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BNA's
Health Care Fraud Report™

Experts: Increased Individual Fraud Prosecutions, RAC Expansion on Tap for 2012

Health care attorneys and industry experts tell Bloomberg BNA that the government in 2012 will continue to focus on prosecuting and excluding providers for health care fraud, as well as increase its use of anti-fraud contractors, Medicare prepayment reviews, and predictive modeling analytics.

Providers will have additional stress in 2012 as the RAC program expands into Medicaid, new screening and enrollment provisions for the Medicare program are put in place, and CMS rolls out additional demonstration programs designed to deter fraudulent behavior.

The Department of Health and Human Services Office of Inspector General has warned it will target individuals for fraud, not just companies, especially through exclusion authority granted by Section 1128 (b)(15) of the Social Security Act (15 HFRA 780, 10/5/11). That section allows the OIG to exclude officers and managing employees if their organization is convicted of health care fraud, even if they had no knowledge of the fraud.

As for prepayment reviews, CMS rolled out a predictive modeling analytics program in July 2011, designed to review all Medicare claims before payment. Furthermore, in November 2011, CMS announced an upcoming demonstration program that will give Recovery Audit Contractors (RACs) the authority to perform prepayment reviews on certain claims (15 HFRA 936, 11/30/11).

Although the program was scheduled to start Jan. 1, CMS announced Dec. 29, 2011, it was delaying its implementation indefinitely to review comments and concerns from providers (*see related item in the Federal News section*).

Provider Exclusions and Prosecutions. Attorney Laurence Freedman, with Patton Boggs, Washington, told Bloomberg BNA the OIG will continue to use its (b)(15) authority to exclude individuals.

''Yes, there is no doubt that the OIG will exercise this authority in 2012 and will do so against a provider or company that reached a global settlement involving a criminal plea after October 2011,'' Freedman said.

He said companies should ensure their senior executives and board members are fully discharging their compliance responsibilities, but he cautioned that may not be enough to prevent an exclusion.

''Given the OIG's unfettered discretion to impose a (b)(15) exclusion against any officer or managing employee of a sanctioned entity without any showing of participation, knowledge, or even 'should have known' of the misconduct, there are limits to what providers can do to mitigate the risk of a (b)(15) exclusion,'' Freedman said.

Attorney Kirk J. Nahra of Wiley Rein, Washington, also said he sees an increase in individual exclusions and prosecutions. ''This is more of a personal risk than a corporate risk in general, and it will place incentives on company executives to act better in situations where the company is acting badly,'' he told Bloomberg BNA.

Nahra voiced concern that government budgetary pressures will lead to more fraud prosecutions and investigations in 2012.

Top 10 Health Care Fraud Issues in 2012

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

1. HHS OIG focus on exclusion of individuals
2. Start of Medicaid RAC program
3. ACOs and impact of anti-fraud waivers
4. New provider screening and enrollment procedures
5. Prepayment claims review
6. Physician sunshine provisions
7. False Claims Act cases for Medicare Part C and Part D
8. Reverse false claims
9. Medical identity theft
10. Expansion of Medicare Fraud Strike Force

''Large dollars of fraud savings have already been factored into the budget calculations,'' he said. ''That is going to put a tremendous premium on meeting and exceeding those fraud savings, which is going to put lots of pressure on fraud investigators and prosecutors and will increase the already enormous tensions between the government and potential fraud defendants.''

Nahra said the equilibrium between the government and defendants has been tilting in the government's favor for several years, and new technology will tip the balance even further.

At the same time, Nahra said the Patient Protection and Affordable Care Act (PPACA) has created many programs, such as accountable care organizations

(ACOs), that require the government to ease fraud and abuse laws to encourage participation.

''The government has to figure out how to encourage participation in these programs (and permit participation in ways that do not inhibit the possibilities of the programs) while still preserving its fraud and abuse agenda,'' Nahra said.

Over the course of 2012, Nahra said he will be watching:

- how the government prosecutes and settles cases;
- how it develops, implements, and promotes fraud and abuse regulations to protect new programs while still encouraging participation; and
- whether this approach proves workable.

Limited Exclusions. Attorney Joseph E. B. White of Nolan & Auerbach P.A., Philadelphia, however, said he does not foresee a dramatic expansion of OIG exclusions in 2012.

''Time will tell if OIG is merely saber rattling when it comes to exercising its authority to exclude individual providers,'' White said. ''For the sake of our country's limited health care dollars, the fraud-fighting community hopes that OIG hangs a few coyotes on the fence, sending a powerful message to the dishonest providers lurking under the radar.''

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—JOSEPH E.B. WHITE, NOLAN & AUERBACH

Thomas S. Crane, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C., Boston and Washington, said he has seen very few examples of the government going after individuals. He said he does not expect cases against individuals will increase in 2012.

''It remains unclear how much the OIG will actually focus scarce investigative resources on cases against individuals that take almost as much time and effort as cases against corporate entities,'' Crane said.

Attorney Kevin G. McAnaney of the Law Offices of Kevin G. McAnaney in Washington, also said he does not foresee an expansion in individual prosecutions under the (b)(15) exclusion authority, which, he said ''is very limited as currently written. It only applies if the individual owner or manager is in place at the time the entity is actually sanctioned.''

McAnaney said individuals could easily escape exclusion by resigning their positions before a settlement or exclusion action takes place.

Unless the (b)(15) authority is amended, individual exclusions will be limited mostly to U.S. Food and Drug Administration strict liability misdemeanor cases and to small, closely held providers, he said.

Expanding RACs. Provider administrative burdens will grow in 2012, experts told Bloomberg BNA, due to the expansion of the RAC program into Medicaid.

Under Section 6411 of PPACA, the RAC program was expanded to Medicare Part C and Part D, as well as Medicaid. Previously, RACs had operated solely within Medicare Part A and Part B.

CMS published a final rule on Medicaid RACs in the Sept. 16, 2011, *Federal Register* that implemented the program on Jan. 1 (15 HFRA 717, 9/21/11).

Louis Saccoccio, chief executive officer of the National Health Care Anti-Fraud Association, Washington, said Medicaid RACs will increase administrative burdens for providers.

''The implementation of the RAC program across Medicare and Medicaid creates an environment in which there is much greater scrutiny of the validity of claims and payments, an environment that providers will have to adjust to.''

Saccoccio said he expects RACs for Medicare Part C and Part D to be launched shortly, possibly within 2012 (15 HFRA 899, 11/16/11).

''Medicaid RAC audits certainly will add to the burden on providers, who already are burdened by layers and layers of audits by contractors.''

—LAURENCE FREEDMAN, PATTON BOGGS

Patton Boggs' Freedman also said Medicaid RACs would escalate compliance burdens for providers.

''Medicaid RAC audits certainly will add to the burden on providers, who already are burdened by layers and layers of audits by contractors,'' he said. ''It's like the watch-watcher-watchers in Dr. Seuss.''

Wiley Rein's Nahra said he had concerns about the entire RAC expansion effort.

''There have been a series of similar programs that have had limited success,'' Nahra said. ''There clearly are situations where the contractors are not as knowledgeable as traditional government investigators.''

He said the entire RAC concept created a significant risk of abuse by contractors, and he predicted the Medicaid RAC program would face a rocky and controversial start in 2012.

As for Medicare Part C and Part D RACs, Nahra said they would create even more risks ''because the program has been tailored to health care providers, and the knowledge base will not transfer well to the Part C and Part D programs.''

Attorney Lynn Shapiro Snyder of Epstein Becker & Green P.C., Washington, said providers should expect extra work as a result of the Medicaid RACs.

''Providers with large Medicaid receivables are not going to be in as strong a position as providers with large Medicare receivables to weather this storm,'' she said.

While administrative burdens may grow as a result of Medicaid RACs, Nolan & Auerbach's White said the contractors were needed.

''Fraud flourishes best in the darkness, and RACs further lift the veil of darkness that is currently masking billions of stolen Medicaid dollars,'' White said.

He said providers will need to embrace Medicaid RAC audits to reassure the public that Medicaid dollars are being appropriately spent.

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Prepayment Review. As the new year moves forward, providers will face both a continuation of CMS's predictive modeling program and a demonstration program allowing RACs to perform prepayment review on selected claims.

Predictive modeling, which was launched by CMS in July 2011, uses data algorithms to review all Medicare fee-for-service claims prior to payment and assigns them risk scores based on their likelihood of fraud (15 HFRA 584, 7/13/11).

However, CMS has already backed off from halting Medicare payments solely on the basis of predictive modeling.

It published a *Medicare Network Learning Matters* article Oct. 19, 2011, that said risk scores would not be the sole basis for initiating an administrative action into a Medicare claim and that Medicare would continue to pay claims promptly, and experts questioned the efficacy of the programs (15 HFRA 922, 11/16/11).

Nolan & Auerbach's White said he was saddened to see CMS weaken an otherwise strong anti-fraud tool.

''After shelling out millions of dollars on new technology, CMS has seemingly caved to the pressures of well-funded lobbyists and quietly backtracked from this commonsense commitment to law enforcement,'' White said.

He said he does not expect CMS to revisit the issue any time soon.

As for the delayed demonstration program authorizing RACs to conduct prepayment claims reviews, CMS said it would give 30 days notice before the program began.

The program would authorize RACs to review Part A claims involving short stays before they are paid.

Historically, these claims have had a high rate of improper payment.

The program is scheduled to run for three years and take place in 11 states (Florida, California, Michigan, Texas, New York, Louisiana, Illinois, Pennsylvania, Ohio, North Carolina, and Missouri).

Suspending Payments. Questions remain whether the government can ever implement effective prepayment review programs, Wiley Rein's Nahra said.

''These programs are a bit of the Holy Grail for anti-fraud programs, but have been exceedingly hard to implement,'' he told Bloomberg BNA.

Payment suspensions associated with prepayment reviews can also lead to political pressures on the government to drop the reviews, he said, adding, ''It will be very interesting to watch how these efforts play out.''

A central risk of prepayment and predictive modeling programs is suspending payment on legitimate claims, Kirk J. Nahra of Wiley Rein, Washington, said.

Nahra said a central risk of prepayment and predictive modeling programs is suspending payment on legitimate claims.

''The challenge will be to apply these principles to the real outliers—entities where there is no legitimate argument on the appropriateness of the claims, but not apply it in judgment or close call situations,'' he said.

Patton Boggs' Freedman agreed CMS will face the challenge of using prepayment review and predictive modeling appropriately.

''I certainly hope that CMS does not suspend payments based on a predictive modeling system,'' Freedman said.

According to Freedman, ''The suspension authority is too broad, and is not open to any due process or challenges, so this use of it would create serious issues for providers if there are not appropriate discussions prior to invoking it.''

NHCAA's Saccoccio said the risks from prepayment review and predictive modeling were not as large as some have made them out to be.

Specifically, Saccoccio said he does not think ''providers should be overly concerned that mere clerical errors will lead to suspensions.''

''Even in the rare case where payments were suspended for clerical errors, the provider eventually would be paid, assuming payment is warranted after review,'' Saccoccio said.

He said CMS will begin to suspend claims payments that are flagged by predictive analytics and validated by further review.

Anti-Fraud Waivers. As accountable care organizations debut in 2012, much attention will be focused on the effectiveness of anti-fraud waivers that were introduced in 2011 by CMS and OIG.

CMS and OIG published an interim final rule on the waivers in the Nov. 2, 2011, *Federal Register* (15 HFRA 854, 11/2/11).

Mintz Levin's Crane said the waivers will help remove roadblocks to joining an ACO. However, he said, the popularity of ACOs remains to be seen.

The waivers apply to certain provisions of the physician self-referral law (known as the Stark law), the anti-kickback statute (AKS), the civil monetary penalty (CMP) law related to prohibiting hospital payments to physicians to reduce services (also known as gainsharing), and the CMP law related to prohibiting inducements to beneficiaries.

''The waivers help broaden potential ACO participation. They are not likely going to be narrowed.''

— Lynn Shapiro Snyder, Epstein Becker & Green

CMS and OIG added several waivers to the interim final rule that were not included in the proposed rule, including a waiver for ACO activity prior to joining the Medicare Shared Savings Program (MSSP) and a waiver for patient incentives designed to increase the use of preventive health care.

The waivers were designed to strip away any obstacles to the formation of an ACO, but they may not function as planned, attorneys told Bloomberg BNA.

Wiley Rein's Nahra said ''to incentivize entities to participate [in ACOs], there needs to be some kind of protection from the potentially draconian results if a fraud case is pursued. So the waivers need to be very strong to give entities appropriate incentives to participate.''

He said ''the challenge will be to get this initial participation, and then still evaluate where there are real fraud risks that have specific diverse consequences to government programs, rather than focus on situations where there are failures to meet specific requirements because of the complexity of the rules.''

Nolan & Auerbach's White said the waivers would do little to deter fraud within the ACO program.

While they were written with the intent of increasing ACO participation, ''they do not construct a fraud-free zone for dishonest health care providers. Fraud follows government health care dollars,'' White said.

''In time, the ACO initiative will sink, when the waiver pendulum swings the other way, constricting these waivers to allow the government to rope in wayward providers,'' he said.

Moreover, some components of the waivers are still too restrictive, Crain said, such as the types of payments and incentives that may be made to beneficiaries to promote their use of health care.

Promoting ACO Participation. NHCAA's Saccoccio, however, said while the waivers are broad and may appear to increase the risk of fraud, they will actually lead to a decrease in overall fraud.

The waivers will help remove roadblocks to joining an ACO, Thomas S. Crane of Mintz Levin, said. However, he said, the popularity of ACOs remains to be seen.

According to Saccoccio, ''ACOs, with their focus on higher quality and lower cost, should decrease the overall incidence of unnecessary care with its attendant risk of fraudulent claims.

''The accountable in ACO will be the key for reducing the overall risk of claims fraud,'' Saccoccio said.

He also said the fraud waivers would encourage ACO participation.

Epstein Becker & Green's Snyder said the broad scope of the fraud and abuse waivers were necessary for increasing ACO participation.

''The waivers help broaden potential ACO participation,'' she said. ''They are not likely to be narrowed. If anything, more waivers are likely to accommodate these new methods to arrange and pay for care.''

McAnaney said the waivers will help eliminate major barriers in forming ACOs.

''The waivers will encourage cooperation between otherwise siloed providers,'' he said. ''That is not fraud. It is the solution to a broken system. Health care regulation needs to enter the 21st century.''

He said there was no way to test the ACOs without a broad waiver of anti-fraud laws, and he said the waivers will make it more likely providers will join ACOs.

Overpayment Reporting. As 2012 moves forward, providers need to keep a close eye on the overpayment reporting requirements mandated by PPACA, Crane told Bloomberg BNA.

Under Section 6402 of PPACA, providers are required to report and return an overpayment within 60 days of identifying it.

''Significant uncertainty remains as to the type of disclosures that providers need to make in addition to simply issuing refunds,'' Crane said.

He also said uncertainty remains over what constitutes identifying an overpayment.

''If a lower level employee finds a computer glitch that results in the provider being paid more than it is entitled to receive, is that the time at which the overpayment has been identified or is it when specific claims are identified?'' Crane said.

CMS needs to issue regulations governing the reporting and refunding of overpayments to clear up any lingering doubts, he said.

Medicare Strike Force Expansion. Another issue for providers is the possible expansion of Medicare Fraud Strike Force teams to additional cities.

The Medicare Fraud Strike Force program, a joint initiative between the Department of Justice and the Department of Health and Human Services, was created in 2007 and is currently operational in nine cities.

Wiley Rein's Nahra said he expected the program would expand to additional cities in 2012.

''I think these programs work well, and address the worst kinds of fraud cases—true criminal cases,'' he said.

''The Strike Forces are being effective, and are still quite a distance away from yielding diminishing returns.''

— Louis Saccoccio, National Health Care Anti-Fraud Association

Nahra said while it was not clear how much money the Strike Forces end up recovering, all of the targets are criminal, unlike some of the larger False Claims Act case, which can be open to interpretation.

Saccoccio also said he expects the Strike Force to expand in 2012.

''The Strike Forces are being effective, and are still quite a distance away from yielding diminishing returns,'' he said.

Saccoccio said there should be a long-term, multi-year commitment to the Strike Force model.

Nolan & Auerbach's White said even if the Strike Force program is starting to see diminishing returns, the benefits are still worth the overall effort.

''The public fisc would be well served if this program was expanded to other cities that are fraught with health care fraudsters,'' he said.

Evolution of Fraud Case Law

The year 2012 will likely prove an important year in the development of case law on the False Claims Act,

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Stark self-referral law, and the anti-kickback statute, health care attorneys told Bloomberg BNA.

The U.S. Supreme Court declined to review a split in the federal appeals courts concerning the extent to which health care providers can be held liable under the False Claims Act for submitting claims to federal health care programs that, while factually correct, are ''legally false,'' health care attorneys told Bloomberg BNA.

Absent Supreme Court guidance, federal circuit and district courts also will have to wrestle with the issue of ''implied certifications'' in FCA cases, as they carve out the extent to which a provider or supplier's noncompliance with state and federal health care laws can render subsequent claims for government payment under the FCA and state counterparts to be false.

For example, over the past few months, courts have wrestled with the reach of the False Claims Act as it applies to providers who have violated Medicare's conditions of participation, White, with Nolan & Auerbach, told Bloomberg BNA.

''Until recently, courts have ruled that these violations do not run afoul of the False Claims Act, for they are not 'express conditions of payment,' '' White said. ''However, a number of recent circuit court decisions have adopted a more sensible approach, finding that these violations can still trigger the False Claims Act when the conditions are, nonetheless, material to the government's payment decision.''

White said the lesson for providers is that they should not ignore regulations simply because they are Medicare conditions of participation.

Wading Into Murky Waters. ''Given the U.S. Supreme Court's recent propensity for misconstruing the False Claims Act, I am hoping, wishing, and praying that the Court refuses to wade into the murky waters of so called legally false claims,'' White said.

White got his wish. The Supreme Court declined to hear one of the cases that could have brought that matter to the fore, *United States ex rel. Hutcheson v. Blackstone Medical Inc.* (1st Cir., No. 10-1505, 6/1/11).

Amgen Inc., a pharmaceutical company, also had asked the high court to hear an appeal of a similar decision by the U.S. Court of Appeals for the First Circuit, *New York v. Amgen Inc.* (1st Cir., No. 10-1629, 7/22/11). However, in December 2011, Amgen withdrew the petition (*see related item in the Court Proceedings section*).

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The term ''legally false claims'' is a ''judicially created construct that has incorrectly derailed hundreds of meritorious False Claims Act actions over the years,'' White said.

Congress intended the FCA's core question of falsity to be whether the government received the benefit of its bargain, White said.

''If a health care provider knowingly deprives the government of that benefit, the FCA is triggered, regardless of whether the underlying obligation is dictated in a contract, a regulation, or a handshake,'' White said. ''Based on its recent track record, however, the U.S. Supreme Court would gladly tack additional, atextual evidentiary requirements to the back of legally false claims.''

No Supreme Court Guidance. Without Supreme Court guidance, however, federal circuit and district courts will continue to grapple with the issues of legally false claims and implied certification.

Crane, of Mintz Levin, defined implied certification as ''a rule of construction under the False Claims Act that generally means that a claim for payment to the government . . . is legally false if that party had an ongoing obligation to comply with an underlying law—regardless of whether that party submitted a factually false claim or directly certified when it submitted the claim that it had complied with that law.''

Many courts have adopted a narrow view of the theory, ''applying it only to underlying violations of law that have a direct link to payment,'' Crane said. ''Other courts, such as the First Circuit, have taken a more expansive view.''

With the Supreme Court's denial of certiorari in *Blackstone*, he said, ''coupled with the significant amount of FCA litigation in the First Circuit, it is likely that future cases out of this jurisdiction, and elsewhere, will further test the boundaries of the implied certification theory.''

Bad Facts Make Bad Law. Attorneys who represent providers are looking with trepidation at another case that eventually will make its way the U.S. Court of Appeals for the Third Circuit, *United States ex rel. Singh v. Bradford Regional Medical Center* (W.D. Pa., No. 04-186E, 11/1/11) (15 HFRA 903, 11/16/11).

The *Bradford* case has the potential to change the framework of Stark self-referral law and the anti-kickback statute, health care attorneys told Bloomberg BNA.

''The Bradford decision was driven by bad facts,'' McAnaney, Law Offices of Kevin G. McAnaney, Washington, told Bloomberg BNA.

In November 2010, Senior District Judge Maurice B. Cohill of the U.S. District Court for the Western District of Pennsylvania granted partial summary judgment to relators and against defendants in the Bradford case.

Cohill found that the arrangement between Bradford Regional and physicians Peter Vaccaro and Kamran Saleh ''took into account'' anticipated referrals.

An overly broad reading of ''take into account'' by the Third Circuit would be a disaster,'' McAnaney said.

Moreover, Lynn Shapiro Snyder of Epstein, Becker & Green, Washington, said: ''It is impossible not to take into account potential referrals, so hopefully this will be better addressed on appeal.''

McAnaney said, ''The district court decision is readily distinguishable from most hospital physician arrangements.''

Crane added that the *Bradford* decision highlights the need for hospitals to have rigorous compliance programs that effectively track financial arrangements

with physicians. This should include tracking contract expiration dates, documenting the ''bona fides of arrangements,'' and proving justification for fair market value, Crane said.

McAnaney said the danger in the case is that the Third Circuit will make the decision worse—a fear well founded given its decision in *United States ex rel. Kosenske v. Carlisle HMA Inc.* (554 F.3d 88 (3rd Cir. 2009).

In *Kosenske*, the Third Circuit said a Pennsylvania hospital named in a False Claims Act qui tam action failed to show that its arrangement with an anesthesiology group satisfied the personal services exceptions in the Stark law and anti-kickback statute.

Rigorous Compliance Programs. Another health care fraud case worth following in 2012, health care attorneys told Bloomberg BNA, is *United States ex rel. Drakeford v. Tuomey*, No. 3:05-cv-02858-MJP (D.S.C. 2010).

Tuomey, a nonprofit health care system, owned and operated a hospital, the only one in Sumter County, S.C. Tuomey also owned and operated specialty groups in areas such as surgery and ophthalmology.

When competition arrived, in the form of an ambulatory surgical center, negotiations began between the hospital and the center, as well as with employees of physicians who might direct revenue away from the hospital.

The groups commissioned a study to determine the hospital's potential lost revenue if the ambulatory surgical center opened.

The health care consulting company favored a compensation package for physicians who worked for the ASC designed to pay 131 percent of the amount received in referrals from the physicians. Eventually an agreement was struck based on this percentage.

The relator, Michael Drakeford, an orthopedic surgeon, and the government argued this compensation was above fair market value and violated the anti-kickback statute.

Tuomey appealed several issues to the U.S. Court of Appeals for the Fourth Circuit. The Fourth Circuit has scheduled oral arguments for Jan. 20 in Charleston, S.C.

DOJ Intervention. Crane said he will also be looking out for developments in *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center* (M.D. Fla., No. 6:09-CV-1002-ORL-31 DAB, *United States intervenes* 9/9/11).

The Department of Justice intervened in the False Claims Act lawsuit against a Daytona Beach, Fla., hospital that allegedly had improper financial ties to physicians who referred Medicare patients to the facility (15 HFRA 744, 9/21/11).

The government partially intervened regarding allegations that Halifax violated the Stark law, which prohibits a hospital from billing Medicare for services referred by physicians that have an improper financial relationship with the hospital.

DOJ said the case ''alleges that Halifax's contracts with three neurosurgeons and six medical oncologists were improper, in part, because they either paid physicians more than fair market value, were not commercially reasonable, or took into consideration the volume or value of the physicians' referrals.''

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