Outlook 2015: Uptick Expected in Stark, Anti-Kickback FCA Cases, Self-Disclosures

Health-care providers and suppliers will have a full plate of compliance challenges facing them in 2015, including provider self-disclosures, an uptick in False Claims Act cases, an increase in the use of enforcement penalties such as payment suspensions and the continued implementation of Affordable Care Act programs.

Providers and suppliers also can expect more pressure to self-disclose Stark and anti-kickback violations to the Centers for Medicare & Medicaid Services and the Department of Health and Human Services Office of Inspector General, respectively, and increased fraud is likely in both the Medicare Part D program as well as within Medicare Advantage and Medicaid managed care.

In the legal arena, practitioners see an increase in false claims cases, even where the government declines to intervene. A key case has reached the U.S. Supreme Court that will have ramifications for the health-care industry even though the case, itself, concerns defense contractors.

The rise in for-profit hospice care facilities could lead to increased government attention to guard against operators falsifying patient records to gain maximum reimbursement and to care for patients who may not qualify for hospice-type care.

Bloomberg BNA spoke with health-care attorneys, trade association executives and health-care consultants to get a sense of the fraud landscape entering 2015 and what providers can do to protect themselves.

Self-Disclosures

Providers increasingly are self-disclosing potential Stark and anti-kickback violations to both the CMS and the OIG, respectively, and that trend likely will continue in 2015.

The CMS self-referral disclosure protocol (SRDP), which was authorized by Section 6409 of the Affordable Care Act, provides an avenue for disclosing potential or actual violations of the Stark law, which prohibits physician referrals of Medicare and Medicaid patients to entities with which physicians or their immediate family members have a financial relationship.

The OIG self-disclosure protocol, on the other hand, covers potential violations of the anti-kickback statute.

60-Day Rule. The CMS’s 60-day repayment rule will likely be the biggest driver for self-disclosures in 2015, Thomas S. Crane, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo in Boston, told Bloomberg BNA.

The CMS published a proposed rule in February 2012 that would require all Medicare providers to report and return any Medicare overpayments within 60 days of identifying them, although it has yet to finalize the rule.

Crane said the CMS has made it clear that the 60-day rule is self-implementing and is already a reality even without a published final rule.
“Nevertheless, there are some important clarifications a final rule would make, for example, a definition of ‘identified’ and the length of the look-back period, especially under reopening rules,” Crane said.

“In light of increasing government enforcement efforts, fewer providers are willing to simply fix potential issues going forward, while not addressing prior problems in hopes they won’t be noticed.”

—LINDA BAUMANN, ARENT FOX

Any clarifications that come with a final rule could make compliance more difficult for providers.

“We may find ourselves better off without definitions we might dislike and arguing legal points on a case-by-case basis,” Crane said.

The language in the final rule could have repercussions for providers, Brian Roark, an attorney with Bass Berry & Sims in Nashville, Tenn., said.

“The proposed rule included several provisions that would be extraordinarily difficult to administer, including a 10-year look-back period, so it will be important to see how the final rule comes down on these issues,” Roark said.

Kevin G. McAnaney, an attorney with the Law Offices of Kevin G. McAnaney, Washington, also agreed that the 60-day rule has become an industry standard despite the lack of a final rule, which he said explains the growth in providers using the CMS self-referral disclosure protocol.

McAnaney said he expected there would be pressure for an additional self-disclosure mechanism covering coding or billing violations if the final 60-day rule includes a six-year look-back period.

“At some point, CMS will move towards a penalty type solution to move the docket on the technical violations,” McAnaney said.

However, he didn’t see much interest in using the OIG’s self-disclosure protocol. “No one wants to admit criminal conduct, and there are not the same clear cut violations as with Stark,” he said.

Linda Baumann, an attorney with Arent Fox in Washington, said the 60-day rule is likely to result in increasing use of both the CMS and OIG self-disclosures.

While many payment problems can be corrected without using the self-disclosure protocol, Baumann said that payment problems that occurred over a year before being identified can pose significant risks to providers and necessitate self-disclosures.

“In light of increasing government enforcement efforts, fewer providers are willing to simply fix potential issues going forward, while not addressing prior problems in hopes they won’t be noticed,” Baumann said.

She said the OIG self-disclosure process has been used more often by providers, which she said will continue “unless CMS takes steps to expedite its process and provides additional clarification on the benefits of using the Self-Referral Disclosure Protocol, i.e., indicating the level of penalties likely to be imposed, at least in certain types of cases.”

Beyond concerns over the 60-day rule, Crane said self-disclosures are growing due to an increase in health-care mergers and consolidations.

“In a high number of mergers and consolidations, due diligence has turned up disclosable financial arrangements that need to be cleaned-up and in many cases self-disclosed,” Crane said.

As a result, the CMS has been inundated with Stark law self-disclosures, he said, and the OIG has “has worked hard over the years to make its SDP [self-disclosure protocol] a user-friendly, fair and timely process.”

**Self-Disclosure Problems.** While interest in Stark self-disclosures is increasing, the process is not without problems, including a lengthy backlog of provider disclosures as well as heavy enforcement burdens on providers, attorneys said.

For example, Kirk Ogrosky, an attorney with Arnold & Porter in Washington, said providers can expect a “backlog will continue to grow at CMS and providers will continue to pour in with new disclosures.”

Roy Snell, chief executive officer of the Health Care Compliance Association, also agreed that the CMS SRDP has a backlog problem.

“Normally, people who see a long line head the other way but in this case this backlog could attract more disclosures,” Snell said.

Providers could be entering into the CMS SRDP in anticipation that the CMS will offer “good deals” to alleviate the backlog, he said.

“They could get more people to work on the backlog,” he added, “but for a number of reasons, I don’t think that will happen or work.”

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—RICHARD KUSSEROW, STRATEGIC MANAGEMENT SERVICES

Richard Kusserow, chief executive officer of Strategic Management Services, Alexandria, Va., and a former HHS Inspector General during the Reagan administration, said the self-disclosure process “has become so punitive that it may no longer serve its purpose as well as it could.”

Kusserow said the updated OIG self-disclosure protocol requires providers to deliver a sample of at least 100 claims that can be used to reach an estimate of any damages owed. This will result in medical reviewers using small sample sizes to determine damages and will end up hurting providers, he said.

“It’s one thing to go with 100 claims and pay back extrapolated overpayments when it is the provider’s choice,” Kusserow said. “It’s another if it’s done by the OIG or other medical reviewers emulating the OIG.”
Program Integrity Contractors

The Recovery Audit Contractor (RAC) program is in a state of flux, with new contracts yet to be awarded, and the potential exists in 2015 for a RAC reform bill.

For example, a draft bill introduced in November 2014, the Hospital Improvements for Payment Act, would make numerous changes to the RAC program, including reducing the current audit look-back period from four years to three years and establishing a website to monitor RAC performance.

The American Hospital Association has also proposed several RAC reforms such as imposing penalties on RACs that have inaccurate audit findings and allowing providers to collect interest when they win an appeal of a RAC claims denial.

Mintz Levin’s Crane said the likelihood of any RAC reform legislation in 2015 “will depend on whether there is a fraud bill that seems to be able to be passed by both houses that is suitable for the president to sign.”

If such a bill is possible, Crane said, it will include RAC reforms. However, he said, it’s doubtful that a stand-alone RAC reform bill will succeed in 2015.

RACs, and other Medicare and Medicaid program integrity contractors, have largely struggled due to a lack of attention from Congress, Kirk Nahra, an attorney with Wiley Rein in Washington, said.

“All of these audit and anti-fraud contractors are simply a revolving door to this point: None of them has worked particularly well, on the whole,” he said.

Compounding their problems is that “Congress and the agencies don’t really give them enough time to work out before they change to a different program,” Nahra said, and he said expects program integrity contractors to struggle in 2015.

However, Snell of HCCA said the very structure of the RAC program may hinder the success of any reform bills introduced in 2015.

“If they change the way RAC’s are paid, no amount of change will ever solve the material problem,” Snell said.

Joseph E. B. “Jeb” White, a partner with Nolan Auerbach & White PA, Philadelphia, said the Republican-controlled Congress is unlikely to take up any revisions to the RAC program.

“While some in the business community view Republicans as susceptible to anti-RAC efforts, the reality is that all members of Congress, regardless of party affiliation, view themselves as warriors against health-care fraud,” White said.

“Unless they change the way RAC’s are paid, no amount of change will ever solve the material problem.”

—ROY SNELL, HCCA

According to Snell, “Consultants [RACs] are being paid based on how much they reduce revenue and the consultants accusations of overbilling are staggeringly inaccurate.”

Open Payments Program

The new year will bring a full year of Open Payments data to the public, and with it, associated risks to providers and drug and device manufacturers.

The CMS released the first round of Open Payments data in September 2014, and payment data for all of 2014 is scheduled to be released in June 2015.

While the September 2014 release only covered payment data from the last five months of 2013, it contained 4.4 million payments totalling roughly $3.5 billion, covering financial transactions between drug and device manufacturers and physicians and teaching hospitals.

One potential danger stemming from the Open Payments program is an increase in False Claims Act qui tam lawsuits. Arnold & Porter’s Ogrosky said he’s already “seeing clever relator’s counsel making use of CMS’[s] open data and Sunshine data.”

Wiley Rein’s Nahra said he “would absolutely expect this program to lead to new lawsuits—it’s going to be an appealing area for enterprising and creative whistle-blowers (and their attorneys).”

However, Nahra said many of the lawsuits won’t be successful, and the Open Payments program would ultimately serve as a source for leads for whistle-blowers.

Arent Fox’s Baumann echoed Nahra and said it’s only a matter of time before whistle-blowers start filing lawsuits based on information from the Open Payments program.

“There may be some start up time while relators and their counsel develop strategies for working with the data, but once they establish a system, numerous qui tam cases could be filed,” Baumann said.

To protect themselves from potential lawsuits, providers and hospitals should make sure that all payment documentation is reasonable, accurate and based on fair market value, Baumann said.

Bass Berry’s Roark said providers need to prepare for a pick-up in qui tam activity.

“CMS’s release of reimbursement data in the Carrier Standard Analytic File and the Open Payments program could increase the filing of new qui tam cases and make the cases that are filed more difficult to dismiss,” Roark said.

Specifically, Roark said the data could lead qui tam relators to investigate providers who are billing a disproportionate amount of procedures, or be used as supporting evidence in situations where qui tam relators have been suspicious of provider billing patterns.

“Providers should closely review the data for accuracy,” Roark said, referring to the Open Payments database. “Providers who are outliers or whose data stand out should be prepared to address any inquiries about the data,” he said.
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—BRIAN ROARK, BASS BERRY & SIMS

While there may not be more qui tam lawsuits as a result of the Open Payments program, McAnaney said, the initiative will definitely “generate a lot of heartburn.”

“All hospitals should be running their medical staff through the list and learning what they don’t know,” McAnaney said. “I suspect there will be a lot of questions involving compliance with conflict of interest policies.”

Teaching hospitals can take several steps to protect themselves from any negative impacts of the Open Payments program, James G. Sheehan, chief integrity officer and executive deputy commissioner for the New York City Human Resources Administration, said.

“Teaching hospitals need to be more aggressive in enforcing their disclosure requirements for faculty and board members, and use existing third party testing techniques for conflict of interest reporting,” Sheehan said.

Qui Tam Hurdles

Stuart I. Silverman, an attorney with the District of Columbia Office of Inspector General’s Medicaid Fraud Control Unit, said that while the Open Payments database is a potential source of information for qui tam lawsuits, it also poses hurdles to those very same lawsuits.

“There are issues that arise in terms of whether a relator can, in the first instance, overcome the public disclosure bar under the False Claims Act when alleging kickback schemes that are uncovered as a result of information reported pursuant to the Sunshine Act, and then made publicly available,” Silverman said.

“The gainsharing proposal, if sufficiently flexible, could substantially increase hospital physician alignment initiatives.”

—KEVIN MCANANEY, LAW OFFICES OF KEVIN G. MCDONALD

The American Hospital Association also said the proposed rule lacks clear regulatory language and could penalize providers who standardize their medical equipment or follow hospital medical protocols.

McAnaney said the proposed anti-kickback safe harbors were insignificant, but he said the gainsharing safe harbors could have a major impact, depending on how the final regulations turn out.

“The gainsharing proposal, if sufficiently flexible, could substantially increase hospital physician alignment initiatives,” he said.

Crane, on the other hand, said the safe harbors were relatively narrow and would have little impact.

“The gainsharing CMPL [civil monetary penalty law] request for comments has been widely viewed as a disappointment that shows little evolution in their thinking,” Crane said.

At best, he added, hospitals can use the data to identify if any of their physicians aren’t reporting outside income on their conflict of interest forms.
Wiley Rein’s Nahra agreed the safe harbors would have little impact on the health-care industry.

“I think the safe harbors are simply trying to fine-tune what the rules are to protect certain limited areas where the government sees enough benefit,” he said.

Public-Private Partnership

The Healthcare Fraud Prevention Partnership (HFPP), which was launched in July 2012, is designed to share information and best practices between the private sector and the government regarding health-care anti-fraud initiatives.

In 2015, it should continue to generate positive results for the government and private sector, Louis Saccoccio, chief executive officer of the National Healthcare Anti-Fraud Association, said.

The HFPP represents close to 40 members, and “several studies have been conducted using both private payer and Medicare data and have shown positive results for the participants,” Saccoccio said.

Participants in the HFPP have resolved legal issues surrounding the Paperwork Reduction Act, such as sharing sensitive medical data; however, questions remain as to how the HFPP will maintain its financial viability, Saccoccio said.

Saccoccio highlighted several fraud trends focused on the health insurance marketplaces that may crop up in 2015, including:

- identity theft through false marketing and tax credit and refund fraud;
- fraudulent insurance policy schemes; and
- enrollment fraud.

Health insurance marketplaces, both at the federal and state level, might also become targets for hackers, Saccoccio said.

Health-Care Legislative Update

Several fraud-focused bills are awaiting action in Congress, including legislation that would strip Social Security numbers from Medicare beneficiary cards as well as require the HHS to consider moving from a paper Medicare card to smartcard-based format.

The Protecting the Integrity of Medicare Act of 2014 (H.R. 5780) was introduced in December 2014 by Reps. Kevin Brady (R-Texas) and Jim McDermott (D-Wash.), the chairman and ranking member, respectively, of the House Ways and Means Subcommittee on Health, and was referred to the two separate committees.

The proposed bill would also:

- allow physician assistants, practitioners or specialists to document a face-to-face encounter before prescribing durable medical equipment, instead of just physicians;
- require Medicare administrative contractors (MACs) to establish outreach and education programs for providers focused on reducing improper payments; and
- increase the terms of MAC contracts from five to 10 years.

Another bill, the Stop Schemes and Crimes Against Medicare and Seniors (Stop SCAMS) Act (S. 2361) was introduced in May 2014 and was referred to the Senate Finance Committee.

The bill, sponsored by Sen. Bill Nelson (D-Fla.), would let private insurers share information about potentially fraudulent providers with Medicare, as well as require Medicare to check if any providers or suppliers enrolling in Medicare previously owned companies that have defrauded the government.

A companion bill (H.R. 5732) was introduced in the House in November 2014 by Rep. Theodore Deutch (D-Fla.) and cosponsored by Rep. Peter Roskam (R-Ill.). It’s fate in the new Congress is uncertain.

Legal Issues in 2015

The steady increase of FCA actions, settlements and judgments in recent years continues to be a top focus for health-care fraud practitioners, and many practitioners Bloomberg BNA spoke to predicted more of the same in 2015.

Sheehan also said FCA cases in which the government has chosen not to intervene is an area of litigation to watch for in 2015, adding that the FCA relator bar has become “much more aggressive at pursuing declined cases.”

McAnaney echoed Sheehan’s thoughts, stating that he thought more declined cases will be litigated “and may create interesting law.”

McAnaney also said the new Republican majority in both houses of Congress “may present some opportunities to address some of the more perverse aspects of the Stark law.”

Wiley Rein’s Nahra predicted an increase in health-care fraud cases centered on electronic health records (EHRs) in 2015, perhaps involving “problematic components of the records” and “alleged connections[s] to overbilling.”

Nahra also said there may be an increase in kickback cases involving EHRs and expected an overlap between health-care fraud and HIPAA investigations “involving marketing and sale of data.”

Laurence J. Freedman of Mitz Levin pointed to physician compensation arrangements as a focus of 2015 FCA actions.

 “[The] DOJ’s successes in litigation and settlement of FCA allegations against hospitals for alleged Stark [law] violations will embolden [the] DOJ, and relators, to file actions against hospitals for their physician compensation arrangements,” he said.

Freedman’s prediction is already being borne out in United States ex rel. Schaengold v. Mem’l Health, Inc. (2014 BL 343436, S.D. Ga., No. 4:11-cv-00058-BAE-GRS, 12/8/14), which will see litigation on Stark law and decisions surrounding physician compensation at a hospital this year.

The court in Memorial Health denied the defendant hospital’s motion to dismiss a reverse FCA count Dec. 8, 2014, on allegations that the whistle-blower—the hospital’s former chief executive officer—advised the hospital’s board of directors of possible Stark law violations from physician compensation arrangements (see related article in the Court Proceedings section).

The government asserted the reverse FCA claim when it intervened in Memorial Health, providing some indication that the government remains focused on this issue.
Life Care Centers Closely Watched

Freedman said the decision in United States ex rel. Martin v. Life Care Ctrs. of Am., Inc. (2014 BL 276533, E.D. Tenn., No. 1:08-cv-00251, 9/29/14), “will increase [the] DOJ’s confidence in its ability to litigate large, complex cases, and if necessary, bring them to trial” (18 HFRA 880, 10/15/14).

The Life Care Centers court denied a motion for partial summary judgment from the defendant to bar the use of statistical sampling evidence from a portion of overall claims at issue as evidence of false claims among a much larger universe of claims in the defendant’s nationwide chain of nursing facilities. The parties in Life Care Centers are in discovery.

Nolan Auerbach’s White applauded the Life Care Centers decision because it “allows the government and relators to focus on proving the underlying fraud scheme without being sidetracked with ancillary issues” such as damage calculations for individual claims.

Ogrosky, with Arnold & Porter, said the Life Care Centers decision “has a potential[ly] huge impact.

However, he said there was a possibility that the DOJ’s “aggressive position” that was accepted in Life Care Centers “has the potential to backfire when providers have the ability” to use statistical sampling of claims in defending FCA actions.

The government’s theory of statistical sampling evidence presented in Life Care Centers is strongly supported by the DOJ and relators’ bar, according to Crane with Mintz Levin, but he added that the theory still “has a long way to go.”

Crane said he expects “to see many more cases where statistical sampling is part of the damages calculation, and obvious pushback from the defense bar.”

Kusserow said statistical sampling and extrapolation evidence in FCA cases might be necessary in some instances where it’s “cost prohibitive” for the government to have to assess each claim for damages.

Kusserow also said that the Life Care Centers decision “may change focus on arrangements or anti-kickback violations where no such claim by claim review would be needed.”

Logistical concerns of proving individual claims was cited by Bass Berry’s Roark as a potential argument that relators and the government would make following the Life Care Centers ruling, which “relieves the government of its evidentiary burden to establish the elements of an FCA claim on a patient-by-patient basis.”

Roark said FCA plaintiffs would ask courts to allow sampling in future cases because proving individual claims were fraudulent would be “too difficult.”

Additionally, Roark said the Life Care Centers decision “is likely to drive up the perceived settlement value of some FCA cases.”

He said defendants might be wary of challenging sampling through cross-examination and competing expert testimony because of the cost involved in discovery and the risk to defendants of adverse judgments.

Reverse FCA Claims Loom Large

Health-care attorneys are also closely following ongoing litigation over the enforcement of the ACA’s 60-day overpayment rule in United States ex rel. Kane v. HealthFirst, Inc. (S.D.N.Y., No. 11-cv-02325-ER, intervenor complaint filed 6/27/14).

The government intervened in the HealthFirst FCA action against several New York hospitals and managed care organization Healthfirst Inc. alleging that the defendants’ failure to repay Medicaid overpayments under the 60-day rule requirement constituted a reverse false claim violation (18 HFRA 641, 7/23/14).

Silverman, of the District’s OIG Medicaid Fraud Control Unit, said HealthFirst was “a significant case to watch” as the first government-intervened reverse FCA case brought under the ACA amendments to the FCA. The case, he said, reveals “an aggressive stance by the government for the ‘reverse false claims’ provision.”

Roark said HealthFirst could “shed light on the scope of FCA liability for retained overpayments,” specifically what constitutes an “identified” overpayment triggering the 60-day repayment period.

The parties in HealthFirst are trading briefs over the defendants’ motion to dismiss the action filed Sept. 22, 2014.

Tuomey Back on Appeal

The Tuomey litigation roller coaster continues to plow the rails of federal courts and is on appeal at the U.S. Court of Appeals for the Fourth Circuit (United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 4th Cir., No. 13-2219, oral argument, 10/31/14).

Arent Fox’s Baumann said she was watching for its ultimate resolution as “one of the few Stark-based FCA cases that actually went to trial.”

Tuomey Healthcare System Inc. was found guilty of Stark and FCA violations by a jury for a second time in May 2013 due to its compensation arrangements with certain physicians and is facing a $237 million judgment (17 HFRA 924, 10/16/13). The Fourth Circuit heard oral arguments from the parties on Oct. 31, 2014.

FCA Issues at U.S. Supreme Court

The U.S. Supreme Court is expected to rule on several FCA issues in Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter (U.S., No. 12-1497, certiorari granted, 7/1/14) (KBR), which concerns the FCA’s first to file bar and the tolling period for the FCA’s six-year statute of limitations (18 HFRA 584, 7/9/14).

The FCA action at issue concerns defense contracting rather than a health-care fraud allegation, but White said the court’s ruling “could greatly discourage—or encourage—future qui tam relators.” Oral argument in the case is set for Jan. 13.

Specifically, the court is being asked to rule on whether the Wartime Suspension of Limitations Act (WSLA) tolls the FCA’s statute of limitations for claims brought by private relators and is triggered without a formal declaration of war.

The court will also rule on whether the FCA’s first-to-file bar prohibits a later filed FCA action to proceed when prior filed actions concerning the same alleged fraud are subsequently dismissed.

Silverman said the KBR decision “presents prospects of significant implications” for FCA cases, and the “ultimate resolution of the issues will have impacts on the health-care sector generally.”
‘Worthless Services’ Theory Viable

Crane said he believed there would still be FCA actions based on a “worthless services” theory of liability, despite the U.S. Court of Appeals for the Seventh Circuit overturning a $9 million jury verdict on Aug. 20, 2014, predicated on a worthless services theory (United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 2014 BL 230754, 7th Cir., No. 13-1886, 8/20/14) (18 HFRA 771, 9/17/14).

Defendant Momence Meadows Nursing Center was alleged to provided service to residents so deficient that they were effectively worthless, but the appeals court said the evidence didn’t show that Momence Meadows’ care was so inadequate that it was worthless.

Crane said “cases of bad facts and unusually bad care tend to cry out for a remedy.”

Hospice Litigation, Enforcement

Increasing fraud in hospice care is another area of health-care fraud Silverman said he is watching for 2015. Some attribute the uptick in hospice fraud to “the rapid rise in the percentage of for-profit companies in this sector” and the government has focused enforcement efforts on this area, he said.

Silverman said one case to watch is United States ex rel. Willis v. Angels of Hope Hospice, Inc. (2014 BL 45437, M.D. Ga., No. 5:11-cv-00041-MTT, 2/21/14).

The court in Angels of Hope in February 2014 denied the defendant hospice facility’s motion to dismiss FCA allegations that it was falsifying patient records to obtain the maximum per patient reimbursement from Medicare (18 HFRA 234, 3/19/14).

However, the court stayed litigation in the matter on Aug. 20, 2014, after the defendant filed for bankruptcy.

Silverman also said the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT ACT) that took effect Oct. 6, 2014, will enhance “oversight and transparency” of hospice providers going forward.

The IMPACT ACT was a “step in the right direction in gaining control over the growing number of fraud schemes involving the Medicare hospice benefit,” he said.

Roark said litigation in United States ex rel. Paradies v. AseraCare, Inc. (2014 BL 341007, N.D. Ala., No. 2:12-cv-00245-KOB, 12/4/14) will “be closely watched” after a Dec. 4, 2014, decision allowing allegations of hospice fraud to move forward (see related article in the Court Proceedings section).

The case “raises interesting issues regarding whether a mere difference of opinion between doctors regarding a patient is terminally ill is sufficient to establish FCA liability,” Roark said.

The AseraCare litigation also incorporates statistical sampling issues similar to those seen in Life Care Centers.

Attorney-Client Communications Questioned

Another case attorneys should pay attention to in 2015, Roark said, is United States ex rel. Barker v. Columbus Reg’l Healthcare Sys. Inc. (2014 BL 240067, M.D. Ga., No. 4:12-cv-00108-CDL, 8/29/14), where a court ruled Aug. 29, 2014, that a hospital waived attorney-client privilege in communications on compensation arrangements and the purchase of a cancer clinic complied with the Stark and anti-kickback laws because it asserted an affirmative defense that its actions complied with the statutes (18 HFRA 783, 9/17/14).

Roark said he was interested in “how this discovery ruling plays out in further litigation” and if future FCA relators or the government make similar plays at obtaining normally privileged attorney-client communications on similar grounds.

PODs in Play

Silverman is watching two related FCA cases filed by the government involving physician-owned distributorships (PODs).

In United States v. Reliance Med. Sys. (2014 BL 313154, C.D. Cal., No. 2:14-cv-06979-DDP-PJW, 11/5/14), the court refused to dismiss an FCA action against a spinal implant sales company on allegations of a physician kickback scheme to induce use of the company’s products (18 HFRA 964, 11/12/14).

Silverman said the continuing Reliance litigation is significant because “it reflects a heightened interest by the government” in PODs, “with prospects that similar enforcement efforts” in the future.

The government also intervened in an FCA action against Aria Sabit, a physician, on Sept. 8, 2014, on allegations that Sabit received kickbacks and performed unnecessary spinal fusion procedures with Reliance products after acquiring an interest in Reliance (United States ex rel. Savitch v. Sabit, No. 2:13-cv-3363, complaint in intervention, 9/8/14) (18 HFRA 768, 9/17/14).

Sabit also was criminally charged and arrested Nov. 24, 2014, for health-care fraud stemming from allegations that he billed for spinal fusion surgeries in which he didn’t actually implant the spinal fusion device (18 HFRA 1056, 12/10/14).

There also is attention on the prosecution of the chief executive officer of Vascular Solutions Inc., Howard Root, who was indicted for selling a vein treatment device for off-label uses and conspiracy to conceal illegal sales of the device (United States v. Vascular Solutions, W.D. Tex., No. 5:14-cr-00926, indictment, 11/13/14).

Silverman said Root’s prosecution is another example of the government’s effort to prosecute more high-level executives involved in health-care fraud.

ERISA Cases Could Impact Providers. Lou Saccoccio, chief executive officer of the National Health Care Anti-Fraud Association, said he was watching several cases that are grappling with whether ERISA appeal procedures apply to private payer overpayment recovery actions against providers.

The cases are:

Penn. Chiropractic Ass’n v. Independence Indemnity Plan, Inc., 7th Cir., No. 14-3174, appeal filed 10/6/14;


Tri3 Enterprises, LLC v. Aetna, Inc., D.N.J., No. 3:11-cv-3921-MAS-TJB, filed 5/16/11; and


Saccoccio said the court’s decisions in those cases will have bearing on “the providers’ claim[s] that the
payer violated ERISA appeal procedures in their efforts to collected overpayments directly from providers.”

By James Swann and Eric Topor

To contact the reporters on this story: James Swann in Washington at: jswann1@bna.com and Eric Topor in Washington at etopor@bna.com

To contact the editors responsible for this story: Kendra Casey Plank at kcasey@bna.com; Ward Pimley at wpimley@bna.com; and Lisa M. Rockelli at lrockelli@bna.com