending on the breadth of the decision, the case could chill relators. In all, it is more likely the outcome will be modest because this issue does not affect the government’s right to bring FCA cases, even if first brought to the attention of the government by a relator.”

Brennan, of Crowell & Moring, said the addition of Chief Justice John G. Roberts Jr. and Justice Samuel A. Alito Jr. to the Supreme Court, both of whom have issued important opinions suggesting an interest in the FCA, resulted in the high court’s taking this “unusual case” in the first place. In previous opinions, Roberts and Alito have read the statute narrowly, Brennan said.

“I therefore believe the Supreme Court will narrow the [U.S. Court of Appeals for the Tenth] Circuit’s definition of original source,” Brennan predicted. “The [Ten]th Circuit says you could be an original source if you have information ‘underlying or supporting’ the allegations of fraud. Other circuits require more, e.g., ‘knowledge of the actual false statement to the government.’”

Narrowly Construed. Silverman said it is interesting that Roberts, while a judge on the U.S. Court of Appeals for the District of Columbia Circuit, wrote the opinion in *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004) in which he construed the language under the FCA very narrowly. Silverman said that could be significant for *Rockwell*.

“This may well indicate how Chief Justice Roberts will view the jurisdictional issue in the *Rockwell* International case, and overturn the decision of the Tenth Circuit as one which views the original source rule too broadly, particularly when it comes to defining the jurisdiction of the federal courts under the FCA,” Silverman said.

Brennan pointed out that the District of Columbia Circuit requires that the original source know “the facts” that made the statement false. He suggested that, if the Supreme Court affirms the Tenth Circuit’s decision in *Rockwell*, it would open the door to more qui tam actions that could be considered parasitic; but, if the Supreme Court were to narrow the original source test, it would reduce the universe of potential whistleblowers.

White acknowledged that it was hard to say which way the Court would go in deciding *Rockwell*.

FCA’s ‘Plain Language.’ “The good news for the government and the qui tam bar is that the plain language of the [FCA] supports affirmance of the lower court decision,” White said. “Moreover, with Senator [Charles E.] Grassley [R-Iowa] weighing in with a powerful amicus curiae brief, the Court will be reminded that the overall purpose of original source exception was to shield the Government from parasitic whistleblower suits and not to silence non-parasitic whistleblowers.”

Nevertheless, Kusserow said he believes there will be a tightening of standards for qualifying as a qui tam relator and reduction of the opportunity for those with unclean hands to benefit from the process.

“I believe everyone will look to this case as a signal for the future,” Kusserow said. “The [Department of Justice] has always maintained reservations and concerns about the qui tam provision and would look to the [high] court to limit the scope of such cases.”

The issue in *Rockwell* is one that goes to the very jurisdiction of a federal court to entertain an FCA qui tam action, Silverman said. He noted that jurisdictional issues are deemed very important by courts and case law suggests that courts construe their own jurisdiction very narrowly.

“That fact may help predict how the Supreme Court in *Rockwell* will construe the original source rule under the FCA,” Silverman said. “As such, a strict construction of the text of the FCA that addresses the original source rule is likely to lead the Supreme Court to require something more than the Tenth Circuit believed was necessary for a relator to be the original source when the public disclosure bar is applicable.”

Silverman said the Tenth Circuit construed the original source language in the FCA broadly in *Rockwell*, which likely stands for the most expansive construction of that language among the courts of appeals. The Tenth Circuit ruled that the relator had “direct and independent knowledge” of the fraud, he said.

By contrast, in *United States ex rel. Mistick v. Housing Auth. of the City of Pittsburgh*, 186 F.3d 376 (3d Cir. 1999), the Third Circuit has ruled that for the original source rule to apply, the relator must have knowledge of the most critical elements of the fraud claims, a finding that is similar to the views expressed by the Eleventh Circuit, in *United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla.*, 19 F.3d 562 (11th Cir. 1984), and the Ninth Circuit, in *United States ex rel. Aflatooni v. Kitsap Physicians Service*, 314 F.3d (9th Cir. 2002), Silverman said.

The D.C. Circuit, in *United States ex rel. Springfield Terminal Railway Co.*, 14 F.3d 645 (D.C. Cir. 1994), and the Eighth Circuit, in *United States ex rel. Minnesota Association of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032 (8th Cir. 2002), however, have taken a middle ground position, Silverman said, and

ruled that the relator need not have knowledge of all of the vital ingredients to a fraudulent transaction, but rather have direct and independent knowledge of an essential element underlying the fraud transaction.

BY KENDRA CASEY PLANK AND JUDITH A. THORN