BNA's
HEALTH CARE FRAUD REPORT
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OUTLOOK 2011: Permissive Exclusions, Increase in Oversight Expected for 2011

Health care attorneys tell BNA that the industry will face an array of fraud-fighting challenges in 2011, including increased use of permissive exclusion authority against individuals, tightened enrollment standards for federal health care programs, and a new generation of anti-fraud contractors.

Providers will be faced with a slew of new regulatory oversight, including the Centers for Medicare & Medicaid Service's self-referral disclosure protocol for Stark law violations as well as the Department of Health and Human Services Office of Inspector General's expanded permissive exclusion authority.

Other challenges will include the expansion of the Recovery Audit Contractor (RAC) program to Medicaid as well as the end of the transition from program safeguard contractors to zone program integrity contractors (ZPICs).

The new year can expect to see an increase in cases involving medical device fraud, Stark law violations, and pharmaceutical false claims act cases, the attorneys told BNA.

Permissive Exclusion Authority

On Oct. 20, 2010, the OIG issued guidance on handling permissive exclusions from federal health care programs, which allows for the potential exclusions of officers and managing employees of sanctioned entities when no evidence exists of direct knowledge of the misconduct (14 HFRA 874, 11/3/10).

This authority has been used already, namely in the case of Marc. S. Hermelin, a former board member of K-V Pharmaceutical Co., who was excluded from all federal health care programs in November 2010 (14 HFRA 1016, 12/15/10).

''The OIG has made it clear that the issue of exclusions of individuals as well as companies is a high priority,'' Lynn Shapiro Snyder, an attorney with Epstein, Becker & Green, Washington, said.

''All companies that are required to check the OIG website for excluded individuals and excluded companies should go back and make sure that the appropriate processes and procedures are in place and working as to this required screening obligation,'' she said.

Kimberly Brandt, an attorney with Alston & Bird, Washington, agreed, saying that senior level executives should take the permissive exclusion authority very seriously.

''The OIG has been sending out the message for several years that they really expect top-level executives to be aware of their businesses. Saying 'I didn't know' is not good enough,'' Brandt said.

She also said that increased individual prosecutions are likely. ''The government is taking this seriously,'' she said. ''Ignorance is no longer an excuse.''

Increased investigation and enforcement are likely as a result of the OIG guidance on permissive exclusion, Linda A. Baumann, an attorney with Arent Fox, Washington, said.

''If providers check employees internally, they should be sure that they have a standard procedure for checking new and current employees/entities against the specified databases on a regular basis (at least annually) to ensure that the individual/entity is not excluded at any point while they are employed/under contract with the provider,'' Baumann said. ''Periodic audits of the system also should be scheduled.''

The OIG's new permissive exclusion authority also signals that the agency is serious about targeting individuals as opposed to just organizations, Stuart I. Silverman, an attorney with the District of Columbia Office of Inspector General's Medicaid Fraud Control Unit, said.

''This is an indication that the government intends to turn its sights to those individuals with fiduciary duties

Top 10 Health Care Fraud Issues for 2011

A survey of *BNA's Health Care Fraud Report*'s Advisory Board members determined that the top 10 fraud issues for 2011 are:

1. Increased government exclusion and prosecution of individuals associated with health care fraud cases. The OIG's enhanced permissive exclusion authority has already been put to use, and the trend is likely to continue.
2. Increased Stark law activity, especially as providers get more comfortable with the self-referral disclosure protocol and decide whether to use it.
3. Expanded use of the False Claims Act in government prosecutions. Prosecutors are likely to become more aggressive in using the FCA.
4. Increased use of predictive modeling and data analysis software by CMS as a fraud prevention and enforcement tool.
5. Increased activity against pharmaceutical companies for manufacturing and marketing drugs not approved by the FDA.
6. Tightened enrollment controls for federal health care programs, including measures such as fingerprinting and criminal background checks.
7. Enforcement initiatives against both the home health and medical device industries.
8. Increased Medicaid enforcement, including the implementation of state-run Medicaid RACs.
9. Expanded fraud investigations within the Medicare Part D program.
10. Increased Stark and Medicaid qui tam cases.

within a health care company who presided over the company's business practices while fraudulent activity was occurring,'' Silverman said.

He said executives ''need to get more involved with their company's compliance programs, or face the potential of exclusion even where there is no knowledge by the officer of wrongdoing by a sanctioned entity.''

Silverman said organizations should conduct due diligence before hiring new employees, especially since exclusions are a matter of public record and can be checked easily.

While individuals are a target for the OIG, health care employers can protect themselves through due diligence, Joseph E. B. White, an attorney with Nolan & Auerbach in Philadelphia, said.

''By placing the onus on the potential employers of excluded individuals, OIG has signaled that health care providers must play an important gate-keeping role when it comes to protecting our limited health care dollar,'' White said.

''Providers can mitigate the risks of employing or contracting by proactively investigating the backgrounds of all individuals or entities associated with the provider,'' he said. ''The bottom-line is that the OIG does not have the time, money, or interest in penalizing providers who make a good faith effort to honor their gate-keeping responsibilities.''

At the same time, however, the permissive exclusion authority may end up affecting executives who are far removed from any Medicare or Medicaid services, Kevin G. McAnaney, an attorney with the Law Offices of Kevin G. McAnaney, Washington, said.

''The interesting issue is whether any one will be able to successfully litigate the OIG's very expansive reading of the effect of an exclusion to reach administrative and executive personnel far removed from any actual Medicare or Medicaid service,'' McAnaney said. ''The more the OIG presses, the greater the likelihood that some indirect provider will challenge the OIG.''

Stark Law/Voluntary Disclosure

The government will continue to prosecute violations of the physician self-referral law, or Stark law, in 2011, attorneys told BNA, and providers will have access to new tools to help mitigate their risk.

For example, CMS released a self-referral disclosure protocol (SRDP) for any Stark law violations on Sept. 22, 2010, with the intent of allowing providers to self-disclose any real or potential violations of the Stark law (14 HFRA 784, 10/6/10).

The facts at hand will indicate whether the risks of filing a self-disclosure outweigh the benefits, but increased enforcement from the government of Stark law violations seems likely, Arent Fox's Baumann said.

''All government agencies seem to be increasingly aggressive in undertaking enforcement efforts,'' Baumann said. ''If a clear Stark Law violation is uncovered, I'd expect government agencies generally to take an aggressive position as to whether the violation should have been discovered and disclosed.''

She told BNA the ''more difficult question involves situations where the alleged violation falls in a gray area or where the issue involves a minor technical violation of the statute.''

Providers also will have limited information on how the self-disclosures will work, Kirk Nahra, an attorney with Wiley Rein in Washington, said, which may reduce the effectiveness of the program.

''The government has been seeking to develop an effective voluntary disclosure program for more than a decade now,'' Nahra said. ''It hasn't worked so far, and there is no particular reason to think it will work again now. Until the government can provide specific details and specific benefits, this kind of a program is unlikely to work.''

The lack of specificity surrounding the self-disclosure protocol may end up limiting its use, Brandt said, adding, ''I've seen a very strong sense of reticence from providers over the SRDP.''

That most likely will last until there is more transparency in the process and until providers see how CMS reacts to the initial SRDPs, she said.

''Stark issues are difficult,'' Brandt said. ''If you've seen one Stark example, you've seen one Stark example. At this stage, providers don't know what's OK and what's not.''

While providers will face a level of uncertainty when filing self-disclosures, the risks of not filing will prove to be too much, Thomas S. Crane, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo in Boston, said.

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''Providers will likely come to grudgingly accept the SRDP,'' Crane said. ''There is generally too much risk for providers to choose not to self-disclose Stark law violations.''

Crane said the ''combination of this factor, together with the new required reporting of overpayments and the possibility of seeing mitigation in the application of the statutory formula for calculating overpayments and penalties, let alone potential whistleblower actions under the False Claims Act if a Stark violation is not reported, makes the SRDP a procedure that will likely be used regularly, despite all of its flaws.''

Crane's comments were echoed by Francis J. Serbaroli, an attorney with Greenberg Traurig in New York, who said that providers will be happy to have the SRDP, even with its flaws.

''It is better to have a self-disclosure protocol—even one as cumbersome and flawed as this one—than not to have self-disclosure available as was the case prior to PPACA's enactment,'' Serbaroli said. ''The risks of self-disclosure depend upon how serious the violation is, how long it went on, whether it was intentional, how promptly the violation was corrected, and other factors.''

Serbaroli said Stark violations ''can be difficult for the government to discover. They are often brought to light by whistleblowers, in which case the government is likely to take a much tougher stance than if they were voluntarily disclosed.''

Upcoming Congressional Activity. Fraud-related activity on the Hill can be expected to heat up now that the 112th Congress has been sworn in. For example, Rep. Darrell Issa (R-Calif.), chairman of the House Oversight and Government Reform Committee, has identified Medicare fraud as one of the main areas for investigation by his committee.

Stalled legislation from the 111th Congress also will be taken up, including the Strengthening Medicare Anti-Fraud Measures Act (H.R. 6130), which was cosponsored by Rep. Wally Herger (R-Calif.), the incoming chairman of the House Ways and Means Subcommittee on Health, and Rep. Fortney Pete Stark (D-Calif.), the subcommittee's minority leader.

Stark said in a statement Dec. 23, 2010, that he looks forward to working with Herger to ensure the bill's passage. H.R. 6130 would give the OIG new authority to exclude individuals from Medicare if they leave a company that is subsequently found to have engaged in fraudulent activity or been excluded by the OIG from federal health programs.

Medicaid Contractors. Increased regulatory oversight is also coming in the form of additional anti-fraud contractors, such as the Medicaid RACs and the ZPICs.

Under a CMS proposed rule, all states were to submit plan amendments for their Medicaid RACs by Dec. 31, 2010, with full implementation to follow by April 1 (14 HFRA 916, 11/17/10). Unlike the Medicare RAC program, which is operated by CMS, Medicaid RACs will be controlled by the individual states.

Of issue to providers is the fact that the Medicaid RACs may have less uniformity than the Medicare program, which has been operational since 2005, first as a demonstration and then as a permanent program, Nolan & Auerbach's White said.

''Currently, the Medicare RACs seem to be in alignment around the same billing issues,'' he said. ''However, when you have more players, as you will with the Medicaid RACs, the auditing priorities will become a mosaic of issues, forcing multi-state providers to wrestle with a myriad of billing concerns.''

As states begin setting up their Medicaid RAC programs, cost will emerge as one of several obstacles, Greenberg Traurig's Serbaroli told BNA.

''The obstacles that states face include the costs, finding the right RAC to contract with, monitoring the RAC's performance, including making sure the RAC is finding underpayments as well as overpayments, and making sure that the RACs afford adequate due process to auditees who want to challenge the RAC's findings,'' Serbaroli said.

Many states are also facing budgetary shortfalls, which will make Medicaid RAC implementations more difficult, Silverman, with the D.C. OIG's office, said.

''The fiscal pressures on state governments is enormous now, with legislatures and governors struggling to cut expenditures to meet balance budget requirements,'' he said. ''Any program implementation imposed by Congress and the administration with regard to Medicaid RACs will likely face fierce competition from other priorities within the state.''

Silverman did say that states might come to see Medicaid RACs as potentially cost effective if they look at the example set by the Medicare RAC demonstration project, which recouped over $1 billion at a fairly low cost.

Even though Medicaid RACs might be able to self-fund themselves through recoveries once they are established, many states are saying they simply do not have the money for implementation, Alston & Bird's Brandt said.

''This is an issue that CMS will have to address, and I'm not sure CMS has the resources to help the states with their funding issues,'' she said. ''The reality is that it will be very hard for all states to meet the Medicaid RAC deadlines this year.''

ZPIC Program. Other contractor issues involve the transition from program safeguard contractors (PSC) to zone program integrity contractors (ZPICs), a process that is expected to be completed in 2011.

Already, the ZPIC program has been the focus of potential conflict-of-interest issues.

Sen. Chuck Grassley (R-Iowa), for example, sent a letter Oct. 29, 2010, to CMS Administrator Donald M. Berwick, citing concerns that some ZPICs and PSCs are subsidiaries of companies that also contract with CMS, placing the ZPICs and PSCs in the position of overseeing their corporate parent companies (14 HFRA 880, 11/3/10).

''The government has tried a variety of contractor-oriented approaches to help with the fight against fraud, with none of them working very well,'' Wiley Rein's Nahra said. ''It is hard to see that this latest effort will fare any better.''

Nahra said the '' 'conflict of interest' problem is an inherent one—if you have reasonable knowledge and experience in the area, you will have some basis for that knowledge and experience that likely will involve a kind of conflict. In addition, the government hasn't yet developed an appropriate framework for these contractors that factors in all of the elements that are needed for effective fraud detection.''

While acknowledging the conflict-of-interest issues, Mintz Levin's Crane said he expected the ZPIC program to expand in 2011.

''There is too much perceived money in these recoveries to not implement this program,'' Crane said.

Compliance Programs. The Patient Protection and Affordable Care Act included numerous program integrity provisions, among them a mandatory compliance program requirement for providers, which took effect Jan. 1 (14 HFRA 910, 11/17/10).

While the provision is now operational, it is unlikely to be a major priority of CMS's, at least for the next year, McAnaney said.

''With all CMS has to do, I think this will be a low priority,'' he said. ''You can expect some activity by the OIG to evaluate compliance in another year or so.''

Nahra agreed, telling BNA that CMS is unlikely to penalize organizations simply for failing to have an effective compliance program in place. Rather, penalties will be increased if CMS discovers a program integrity violation and then discovers that the organization does not have an effective compliance program.

''The government should provide lots of advice and information about these programs, but should not be too aggressive, especially in early years, about taking action against reasonable good faith efforts to develop appropriate compliance programs,'' Nahra said.

Arent Fox's Baumann also said that CMS would take a slow track approach to enforcing the compliance programs, waiting for final regulations to be released.

''I wouldn't expect CMS to conduct detailed reviews of provider compliance programs as part of the enrollment process until after the implementing regulations are issued,'' Baumann said. ''However, in the interim, I'd expect CMS to insist each provider have a compliance program that appears to have the seven basic elements'' (14 HFRA 880, 11/3/10).

Realistically, CMS enforcement of the mandatory compliance programs will depend on whether it has the proper level of resources, Greenberg Traurig's Serbaroli said.

''It will be interesting to see how this plays out and whether CMS has the resources to check on this,'' Serbaroli said. ''More likely, in the course of an audit, investigation or whistleblower suit, if CMS or OIG finds out that a provider didn't have a compliance program or the program was inadequate, it will result in increased penalties, more burdensome Corporate Integrity Agreements, suspension or exclusion, and other unpleasantness.''

While CMS actively cares about enforcing compliance programs, availability of resources will determine how diligent they will be, Brandt said.

''The issue for CMS is whether they have the resources to do this, what with having to roll out a number of other programs,'' she said. ''Are they really going to be able to keep an eye on compliance programs?''

Data Analytics

Predictive modeling, data analytics, and other advanced technologies also have received increased attention from CMS as the agency looks to expand its arsenal of program integrity tools.

At a regional health care fraud summit in Boston Dec. 16, 2010, HHS Secretary Kathleen Sebelius said that CMS is issuing a solicitation for analytic tools that will help the agency prevent and prosecute fraud (*see related item in the Federal News section*).

Contracts are expected to be rewarded by April.

McAnaney told BNA that for ''real fraud prevention, the most important tool is real time claims data and analysis. Next to that, I think the pre-enrollment reviews will be important. The issue is going to be whether CMS can actually implement these given their manpower.''

Advanced technology represents the next big wave for health care, Brandt said.

''When Congress passed the Small Business Jobs Act of 2010 (H.R. 5297), it sent a very strong signal that they support predictive modeling technology,'' she said. ''Providers need to become much more aware of their own data, and they should be using their data to find out any problems before the government does.''

H.R. 5297, which was signed into law on Sept. 27, 2010, authorizes the HHS secretary to select predictive modeling contractors to review Medicare data from the 10 states identified as having the highest risk of Medicare fraud, waste, and abuse (14 HFRA 651, 8/11/10).

The data review is scheduled to begin on July 1, and the program is expected to expand in subsequent years. The program received $100 million in funding.

''The government will get much more aggressive with their use of technology,'' Brandt said. ''Providers need to ask themselves, 'Can I get by without using the same technology?' The big issue will be if the right technology is available right now.''

Emerging Trends

Hospice and home care services are two areas where fraud can be expected to grow, Mintz Levin's Crane said.

''They remain two of the most complicated programs to get right,'' he said. ''Providers have significant compliance headaches tracking all of the program requirements. These two services will likely see increased attention by prosecutors.''

The durable medical equipment industry, which has long been a target of fraud, also remains at risk, according to Nolan & Auerbach's White.

''DME manufacturers seem to be slow learners when it comes to compliance,'' he said. ''The fraudulent business practices that permeated the pharmaceutical industry three years ago are now being embraced by the DME industry.''

Physicians also may come under more increased scrutiny, Arent Fox's Baumann said, due to the OIG's release of the *Roadmap for New Physicians*.

The Roadmap was released Nov. 5, 2010, and provides new physicians with tips and best practices for avoiding fraud, waste, and abuse.

While risks remain, the government has more tools at hand to fight fraud, Silverman said.

''The recently enacted health care reform legislation mandates constructive steps, particularly in the licensure area, that will help prevent questionable providers and suppliers from becoming participants in the Medicare program,'' Silverman, with the D.C. OIG, said.

''The DOJ strike force initiatives, with the ability to collect and assess real time claims data, will also enhance the government's ability to identify in a reason-

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ably prompt manner billing fraud, and suspend further payments, thus protecting the public fisc,'' he said.

Silverman said that the new fraud-fighting tools signal a shift away from the ''pay and chase'' model of enforcement and toward a model that looks to identify fraud and prevent it from happening.

With a new Congress in place, certain provisions of PPACA may be re-evaluated, but all attorneys agreed that fraud sections would survive undiluted.

''There is no particular reason to connect the dissatisfaction with the health care reform laws to anti-fraud efforts,'' Nahra said. ''There has been an increased recognition throughout the government—in both parties—that spending money on effective anti-fraud programs ultimately saves costs and improves health care.''

White agreed, saying that fraud represents a rare bipartisan issue.

''Fighting health care fraud has become a political gold ring, with both sides vying for the title as the 'Fraud-Fighting Party,'' he said. ''The true winner, of course, is the American health care dollar, for appropriated funds to the OIG and DOJ will only increase, no matter which party is in the majority.''

Moving forward, however, certain anti-fraud programs may become less effective, such as the Medicare Fraud Strike Force, Mintz Levin's Crane said.

''The Strike Force has already likely hit the law of diminishing returns, and so it is unlikely that putting more money into this program will yield the same results as we have seen to date,'' he said.

As the Strike Force concept expands to additional cities, it might also become less valuable as a deterrent tool, McAnaney said.

''There is a real question as to how valuable the Strike Force approach is as it expands outside of the core fraud epicenters of Florida, Texas, and California,'' he said. ''I think the issue will be that these criminal enterprises will simply go elsewhere, but I believe Congress will look at how well they are performing in these expanded cities.''

While there may be some diminishing returns from the Strike Force program, new technology should help keep it successful, Brandt said.

''You're always going to have areas where you get a lot of convictions, such as Miami-Dade, so there will be diminishing returns as you expand to other areas, but new technologies like predictive modeling should allow for the uncovering of harder to find fraud, such as upcoding,'' she said.

Fraud Cases to Watch

On the legal front for 2011, health care attorneys told BNA that the top court cases to watch involve False Claims Act issues dealing with public disclosure, implied certification, kickbacks, and pleading requirements. Experts also say to expect more criminal prosecutions of individuals and more enforcement attention on private insurance fraud.

Public Disclosure. In 2011, the U.S. Supreme Court may issue a decision in *Schindler Elevator Corp. v. United States ex rel. Kirk* (U.S., No. 10-188), to determine whether a whistleblower proceeding with a False Claims Act qui tam action is automatically barred from asserting claims based on documents obtained through a Freedom of Information (FOIA) request.

The American Hospital Association (AHA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the U.S. Chamber of Commerce filed a friend-of-the-court brief in support of Schindler Elevator Corp., which is challenging a ruling by the U.S. Court of Appeals for the Second Circuit that held documents obtained through a FOIA request do not automatically bar an FCA relator's action (14 HFRA 1028, 12/15/10).

James F. Segroves, an attorney with Proskauer Rose, Washington, told BNA that in *Schindler*, the Supreme Court will decide whether a federal agency's response to a FOIA request triggers the FCA's public-disclosure bar.

Oral argument is scheduled for March 1, and the court is expected to issue a decision before it leaves for its summer recess, Segroves said.

Commenting on the case, Joseph E. B. White, an attorney with Nolan & Auerbach PA, Philadelphia, told BNA, ''For the eighth time in 10 years, the U.S. Supreme Court has decided to dissect the False Claims Act. . . . This latest examination focuses, once again, on the so-called public disclosure bar, which precludes a whistleblower from merely parroting allegations that are widely available to the general public.''

White said that when Congress drafted the public disclosure bar, lawmakers were concerned that, among other things, whistleblowers would build their allegations from specific sources that likely had already put the government onto the trail of the fraud.

''Responding to FOIA requests oftentimes involves a low-level government employee making copies of seemingly innocuous government documents,'' White said. ''This is not the kind of 'public disclosure' that should silence a meritorious whistleblower lawsuit.''

According to attorney John T. Boese, with Fried Frank, Washington, while the *Schindler* case is important, the issue before the court is a rather narrow one—whether documents released under a FOIA request are ''publicly disclosed'' for purposes of the ''public disclosure/original source'' defense if what is released under FOIA is not itself a federal or state agency report or investigation.

One of the most important health care fraud issues in the pipeline is the implied certification theory now on appeal in the U.S. Court of Appeals for the First Circuit, Thomas S. Crane, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, Boston, told BNA.

''That is a very narrow issue affecting very few decisions,'' Boese said. ''Of course, what the court has to say about 'public disclosure' is always important since there are so few decisions in this area, but the most important part of the Second Circuit decision is not before the court.''

Boese was referring to his comments in his Sept. 29, 2010, FraudMail Alert (No. 10-09-29), in which he said

that Schindler's petition did not address the holding by the Second Circuit that the FCA provision 31 U.S.C. § 1354(a)(12) and the implementing regulation made any claims by a contractor who had submitted reports at issue in *Schindler* false as a matter of law because the contractor ''implicitly certifies compliance'' with the reporting requirement.

Boese said that Schindler's argument that the definition of public disclosure under the FCA should be broadly interpreted essentially invokes the policy reasons behind the false certification. The better result, he said, would have been to ask the Supreme Court to address this issue directly.

PPACA Cases. ''It will be interesting to watch for significant increases in cases brought in 2011 under the federal FCA that may arise directly from the enhanced fraud fighting provisions of the [PPACA],'' Stuart I. Silverman, an attorney with the Office of the Inspector General for the District of Columbia Government, Medicaid Fraud Control Unit, said. ''For example, PPACA amended the federal False Claims Act in several respects that will make it easier for relators to file qui tam actions.''

Specifically, he said that PPACA limited the ''public disclosure'' provisions and broadened the ''original source'' provisions.

PPACA made significant changes in the public disclosure bar and original source exception allowing a whistleblower with independent knowledge of already publicly disclosed allegations to be an original source.

The new public disclosure bar maintains the essential structure of the previous provision by requiring courts to dismiss a whistleblower's FCA qui tam lawsuit if the allegations were ''publicly disclosed,'' unless the relator is an ''original source'' of the information underlying the allegations (14 HFRA 309, 4/7/10).

Implied Certification. One of the most important health care fraud issues in the pipeline is the implied certification theory now on appeal in the U.S. Court of Appeals for the First Circuit, Thomas S. Crane, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, Boston, told BNA.

The First Circuit is considering an appeal of the case, *United States ex rel. Hutcheson v. Blackstone Medical Inc.* (1st Cir., No. 10-1505), in which the U.S. District Court for the District of Massachusetts dismissed a lawsuit filed by whistleblowers Susan Hutcheson and Philip Brown.

The court determined they failed to state a claim under Federal Rule of Civil Procedure 12(b)(6) because the express certification by the hospitals in seeking payment for the use of Blackstone's devices was personal to the hospital and with no allegations that the hospital knew of the kickbacks, those claims were not false, and the false express certification by the physicians were not material (14 HFRA 416, 5/19/10).

Crane and Nolan & Auerbach's White said that in addition to *Blackstone*, another appeal in the First Circuit is *United States ex rel. Westmoreland v. Amgen* (1st Cir., No. 10-630J).

The appeal is based on the decision by federal district court in Massachusetts in April 2010, in which the court threw out complaints brought by a whistleblower and several states against biotech drug company Amgen Inc. and other affiliated entities. The lawsuit alleged a scheme to pay kickbacks in the form of free products to induce providers to switch to its anemia drug Aranesp from a rival medication.

The court found that the plaintiffs did not allege that when the providers signed enrollment forms, they knew that they would be accepting kickbacks from the defendants in violation of the anti-kickback statute. Therefore, the relators' complaint failed to state a legally false claim under the express certification theory, the court concluded.

Moreover, the court found the states' complaint similarly failed to state a legally false claim under the express certification theory (14 HFRA 416, 5/19/10).

Crane told BNA that while a majority of courts have adopted the implied certification theory, there is other litigation appealing decisions by the U.S. District Court for the District of Massachusetts that have narrowed the implied certification theory in the context of wrongdoing by manufacturers causing innocent parties to submit claims.

Crane included *United States ex rel. Rost v. Pfizer Inc.* (1st Cir., No. 10-2215), in which the lower court dismissed whistleblower Peter Rost's FCA qui tam action alleging that Pharmacia Corp. engaged in illegal off-label marketing of a human growth hormone that caused pharmacies to submit false claims to government health programs.

Whistleblower Peter Rost, a former vice president of marketing for Pharmacia Corp. (now part of Pfizer Inc.), Oct. 28, 2010, appealed to the U.S. Court of Appeals for the First Circuit a lower court's dismissal of his False Claims Act qui tam.

Specifically, Rost is appealing the September 2010 decision from the district court that dismissed his lawsuit alleging that Pharmacia's marketing of Genotropin for uses not approved by the Food and Drug Administration, and its provision of illegal kickbacks to physicians, led to the submission of false claims for reimbursement of unreimbursable, off-label drug prescriptions.

The district court held that the claims for Genotropin submitted by the pharmacies were not ''false or fraudulent'' under a theory of implied certification (14 HFRA 934, 11/17/10).

Meanwhile, a judge in the federal district of Massachusetts issued an opinion in October 2010 explaining why he refused to dismiss a whistleblower's fourth amended complaint alleging that Amgen Inc. violated the FCA with a kickback scheme that induced providers to claim reimbursement for dosages of its anemia drug Aranesp.

In *United States ex rel. Westmoreland v. Amgen* (D. Mass., No. 1:10-mc-10389-WGY), while the court dismissed whistleblower Kassie Westmoreland's third amended complaint for failure to allege a ''false claim,'' it found new evidence in the fourth amended complaint sufficient to do so.

Specifically, the court found factual and statistical evidence supporting the conclusion that since the defendants began giving kickbacks, providers involved in the kickback scheme have likely re-enrolled and made knowingly false statements on their re-enrollment forms (14 HFRA 803, 10/6/10).

Anti-Kickback Claims. ''After many years where very few fraud and abuse cases were litigated (largely because of the government's ability to exclude the provider from federal health care programs in any event),

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we are beginning to see an increase of cases going to court, rather than settlement,'' Linda A. Baumann, an attorney with Arent Fox, Washington, told BNA. ''I'd expect these cases to involve kickbacks, Stark violations, as well as other types of false claims.''

Kevin G. McAnaney told BNA that the courts may finally begin addressing Stark and [the anti-kickback statute] issues as part of FCA cases, especially in FCA cases in which the Department of Justice declined to intervene in the FCA qui tam cases.

According to White, in *Westmoreland* and *Hutcheson*, the First Circuit also will examine the interrelationship between the FCA and anti-kickback allegations.

In addition, a decision may be reached in 2011 in the FCA complaint filed by the United States in January 2010 against Johnson & Johnson and two subsidiaries, alleging they paid millions of dollars in kickbacks to nursing home pharmacy company Omnicare Inc., White said.

The government filed its complaint in the federal district court of Massachusetts after deciding to intervene in two consolidated whistleblower FCA actions filed by Bernard Lisitza, a pharmacist licensed in Illinois, and David Kammerer, a financial analyst for Omnicare, from 1997 to 2002.

The government alleged that J&J, Ortho-McNeil-Janssen Pharmaceuticals Inc., and Johnson & Johnson Health Care Systems Inc. paid kickbacks to induce Omnicare, the nation's largest pharmacy that specializes in dispensing drugs to nursing home patients, to purchase and recommend J&J drugs, including the antipsychotic drug Risperdal (14 HFRA 69, 1/27/10).

''In recent months, some of the lower courts have sought to limit the reach of the False Claims Act, as it applies to doctors who are accepting bribes in exchange for prescribing a company's product,'' White said. ''The bottom line is that the doctor is tainted by bribes, so all claims that flow up the system from his prescription pad should trigger False Claims Act liability.''

Stuart I. Silverman, an attorney with the DC government's OIG office, told BNA that ''PPACA also amended the federal anti-kickback statute to allow actions to be filed successfully under the federal False Claims Act using the implied certification theory.

He said several courts have ruled that there was no cause of action under the implied certification theory involving kickbacks because neither the anti-kickback statute nor regulations expressly stated that compliance with that federal statute was a precondition to Medicare or Medicaid payments.

''Thus,'' he said, ''it is reasonable to conclude that more actions under the federal False Claims Act will be brought using the implied certification theory for kickback schemes.''

Particularity Rule. Proskauer Rose's Segroves told BNA that clarification regarding what Federal Rule of Civil Procedure 9(b) requires for FCA qui tam complaints will be an issue to watch in 2011. The rule provides that ''[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.''

He said ''[e]very federal court of appeals to address the issue has held that Rule 9(b) governs qui tam complaints filed under the FCA; however, courts have disagreed as to what level of detail Rule 9(b) requires of qui tam complaints.''

He said, as an example, that ''some courts have suggested that relators must plead the who, what, where, and when of at least one false claim for payment with specificity. Other courts have applied a more lenient standard favorable to relators.''

Segroves predicted that recent events suggest the Supreme Court may resolve this issue in 2011. Specifically, he pointed out that, in May 2010, the Office of the Solicitor General responded to an invitation by the Supreme Court to file a brief expressing the views of the United States as to whether review should be granted in an FCA case, *Ortho Biotech Products LP v. United States ex rel. Duxbury* (U.S., No. 09-654, *petition denied* 6/21/10.

Although the Supreme Court eventually denied review in that case, Segroves said, given the frequency with which the Rule 9(b) issue arises in FCA cases, one can reasonably expect that an appropriate Supreme Court vehicle may come before the justices in 2011.

Boese told BNA that 2010 was a particularly good year for False Claims Act defendants and he looks for that to continue in 2011. He said that, except in the particularity requirement of Federal Rule of Civil Procedure 9(b), almost all of the major FCA decisions either have cut back on FCA liability or strengthened FCA defenses.

''No particular cases jump out, but the trend in limiting the scope of the FCA will continue,'' Boese said. ''Legislatively, I think the era of Congress amending the FCA to favor the government or qui tam relators is over for a while.''

Insurance Fraud. ''It is reasonable to assume that insurance fraud will be an important issue to prosecutors,'' Silverman told BNA. He cited a case pending in New York, *People v. Boothe* (N.Y. Sup. Ct., No. 02237-2008), in which a 15-count fraud indictment was returned against a former executive of Healthfirst, New York's largest Medicaid managed care provider.

The defendant faces trial for alleged concealment, or offering false statements. The case involves a contract that Healthfirst had with New York City and several counties to enroll in the state's Medicaid managed care program individuals who qualified for Medicaid.

The contract with the state required Healthfirst to reward marketing agents based on quality of performance and not on the basis of the number of individuals who were enrolled, and the New York attorney general charged that Healthfirst violated its contract by rewarding bonuses to its agents based on the number of people who were signed up. Trial is pending the outcome of the state's appeal of a dismissal of two counts by the trial court, he said.

''Taking the long view, [i]nsurance fraud will be a particular concern as the nation takes steps to implement state insurance exchanges, Silverman said. ''With more dollars being expended, both by government (via subsidies) as well as by individuals and small businesses, for health insurance coverage, the opportunities for fraud schemes at the state level will increase.''

Silverman also said that under the Medicare Advantage (MA) plans, the prospects of insurance fraud is always present.

''For example, CMS recently ordered Universal American and Arcadian to suspend marketing and en-

rollment activities for their prescription drug and MA plans, citing improper marketing activities by sales agents, by misleading beneficiaries about network providers and formulary drugs,'' he said.

Criminal Cases. Silverman told BNA that it will be interesting to watch the outcome of a federal prosecution in the U.S. District Court for the Western District of Pennsylvania.

In *United States v. Pepala* (W.D. Pa., No. 10-cr-180-MBC, *indictment* 9/15/10), the defendant, Paul C. Pepala, who was employed as a surgical instrument technician at the University of Pittsburgh Medical Center's Shadyside Hospital, was charged with illegally disclosing individually identifiable health information for personal gain.

''This is the first prosecution in the Western District of Pennsylvania for violation of the Health Insurance Portability and Accountability Act of 1996,'' he said.

Another significant criminal case to watch is one brought against Stryker Biotech LLC, and several executives, Silverman told BNA.

In that case, *United States v. Stryker Biotech LLC*, D. Mass., No. 09-10330, *filed* 10/28/09, indictments charged Stryker, its former president, and several sales managers participated in of an off-labeling scheme involving the use of medical devices during invasive spinal and long bone surgeries.

The indictment charged the defendants with mail and wire fraud, conspiracy to defraud FDA of its lawful regulatory authority to ensure the safety of medical devices, conspiracy to commit misbranding, and misbranding.

The defendants argued that the information disseminated for the off-label use pertained to matters ''of bona fide medical and scientific discussion and debate,'' and were protected by the First Amendment. The government argued that the case is, ''at its heart,'' a fraud case and thus ''it is well settled that the First Amendment does not shield fraud,'' Silverman said.

The indictment follows a civil settlement reached on Aug. 25, 2010, of allegations brought by the Massachusetts attorney general under the Massachusett's Consumer Protection Act, he said.

In August 2010, the Massachusetts attorney general announced that Stryker will pay $1.35 million to settle Massachusetts state allegations that the company marketed products for uses not approved by the federal Food and Drug Administration and misled health care providers about the appropriate uses for the products (*Massachusetts v. Stryker Biotech LLC*, Mass. Super. Ct., No. 10-3365) (14 HFRA 764, 9/22/10).

Crane told BNA that the government is showing more interest in prosecuting and excluding individuals.

He pointed out the indictment of GlaxoSmithKline associate general counsel Lauren Stevens (*United States v. Stevens*, D. Md., No. 8:10-cr-00694-RWT, *plea entered* 11/30/10) (14 HFRA 1025, 12/15/10); the exclusions of founder and former chief executive officer Jeffrey Owen, for Sentient Medical Systems (SMS) of Hunt Valley, Md., who agreed to pay $2.7 million to settle the nationwide charges brought by prosecutors under the federal False Claims Act (14 HFRA 976, 12/1/10); the exclusion of Marc Hermelin (former board member of K-V Pharmaceuticals) following the company's history of problems with Food and Drug Administration manufacturing compliance (14 HFRA 1016, 12/15/10), and the criminal sentencing of former InterMune CEO Scott Harkonen (*United States v. Harkonen*, N.D. Cal., No. 08-cr-00164-MHP, *hearing* 11/15/10) (13 HFRA 472, 6/17/09).

He said those cases are ''significant signs'' of the government's increased interest in trying to hold individuals accountable for corporate fraud.

Crane told BNA about a new tool the government has as a result of PPACA.

''Once [the government] obtains a conviction under any of the federal health care offenses, the amount of loss, one of the most important factors driving the length of a sentence, is to be determined for sentencing purposes as 'the aggregate dollar amount of fraudulent bills submitted to the Government health care program shall constitute prima facie evidence of the amount of the intended loss by the defendant (Pub. L. No. 111-148, § 10606(a)(2)), (directing the Federal Sentencing Commission to amend the Federal Sentencing Guidelines),' '' Crane said.

Medical Credentialing. Silverman told BNA providers ''can expect more scrutiny of hospital practices when it comes to credentialing of its medical staff. We can see this, for example, in the decision by the federal government to partially intervene in [*United States ex rel. Rogers v. Azmat*, S.D. Ga., No. 5:07-CV-00092, *complaint filed* 7/27/10].

In that case, he said, the relator alleged that Satilla Regional Medical Center submitted claims for a staff surgeon's medically substandard and unnecessary services.

He said the FCA qui tam complaint alleged that claims were submitted for procedures performed by the surgeon when that individual was neither qualified nor properly credentialed (14 HFRA 654, 8/11/10).

FERA-Related Cases. Segroves pointed out two other FCA cases, neither of which directly involves the health care industry, but both of which have potential ramifications for the health care industry.

One case is *United States ex rel. Sanders v. Allison Engine Co.*, 6th Cir., No. 10-3818 (*oral argument not yet scheduled*). The second case is *United States v. Science Applications International Corp.* (D.C. Cir., No. 09-5385, *panel decision issued* 12/3/2010).

In *Allison Engine*, the United States was granted permission to file an interlocutory appeal after a district court rejected the Department of Justice's position on the retroactivity of the amendments to the FCA's false-statements provision in the Fraud Enforcement and Recovery Act of 2009, based on both statutory and constitutional grounds, Segroves said.

In October 2010, the U.S. District Court for the Southern District of Ohio held that the retroactivity language in the FCA, as amended by FERA, applies to ''claims'' and not ''cases.'' Under FERA's effective date, the FCA liability amendments would apply prospectively except for 31 U.S.C. § 3729(a), which takes effect on the date that *Allison Engine* was decided—June 7, 2008—making that amendment retroactive.

The Supreme Court found in *Allison Engine* that even when a subcontractor in a large government contract knowingly submits a false claim to a general contractor and is paid with government funds, there can be no liability unless the subcontractor intended to defraud the federal government.

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FERA removes the requirement of proving that false records or statements were supplied with the ''intent'' that the false claims be paid by the government. Under FERA, liability will depend on whether a false record or statement was ''material'' to getting a false claim paid (13 HFRA 419, 6/3/09).

''With two exceptions, FERA's amendments apply to conduct occurring on or after May 20, 2009,'' Segroves said. ''The first exception states that FERA's amendments to the FCA's false-statements provision 'take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 et seq.) that are pending on or after that date.' ''

He added that the second exception to FERA's forward-looking effective date instructs that certain other amendments to the FCA ''apply to cases pending on'' May 20, 2009.

Federal trial and appellate courts have disagreed as to whether the word ''claims'' in the first exemption means payment claims or legal claims, with the Department of Justice advocating the latter position in order that FERA's amendments to the FCA's false-statements provision apply retroactively to FCA legal claims that were pending on June 7, 2008.

This issue is cleanly presented in the *Allison Engine* appeal currently pending before the Sixth Circuit, which may eventually provide the vehicle for the Supreme Court to resolve this issue, Segroves told BNA.

''As there is currently a circuit split on the retroactivity issue, don't be surprised if this case makes its way back to the Supreme Court,'' Segroves told BNA.

The second pending cast that Segroves noted, is *United States v. Science Applications International Corp.* (D.C. Cir., No. 09-5385, *panel decision issued* 12/3/2010).

A three-judge panel in this appeal recently ordered a new trial after it rejected the government's use of the ''collective knowledge'' theory, whereby the Department of Justice argued that a jury should be allowed to aggregate every employees' knowledge—no matter how innocent the knowledge and no matter how low-level the employee—into a ''collective pool'' when determining whether a defendant-corporation knowingly submitted false claims, Segroves said.

''The decision also contains a significant discussion of the implied false certification theory, materiality, and how to calculate the government's damages,'' Segroves said. ''Given the nature of the panel's ruling, I wouldn't be surprised if both sides eventually seek en banc rehearing and, failing that, Supreme Court review.''

By James Swann and Judith A. Thorn

H.R. 5297 is available at http://www.gpo.gov/fdsys/pkg/BILLS-111hr5297enr/pdf/BILLS-111hr5297enr.pdf.

OIG's Roadmap for New Physicians *is available at http://oig.hhs.gov/fraud/PhysicianEducation/.*