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False Claims Act Cases, Individual Enforcement, 60-Day Rule Anticipated in Coming Year

By James Swann and Eric Topor

The health-care industry can expect to face a wide range of compliance challenges heading into 2016, including an increase in False Claims Act cases and increased enforcement actions against corporate executives.

The new year will also ring in more fraud and abuse regulations from the government, as well as an increase in the government's use of civil monetary penalties.

On the regulatory front, the Department of Health and Human Services Office of Inspector General is scheduled to release revisions to three fraud and abuse rules by spring 2016, and the Centers for Medicare & Medicaid Services will release the final Medicare overpayments return rule, also known as the 60-day rule.

Bloomberg BNA spoke with health-care attorneys, trade association executives and health-care consultants to get a sense of the health-care fraud landscape for 2016 and what providers can do to protect themselves.

Stark and the False Claims Act

When it comes to FCA cases, there was broad agreement that the health-care industry can expect an uptick in the number of cases being filed, especially those alleging a Stark law violation.

Kevin McAnaney, an attorney with the Law Office of Kevin McAnaney in New York, told Bloomberg BNA he expects there will be more FCA cases alleging Stark law violations involving physician or hospital compensation issues.

"The government and relators have taken very aggressive positions regarding what it means to 'take into account' referrals in establishing compensation and the courts have gone along at least for purposes of motion practice," McAnaney said.

The physician self-referral, or Stark, law prohibits physicians from referring Medicare patients to entities with which they or their immediate family members have a financial relationship.

In addition, settlements to date have been large, and McAnaney said, whistle-blower attorneys have taken notice.

"Any rational health system general counsel is having sleepless nights," McAnaney said.

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>
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The Department of Justice recovered $1.9 billion in fiscal year 2015 from health-care related FCA cases, accounting for 54 percent of all DOJ recoveries from FCA cases in FY 2015.

Liability Concerns

Linda Baumann, an attorney with Arent Fox in Washington, said her clients are concerned with potential Stark law liability.

"There have been a number of extremely large Stark-law related settlements recently, but there are few 'bright lines' or other guidance to help providers know how to comply in the face of complex, and often ambiguous, legal requirements," Baumann said.

Baumann said that while new Stark regulations in the 2016 Medicare physician payment rule are helpful, they don't address many of the issues that have arisen in several recent Stark cases.

BNA Snapshot

Top 10 Health-Care Fraud Issues in 2016

According to BNA's Health Care Fraud Report Advisory Board, the following are the top issues to watch in 2016:

1. Increase in False Claims Act cases related to the Stark law and anti-kickback statute.
2. Increased enforcement against corporate executives and management.
3. The release of the 60-day final rule.
4. The release of new regulations revising fraud and abuse laws.
5. Increased civil monetary penalty enforcement.
6. Focus on specialty pharmacy fraud.
7. Aligning alternate payment models with the Stark law and the anti-kickback statute.
8. Use of statistical sampling to support False Claims Act cases.
9. Kickbacks to pharmaceutical and medical device manufacturers.
10. Attention on defective medical devices.

"Clients find it extremely difficult, as a practical matter, to determine what constitutes fair market value, commercially reasonable compensation that doesn't reflect the volume or value of referrals," Baumann said.

There's little published case law on these issues, Baumann said, which has increased the risk for providers and "created a potential gold mine for whistle-blowers and a continuing nightmare for providers who are trying to do the right thing."

Stark Rule Revisions

The Stark rule revisions in the Medicare physician fee schedule included several provisions intended to ease provider compliance, including allowing an arrangement that qualifies for a Stark exception to continue indefinitely after the arrangement's expiration date and allowing for the sharing of office space assuming the arrangement is in writing and is between a hospital and a physician.

Kirk Nahra, an attorney with Wiley Rein in Washington, said he's seen a growing focus on Stark and anti-kickback issues because the rules are complex.

"These rules are affecting normal and unproblematic business transactions because of uncertainty, even where there clearly is no real fraud risk," Nahra said.

Nahra said this is an ongoing problem for the overall health-care system due to the number of overlapping rules and a general sense that the government doesn't always act fairly.

"The fraud folks could take a lesson from some of the privacy enforcement agencies where there is a much better sense of how to address sincere compliance efforts and unimportant errors rather than real compliance problems," Nahra said.

Individual Enforcement

"Another issue sure to crop up in 2016 is the continued push by the federal government to prosecute individuals for health-care fraud, with a focus on looking for individual culpability at the start of an investigation and only granting immunity in exceptional circumstances to culpable individuals as part of as part of a corporate resolution."

In September 2015, for example, Deputy Attorney General Sally Quillian Yates issued a memo encouraging prosecutors to go after individuals, as opposed to the overall corporation, and requiring civil and criminal prosecutors to work together to bring civil and criminal charges.

Arent Fox's Baumann said the health-care industry is concerned about the possibility of more individual enforcement, especially after numerous statements from government officials calling for increased enforcement.

However, she said it's not clear how many individual enforcement actions will proceed in 2016 since individuals have more of an incentive to litigate, especially if they face criminal charges, and the government is always concerned about setting a bad precedent.

Stuart Silverman, an attorney with the District of Columbia Office of the Inspector General, said the Yates memo has already yielded a bump in individual enforcement with the October indictment of the former president of pharmaceutical company Warner Chilcott for alleged payment of kickbacks to physicians to induce sales of the company's drugs.

"DOJ's coordinated efforts regarding this matter lends credence to the policy announced in the Yates memo, with more of such coordinated enforcement on the horizon," Silverman said.

Company, Executives Tension

Wiley Rein's Nahra said the government is likely to continue exerting enforcement pressure on individuals in 2016, which will create tension between companies and their executives.

"I think DOJ will be looking for ways to pursue actions against individuals that are not always criminal—meaningful fines, exclusions, etc, rather than full-out prosecutions."

—Kirk Nahra, Wiley Rein

At the same time, Nahra said the DOJ success rate when individuals are pursued but do not settle is not very good.

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Small businesses may bear the immediate brunt of the government's push to increase individual enforcement, McAnaney said, because prosecutors will find it easier to demonstrate an individual's culpability and knowledge of fraud.

"I think there will be more emphasis on companies as a condition of settlement having to admit to certain facts and conduct and also perhaps cooperate in investigations of individuals," McAnaney said.

This could impact settlements and make it harder for companies to conduct their own investigations due to a lack of cooperation from employees, McAnaney said.

Medicare Overpayments

Providers and suppliers have been waiting three years for the final Medicare 60-day rule, and its release may lead to a flood of provider self-disclosures, attorneys told Bloomberg BNA. The rule requires a provider to return any identified Medicare overpayment to the program within 60 days.

Arent Fox's Baumann said the final rule could prompt many provider self-disclosures if it includes a 10-year look-back period.

"Many clients simply will not have all the records necessary from that time period to be able to fully investigate a compliance issue that is subsequently raised," Baumann said.

In addition, providers may look to self-disclose because they won't have sufficient time to fully investigate and determine whether an overpayment has actually occurred, Baumann said.

The 60-day rule was originally proposed in February 2012 and requires providers to repay an overpayment and "to notify the Secretary, State, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment," all within 60 days of first identifying the overpayment.

Joseph E.B. White, an attorney with Nolan Auerbach & White PA in Philadelphia said he expects the 60-day final rule will drive providers to the OIG self-disclose overpayments.

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The 60-day rule removes any confusion over repaying overpayments and creates a bright-line starting point for FCA liability, White said.

Laurence Freedman, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C, Washington, likewise said the 60-day final rule would likely continue the trend toward provider self-disclosures.

"The final rule will likely impose a six-year look-back period, which will add some clarity," Freedman said. Freedman said the rule's overpayment requirements are driving many of the OIG and CMS self-disclosures, and expects it will continue once the rule is released.

Not all attorneys agreed that the 60-day rule would result in increased provider self-disclosure.

McAnaney said most organizations have already adjusted to the rule, and said its existence tends to make the enforcement community downplay the significance of voluntary disclosures.

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—Laurence Freedman, Mintz Levin

Thomas S. Crane, an attorney with Mintz Levin Cohn Ferris Glovsky and Popeo PC in Boston and Washington, said there's a possibility the 60-day final rule will be anticlimactic.

Additionally, the CMS has softened its stance on many key compliance areas that have triggered self-disclosures based on petty infractions, Crane said, so self-referral disclosure protocol filings will start to level off.

Compliance Programs

Maintaining an effective compliance program will continue to be essential in 2016 if an organization wants to avoid government attention, and that's especially true now due to the DOJ's recent hiring of a compliance counsel expert.

Hui Chen, who was retained by the DOJ's Fraud Section as of Nov. 3, 2015, will be responsible for providing guidance to Fraud Section prosecutors on compliance program issues, such as the existence and effectiveness of a company's program as well as whether the company has done anything to fix compliance errors.

Chen will also help develop compliance program benchmarks that prosecutors can use and help prosecutors evaluate a company's conduct after a fraud settlement has been reached.

"Experienced compliance professionals can easily spot people that are interfering with the compliance program," Roy Snell, chief executive officer of the Health Care Compliance Association, said.

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Good leadership has always seen compliance officers as allies in deterring employees from pushing the boundaries of what's legal, Snell said, and any employees who still insist on skirting the law should take note of Chen's hiring.

The increasing trend of individual health-care fraud prosecutions will further cement the need for an alliance between a company's leadership and the compliance officer, Snell said.

Litigation Outlook

The coming year promises to bring significant litigation rulings for attorneys on all sides of the health-care fraud bar, with issues concerning overpayment, statistical sampling and physician payment issues primed for court action.

The most hotly anticipated case will have the U.S. Supreme Court once again ruling on an FCA issue (as it did in 2015 with its decision in *Kellogg Brown & Root Svcs., Inc. v. United States ex rel. Carter* (2015 BL 163948, U.S., No. 12-1497, 5/26/15) (19 HFRA 465, 6/10/15)), perhaps signaling that the high court is paying attention to the number and size of settlements and judgments that the FCA is producing.

FCA Heads to High Court

The U.S. Supreme Court will decide in 2016 the validity and scope of the "implied false certification" theory of FCA liability after granting review in *Universal Health Servs., Inc. v. United States* (U.S., No. 15-7, *review granted* 12/4/15), which will make or break many current and future whistle-blower lawsuits (19 HFRA 891, 12/9/15).

Under this theory of FCA liability, an entity, like a health-care provider, has implied certification with certain federal rules and regulations by submission of a claim for payment, even if there wasn't an explicit certification made by the entity.

The implied certification theory of FCA liability is subject to a circuit split. A majority of the federal circuits have adopted an implied certification theory of liability in some fashion (including the First Circuit which decided *Universal Health*), though the Fifth Circuit and Seventh Circuit haven't.

The Supreme Court will decide if these types of regulatory violations not directly tied to a specific claim result in FCA liability, which will have resounding implications for health-care providers, whistle-blowers and their respective attorneys.

"If the Court holds that the Act only applies when a condition is explicitly labeled as a 'condition of payment,' a sizeable percentage of False Claims Act cases will be torpedoed."

—Jeb White, Nolan Auerbach & White

"For years, all sides of the False Claims Act bar have wrestled with whether the False Claims Act applies to misconduct that violates Medicare's conditions of participation, as opposed to conditions of payment," White said.

"If the Court holds that the Act only applies when a condition is explicitly labeled as a 'condition of payment,' a sizeable percentage of False Claims Act cases will be torpedoed," he added.

Baumann said a decision in *Amarin Pharma, Inc. v. FDA* (S.D.N.Y., No. 1:15-cv-03588-PAE, *stayed* 10/30/15) could "likely impact" off-label drug marketing enforcement in 2016.

Plaintiffs Amarin Pharma and a group of physicians sued the FDA in May 2015 and alleged that FDA regulations prohibiting truthful statements about the drug Vascepa that pertained to off-label use violated the First Amendment.

The U.S. District Court for the Southern District of New York granted Amarin preliminary relief on Aug. 7, 2015, ruling that Amarin could make truthful and nonmisleading statements about Vascepa treatments that weren't FDA-approved for the time being because it was likely to succeed on the merits.

Litigation in *Amarin* has been stayed since Aug. 31, 2015, so the parties could discuss a possible settlement.

Baumann said that off-label marketing enforcement appears to have already decreased since the U.S. Court of Appeals ruled in favor of pharmaceutical company sales representative Alfred Caronia in 2012, holding that the government couldn't criminalize truthful statements about off-label drug use in *United States v. Caronia* (2012 BL 316528 (2d Cir. 2012)) (16 HFRA 974, 12/12/12).

A decision in *Amarin* for the plaintiffs "could lead to even fewer cases in this area," Baumann said.

60-Day Rule Litigation

Providers in 2016 will be grappling with when the 60-day overpayment rule is triggered. But what exactly constitutes an "identified overpayment" isn't precisely defined and is currently being litigated in New York federal court.

Baumann said the case in the Southern District of New York (*United States ex rel. Kane v. Healthfirst, Inc.* (2015 BL 249012, S.D.N.Y., No. 1:11-cv-02325-ER, 8/3/15) has signaled that identification occurs "very early in the process."

"Many clients are extremely concerned that such an interpretation doesn't give them sufficient time to fully investigate the matter," Baumann said.

The case was originally brought by a qui tam relator who alleged that Healthfirst had 900 potential Medicaid overpayments that resulted from a billing software error from 2009 to 2010.

The *Healthfirst* court held that the 60-day repayment rule was triggered in that instance when the providers generally knew there was an obligation to repay, even though the exact amount to be repaid wasn't determined. The government intervened in 2014, alleging that Healthfirst was in violation of the 60-day rule.

Baumann said clients are also concerned about whether returning an overpayment will fully protect them from exposure to a qui tam complaint.

"There have been disturbing reports that providers who have self-disclosed certain matters subsequently face FCA liability and/or are not given much, if any, credit when previously filed FCA cases are settled," Baumann said.

Silverman predicted the 60-day overpayment rule would be "fertile ground" for relators bringing FCA actions in 2016 and beyond, especially after the government's defeat of a motion to dismiss from defendant providers' in *Healthfirst*.

Silverman said the *Healthfirst* court's ruling on when an overpayment was "identified" for purposes of the 60-day rule "will likely result in more qui tam lawsuits."

However, Silverman also noted that "these overpayment cases will be heavily fact-specific," as was the case in *Healthfirst*, which included allegations that one defendant waited months before investigating a billing error and immediately terminated the employee-turned-whistle-blower after he identified hundreds of alleged overpayments.

Future courts examining when an overpayment is identified "will look to whether there is indicia of an effort by the provider to conceal, or avoid, the legal duty to refund overpayments."

—Stuart I. Silverman, D.C. Office of Inspector General

The court in *Healthfirst* said a violation of the 60-day rule didn't transform into an FCA violation unless a provider "knowingly" avoided repayment, but Silverman cautioned that "providers are now put on notice that it is best to be vigilant in responding to reports of possible overpayments, even in the absence, at least initially, of a definitive determination of total overpayments."

Silverman said future courts examining when an overpayment is identified "will look to whether there is indicia of an effort by the provider to conceal, or avoid, the legal duty to refund overpayments."

Statistical Sampling

Another topic, the use of statistical sampling in determining liability in FCA cases, was a hot topic for health-care fraud attorneys in 2015, and will continue to generate discussion in 2016, according to Silverman.

Several federal district court cases involving the use of statistical sampling brought the issue to the attention of health-care practitioners and providers alike, and a potential federal circuit court ruling on the issue looms in 2016.

The use of statistical sampling as a means to prove false claims liability gained nationwide notoriety when the government defeated a motion for partial summary judgment on the issue from nursing home provider Life Care Centers in September 2014 (18 HFRA 860, 10/15/14).

Momentum built further with two other federal district courts sanctioning the use of statistical sampling in as evidence of FCA liability with rulings in *United States v. Robinson* (2015 BL 92121, E.D. Ky., No. 3:13-cv-00027-GFVT-EBA, 3/31/15), and *United States ex rel. Ruckh v. Genoa Healthcare, LLC* (2015 BL 122821, M.D. Fla., No. 8:11-cv-01303-SDM-TBM, 4/28/15).

Litigation in *Robinson* concluded with a jury finding a physician and his employer guilty of false claims submissions (and joint liability of over $1.2 million), while litigation in *Ruckh* is ongoing.

However, a more definitive answer in the acceptable scope of statistical sampling use for FCA liability purposes could be pending at the Fourth Circuit in *United States ex rel. Michaels v. Agape Senior Cmty., Inc.* (4th Cir., No. 5-2147, *filed* 9/29/15).

The whistle-blowers and defendant Agape Senior Community Inc. settled allegations that false claims were submitted for hospice and general inpatient care to Medicare, Medicaid and TRICARE for $2.5 million, but the government objected to the settlement amount as too low.

The *Michaels* case involved over 50,000 claims, and the government, which didn't intervene in the case, said potential liability for Agape was roughly $25 million.

The district court in the *Michaels* litigation rejected the use of statistical sampling, but said the government had the authority to object to FCA settlements even in nonintervened cases. However, the court certified both issues for interlocutory appeal at the Fourth Circuit for a more definitive answer.

Silverman said that "[a] ruling from the Fourth Circuit favoring the government's reliance on statistical sampling will be a significant outcome in support of False Claims Act cases, both for the government and the relator's bar, and will alter the legal landscape for defendants in a negative way."

"For the defense bar, statistical sampling takes away an important defense that allows defendants to challenge the evidence," Silverman said.

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Mintz Levin's Freedman also said statistical sampling is likely to grow in 2016.

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Freedman said the Fourth Circuit's ruling in *Michaels* will influence whistleblower and government efforts to take shortcuts during trials involving large numbers of individual patient records and claims.

Pharma an FCA Target

As the year opens, there is a spate of pending litigation involving pharmaceutical companies accused by FCA whistle-blowers of paying kickbacks to physicians and engaging in illegal off-label marketing to increase drug prescriptions, and resulting in false claim submissions to Medicare and Medicaid.

Kirk Ogrosky, an attorney with Arnold & Porter, said he was paying particular attention to this subset of FCA litigation.

Drugmaker Cephalon Inc. is currently litigating two FCA actions that attorneys representing pharmaceutical companies will be watching closely in 2016. The first is a reverse FCA action in which whistle-blowers claim that an alleged violation of a corporate integrity agreement by Cephalon triggered an affirmative obligation to pay fines specified in the CIA.

The whistle-blowers said Cephalon (acquired by Teva Pharmaceuticals in 2011) hid its illegal promotional activities from the government to avoid paying the fines specified in the CIA (*United States ex rel. Boise v. Cephalon, Inc.*, 2015 BL 232385, E.D. Pa., No. 2:08-cv-00287-TON, *motion to dismiss denied* 7/21/15).

The U.S. District Court for the Eastern District of Pennsylvania refused to dismiss the lawsuit, holding that the CIA fines were an "established duty," and could support a reverse false claim action.

The parties are currently litigating a motion to modify the court's July 30 order denying a motion to dismiss claim related only to the drug Provigil based on a prior filed lawsuit (19 HFRA 609, 8/5/15).

Cephalon is also facing allegations from a former employee that it used flawed clinical studies to push misleading claims of the effectiveness of Treanda as a "front-line" treatment for indolent non-Hodgkin lymphoma, and paid physician's kickbacks to induce off-label Treanda prescriptions.

The U.S. District Court for the Eastern District of Pennsylvania denied Cephalon's motion to dismiss the lawsuit on June 3, citing Cephalon's own sales documents purporting to show a return on investments in Treanda sales from physicians alleged to have received kickbacks (*United States ex rel. Cestra v. Cephalon, Inc.*, 2015 BL 174720, E.D. Pa., No. 2:14-cv-01842-TON, *motion to dismiss denied* 6/3/15) (19 HFRA 497, 6/24/15). Judge Thomas N. O'Neill Jr. is presiding over both Celphalon cases.

On July 6, 2015, an FCA action against Biogen Idec Inc. was unsealed in the U.S. District Court for the District of Massachusetts alleging that Biogen paid physicians kickbacks to induce prescriptions of two multiple sclerosis drugs, Avonex and Tysabri.

A former Biogen director of regional marketing filed the whistle-blower lawsuit alleging that Biogen paid high-prescribing physicians millions in consulting and speaking fees to induce continued prescriptions of the drugs, and to persuade other physicians to prescribe Biogen drugs over competing drugs (*United States ex rel. Bawduniak v. Biogen Idec Inc.*, D. Mass., No. 12-cv-10601-IT, *unsealed* 7/6/15).

The Biogen case was unsealed after the federal government declined to intervene, and is in the preliminary stages of litigation.

Drugmaker Allergan is also facing charges of paying physicians kickbacks to induce drug prescriptions, in this case allegedly masking the kickbacks as speaking fees, trips that included stipends and offers to fund research.

The U.S. District Court for the Eastern District of Pennsylvania partially denied Allergan's motion to dismiss the action May 26, 2015, holding that the allegations that the kickbacks cause false claim submissions by pharmacists of kickback-tainted prescriptions for Allegan drugs, satisfied FCA pleading standards for the Third Circuit (*United States ex rel. Nevyas v. Allergan, Inc.*, E.D. Pa., No. 09-cv-432, *motion to stay*, 12/11/15)(19 HFRA 468, 6/10/15).

The presiding judge ordered the parties to hold settlement talks in February 2016, but Allergan recently filed a motion to stay the litigation pending the Supreme Court's decision in *Universal Health Services*, expected by June 2016.

Allergan argued in its motion to stay that the Supreme Court's decision on the validity of the implied certification theory of liability in FCA actions could "necessitate a complete dismissal or significant narrowing" of the whistle-blower's claims.

Physician Kickbacks

Celgene Corp. is litigating allegations of paying physicians kickbacks as well, in addition to illegal off-label drug promotion, for purposes of inducing off-label prescriptions for cancer drugs.

A former Celgene sales representative filed the FCA action, in which the government declined to intervene, and said the two schemes resulted in false claims to the Medicare and Medicaid programs (*United States ex rel. Brown v. Celgene Corp.*, C.D. Cal., No. 10-cv-03165-GHK-SS, *complaint unsealed* 2/5/14)(18 HFRA 148, 2/19/14).

The U.S. District Court for the Central District of California denied motions to dismiss and for partial judgment on the pleadings in 2014 in *Celgene*, and the parties were ordered to pursue mediation—unsuccessfully so as of a Nov. 23, 2015, status report.

The court scheduled motions for summary judgment to be filed by April 16, 2016.

Finally, Novartis is still facing a whistle-blower lawsuit alleging it paid physicians sham speaker fees as kickbacks to increase drug sales (*United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 2014 BL 271436, S.D.N.Y., No. 1:11-cv-00071-PGG, *motion to dismiss denied* 9/30/14).

The U.S. District Court for the Southern District of New York ruled in September 2014 that the allegations satisfied FCA pleading standards in an order denying Novartis's motion to dismiss, and the parties are currently engaged in factual discovery scheduled to end in July 2016 (18 HFRA 858, 10/15/14).

Hospitals and Stark, Post-Tuomey

Both Crane and McAnaney predicted more FCA cases against hospitals would crop up in 2016 with allegations that physician compensation arrangements violated the Stark law.

Crane said this type of litigation would be a focus in 2016 in light of the litigation between Tuomey Healthcare System and the federal government. The Tuomey litigation, in which a hospital was alleged to have paid physicians with above market compensation packages in order to induce referrals, settled in October 2015 for $72.4 million (after being held liable for a $237 million judgment) (19 HFRA 795, 10/28/15).

McAnaney echoed Crane's assessment, and said "the government and relators have taken very aggressive positions regarding what it means to 'take into account' referrals" for purposes of the Stark law, and "the courts have gone along at least for purposes of motion practice."

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McAnaney added that "settlements have been enormous and the relators' bar has taken notice."

Both Crane and McAnaney also cited factual admissions in FCA settlements as a big issue to watch in 2016. Extensive factual admissions were included in a $390 million settlement paid by Novartis Pharmaceuticals in November 2015 in which Novartis admitted to using valuable referrals of its drug Exjade to incentivise speciality pharmacies to increase refill rates (19 HFRA 860, 11/25/15).

Additionally, Crane and McAnaney said health-care practitioners should pay attention to the scope of release provided to corporate managers and officers in FCA settlements with the government. McAnaney said a push for concessions in either of these areas from the government "will make settlements more difficult to achieve."

There currently are several ongoing FCA cases alleging Stark law violations against health-care providers for improper physician compensation arrangements.

In *United States ex rel. Jacobs v. CDS, PA* (D. Idaho, No. 14-cv-00301-BLW, *filed*, 7/24/14), a physician whistle-blower is alleging that a clinic located in a hospital center illegally shifted physician recruiting expenses to the hospital in order to induce referrals to the hospital, in violation of the Stark law. The whistle-blower filed a second amended complaint on Nov. 20, after the court partially dismissed an earlier complaint on Sept. 28.

Health First Inc., a health system in Florida, is facing allegations it paid kickbacks (in the form of facility ownership investments, medical directorships, billing perks from Health First's in-house insurance plan and eventual purchase of the physician group above market value) to a physician group in order to induce referrals of government-insured patients to Health First hospitals (*United States ex rel. Doe v. Health First, Inc.*, M.D. Fla., No. 14-cv-00501-RBD-DAB, *filed* 3/27/14).

Health First has a pending motion to dismiss the FCA and Stark allegations.

Another Florida health system, BayCare Health System, is currently in litigation involving allegations that it used real estate concessions to physicians in the form of a parking easement and lease discounts worth millions to induce Medicare referrals to its hospital (*United States ex rel. Bingham v. BayCare Health Sys.*, M.D. Fla., No. 8:14-cv-00073-SDM-JSS, *motion to dismiss denied* 8/14/15).

The U.S. District Court for the Middle District of Florida denied BayCare's motion to dismiss Aug. 14, and the parties are currently in discovery (19 HFRA 694, 9/16/15).

FTC Investigations

Silverman also said that health-care fraud enforcement actions beyond FCA prosecutions and criminal health-care fraud statutes will continue in 2016, and cited a Federal Trade Commission action against misleading health-care "discount" cards as one example.

The FTC was successful in getting a temporary restraining order, and later a permanent ban, against two individuals from selling discount cards falsely marketed as comprehensive ACA medical insurance plans in *FTC v. Partners In Health Care Association, Inc.* (S.D. Fla., No. 1:14-cv-23109-RNS, *restraining order* 8/25/15).

Silverman said there would be further enforcement actions from the FTC and states attorneys against "those who perpetrate fraud schemes for the sale of health insurance to unsuspecting consumers, under the guise that these bogus insurance products offer bona-fide health insurance coverage."

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