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Inside this issue

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Latest Fraud Takedown and CMS Fraud Detection Strategies Yield Big Returns

The U.S. Department of Health and Human Services (HHS), its Office of Inspector General, the Federal Bureau of Investigation, and the Justice Department's Criminal Division recently announced a nationwide "takedown" of 243 individuals in connection with an alleged Medicare fraud scheme involving more than $700 million in false billings. That takedown and a Centers for Medicare and Medicaid Services announcement regarding its Fraud Prevention System highlight the recent successes the government is having with using the latest in technology to fight fraud.

More Strategic Efforts Lead to Takedown

The individuals charged include 46 doctors, nurses and other licensed health care professionals. "The coordinated takedown is the largest in Strike Force history, both in terms of the number of defendants charged and the loss amount," according to an HHS press release.

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Whistleblower Employees May Not Have Carte Blanche to Confidential Information

Typically employees (or former employees) who turn whistleblower and file a *qui tam* lawsuit claiming that his/her employer violated the False Claims Act are protected from retaliation.

However, a whistleblowing employee's protections are not absolute. Employers are beginning to challenge these *qui tam* lawsuits on the grounds that the employee had no right to take and make public trade secret and other business proprietary information to support the *qui tam*—and it's working.

Example: Lorraine Notorfransesco, the billing manager of Springfield, Pa.-based Surgical Monitoring Assoc. (SMA), a private practice specializing in intraoperative neurophysiological monitoring, filed a whistleblower action against her employer alleging that SMA violated the False Claims Act. To substantiate her claim, she submitted patient records, invoices, billing records and customer billing rates. SMA countersued her, claiming that her action placed into the public record confidential and proprietary business information that was "commercially valuable" and that its release could cause it "irreparable harm."

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Whistleblower Employees May Not Have Carte Blanche, *from page 1*

Notorfransesco asked the court to dismiss the counterclaim on the grounds that the information wasn't confidential, she was under no obligation to keep the documents confidential, and that the counterclaim should be barred on public policy grounds.

The federal district court refused to dismiss the counterclaim, essentially saying that whistleblowers do not have carte blanche to take someone else's documents in order to file a *qui tam* lawsuit. First, Notorfransesco had signed a confidentiality agreement covering the documents at issue, agreeing to keep them confidential; the employee handbook also required employees to keep SMA's trade secret information confidential. And while there is a strong public policy argument for supporting whistleblower claims alleging improper billing, SMA's counterclaim is for "independent damages" for the competitive disadvantage it would suffer from the use of the information by competitors—so SMA could bring the counterclaim, the court said.

> ***"The best defense is a good offense. It's one of the hottest tactics [defendants are using]."***
>
> **—Gordon Schnell, Attorney, Constantine Cannon**

Whether SMA will prevail will depend on the nature of the documents and whether Notorfransesco took more than necessary to support her *qui tam* claim. The lawsuit is still pending.

Public policy prevails—to a point

This case is just one in a growing area in False Claims Act defense. "The best defense is a good offense. It's one of the hottest tactics [defendants are using]," explains attorney Gordon Schnell, with Constantine Cannon, a whistleblower practice, in New York City. While the False Claims Act as a matter of public policy supports whistleblowers' right to collect evidence to support a claim, particularly if the whistleblower believes that the employer may destroy the evidence, this defense is viable because it's not seen as retaliation but instead involves damages independent of False Claims Act liability.

The strength of an employer's challenge also depends on what records were taken. In addition to the confidentiality concerns, there also are no universal standards regarding the extent to which a whistleblower can gather company documents to support his or her False Claims Act action, according to attorney Judi Williams-Killackey, with Quarles & Brady in Milwaukee. "It's all over the board, and depends on the circumstances," she explains. Where an employee has gone too far in information gathering to support the claim, the court is more likely to allow the employer's counterclaim, says Williams-Killackey.

How labs can protect themselves

To reduce the risk that an employee will take confidential business information, labs should not leave such data unprotected and make sure that only employees who need access to it pursuant to their job responsibilities have such access.

Employees should also sign separate confidentiality agreements protecting proprietary trade secret and business information. This way it will be harder for an employee to claim that he or she didn't have an obligation to keep it confidential, as in the Notorfransesco case. And don't rely on a confidentiality provision in an employee handbook, because a court may not see a handbook as a "contract" and thus the confidentiality provision may not be enforceable, warns Williams-Killackey.

If your lab does end up as a defendant in a whistleblower lawsuit, tread carefully before using this tactic.

Also make sure that the confidentiality agreement isn't overreaching. It's okay for an employer to have language requiring an employee to keep proprietary business, trade secret and competitively sensitive information confidential, but overbroad language requiring confidentiality of "any documents" is probably not enforceable, says Schnell. If your state has particular requirements for these types of confidentiality agreements, make sure your agreements conform to these laws, says Williams-Killackey.

If your lab does end up as a defendant in a whistleblower lawsuit, tread carefully before using this tactic. Any counterclaim needs to be in good faith and not in retaliation for having filed the claim. "You don't want to create more problems by challenging the *qui tam*," says Williams-Killackey.

You'd also want to determine whether you have good grounds to challenge the lawsuit this way. For instance, Schnell recommends to his whistleblower clients that employees don't go fishing for documents, don't collect documents that would fall outside of one's job responsibilities, don't take original documents, take only what's needed and take documents directly related to the False Claims Act claim. "Reasonableness is the strongest defense to these counterclaims," he says.

(*Notorfransesco v. Surgical Monitoring Assocs.*, No. 09-1703 (E.D. Pa. Dec. 12, 2014)).

Takeaway: Labs may not be able to stop employees from becoming whistleblowers, but they can better protect their confidential business information from exposure in a qui tam lawsuit—and may be able to forestall the suit from being filed. G2

Original Source Rule Clarified in 9th Circuit

While the *Notorfransesco* case addresses the documents a whistleblower can use to make a *qui tam* claim, the 9th Circuit Court of Appeal clarified a rule that governs who can bring a whistleblower or *qui tam* cause of action. The 9th Circuit revisited a decades old interpretation of a rule that barred whistleblower actions based on publicly disclosed allegations unless the person bringing the action was the original source of the information. Federal law defines an original source as someone with "direct and independent knowledge" of the facts and who "voluntarily provided the information to the Government before filing" the whistleblower action.

The case involved claims brought by two different employees relating to Medicare claims for a wound healing device. These claims were initially denied because the court determined that the information on which the claims were based had already been publicly disclosed and the whistleblowers weren't the original source of the information.

Previously, the 9th circuit had interpreted original source rule to require three criteria be satisfied to find a whistleblower plaintiff is an original source: 1) direct and independent knowledge of the relevant information; 2) voluntary submission of the information to the government before filing a whistleblower claim; and 3) having a "hand in the public disclosure" of the information. The 9th circuit reviewed that old interpretation and decided that it was contrary to the language in the False Claims Act. Noting that other circuit courts didn't impose the "hand in public disclosure" requirement, the 9th Circuit declared it would give that requirement "a respectful burial," leaving only the first two requirements.

The court also addressed a "first-to-file" rule that prevents piggybacking of whistleblower claims. Only the first whistleblower to file can bring and profit from a *qui tam* or whistleblower action. No one else can file a whistleblower claim based on the same facts. In this case, while both employees asserted claims related to misuse of a modifier, the second whistleblower also had claims that related to violations of a different Medicare requirement—the need for Detailed Written Orders to support delivery and treatment with the wound healing device at issue. The court agreed that those claims were not made in the first whistleblower's complaint so the second whistleblower could bring those specific claims separately without violating the first-to-file rule.

(*U.S. ex rel Hartpence v. Kinetic Concepts, Inc.*, Nos. 12-55396, 12-56117 (9th Cir. July 7, 2015)).

AG's Office Offers Compliance Tips While Noting New Enforcement Strategies

The Department of Justice's Assistant Attorney General for the Criminal Division has offered some helpful tips regarding how to avoid liability for compliance violations relating to Medicare reimbursement. Assistant Attorney General Leslie R. Caldwell, recently addressed two compliance audiences and taken together, her comments highlight new strategies for fraud enforcement and suggestions for avoiding compliance problems that laboratory compliance officers should consider.

Why You Should Listen

Noting that "Medicare Fraud remains a serious drain on our health care system," Caldwell addressed the American Bar Association's 25th Annual National Institute on Health Care Fraud and discussed future enforcement efforts, specifically highlighting laboratory services. "Strike Force is looking at emerging fraud trends, and we are seeing those in areas including Medicare Part D, laboratory services, hospital-based services and hospice care. These are the latest frontiers in Medicare fraud. … [W]e are working hard to identify those engaged in these new schemes and to bring them to justice."

> *"The Strike Force is a model of 21st Century data-driven policing."*
>
> —Leslie R. Caldwell, Assistant Attorney General

Caldwell contrasted early enforcement efforts, which relied on the Centers for Medicare and Medicaid Services to refer cases to the Department of Justice, with current efforts in which the Medicare Fraud Strike Force's "intensive health care fraud enforcement efforts" target billing issues most often subject to fraud. Advances in data collection and usage are helping Strike Force achieve its success, according to Caldwell. "The Strike Force is a model of 21st Century data-driven policing." Strike Force now uses nearly real-time billing data from CMS to "bring cases more quickly" and "identify emerging fraud schemes and new types of Medicare fraud" or existing fraudulent conduct that is expanding geographically. She also advised that the Division is using "traditional investigative techniques" including undercover officers, wires, bugs, hidden cameras, and GPS tracking. Strike Force is also pursuing high-level individuals including physicians and executives as well as multi-district cases, she noted. See page 9 for how the Centers for Medicare and Medicaid are similarly using the latest in data analytics to ferret out improper payments.

Check for Hallmarks of an Effective Compliance Program

Addressing the Compliance Week Conference, Caldwell highlighted the "hallmarks of effective compliance programs" for all types of organizations noting that "compliance programs are too often behind the curve, effectively guarding against yesterday's corporate problem but failing to identify and prevent tomorrow's scandals." The hallmarks she referenced echo the principles espoused in the OIG Compliance Program Guidances:

- Senior leadership promotes a culture of compliance and "provide[s] strong, explicit and visible support" for compliance policies—noting the Division looks not just at written policies but other messaging through meetings, emails, incentives and bonuses.
- Senior level executives take responsibility for overseeing compliance.
- Clear and easily understood compliance policies.

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Outcome of LDT Regulation Controversy Defies Forecasting

Few, if any, device regulatory issues are as controversial or as important as FDA's proposal to regulate Laboratory-Developed Tests (LDTs). If FDA LDT regulation does occur, it would represent the largest change in the regulation of diagnostic tests since Congress enacted the Clinical Laboratory Improvement Amendments (CLIA) in 1988. It would also represent the largest expansion in FDA regulation over a class of products since Congress gave FDA the authority to regulate tobacco products. Given the growing number and clinical importance of laboratory tests, the impact would be profound indeed.

The current loud debates represent the culmination of a process that quietly began 23 years ago.

Underscoring the complexity of the issue, the LDT debate implicates all three branches of the federal government. First, the Executive Branch, through FDA, the Department of Health and Human Services (HHS), and the Office of Management and Budget (OMB) will need to review and endorse any LDT proposal before it takes effect. Second, if a final LDT guidance is adopted, litigation appears inevitable. The American Clinical Laboratory Association (ACLA) has already announced the hiring of two prominent litigators and filed comments strenuously objecting to FDA regulation. Third, Congress may weigh in.

History Behind LDT Debate

The current loud debates represent the culmination of a process that quietly began 23 years ago. In 1992, FDA issued a draft compliance policy guide relating to the regulation of "Research Use Only" products. FDA inserted one inconspicuous sentence that stated, in an almost off-handed manner, that FDA had the authority to regulate LDTs (known as "home brews" back then).

That assertion of power prompted a citizen petition—filed by the author—challenging FDA's authority to regulate LDTs. Five years later, FDA made it clear that the petition would be denied when the preamble to the Analyte Specific Reagent (ASR) regulation emphatically reaffirmed FDA's power to regulate LDTs. The next year FDA formally rejected the citizen petition.

While asserting in the 1997 ASR preamble that it had the power to regulate LDTs, FDA disclaimed any present intention to invoke that power. However, as the role of laboratories has evolved, so have FDA's views. FDA now proposes active regulation of virtually all LDTs.

For many years after publication of the ASR regulation, FDA, in fact, did not seek to regulate LDTs. The rise of more complex, multi-marker tests in which scores were generated through an algorithm, prompted a change in approach. On September 7, 2006, and again on July 26, 2007, FDA unveiled a proposal to regulate a cumbersomely named new class of tests: In Vitro Diagnostic Multivariate Index Analyses (IVDMIAs). The proposal drew considerable criticism on a variety of grounds, including that it was technology-based, not risk-based. Commenters also noted the difficulty in telling whether a test qualified for IVDMIA status. In the face of this opposition, FDA backed off its IVDMIA proposal.

FDA instead said it was considering a vastly expanded proposal: the regulation of all LDTs. FDA announced that it was contemplating regulating all LDTs on a risk-based approach. In June 2010, FDA held a public meeting to get feedback on this new strategy.

At the urging of laboratories concerned by the prospect of FDA regulation, Congress enacted a provision in 2012 that required FDA to give Congress 60 days notice before issuing a draft guidance or regulation covering LDTs. Adhering to that requirement, on July 31, 2014, FDA gave Congress notice of its intent to issue two draft guidance documents establishing a regulatory framework for LDTs.

During that 60-day period, the House Committee on Energy & Commerce Subcommittee on Health held a public hearing on the proposal, but Congress took no other action. On October 3, 2014, FDA duly issued the Framework for comment to the public, with only a handful of minor changes.

While some of these arguments can be sharply contested, one other factor cannot be disputed: that LDTs play a much more important role in health care today than they did years ago.

Implications of Current Proposed Framework

The proposed Framework would transform the regulation of LDTs by largely applying the device regulatory regime to them. Currently, LDTs are regulated at the federal level under CLIA. Laboratories also are subject to state regulation, most notably by New York State, as well as by professional organizations, such as the College of American Pathologists. While these regulatory requirements are extensive, FDA's device regulations would impose many new obligations.

In announcing the Framework, FDA explained why it believed the current regulatory regime was inadequate. FDA cited, among other factors, the change in the laboratory industry, particularly a shift from tests conducted locally to LDTs run on samples collected throughout the country. FDA asserted that CLIA did not provide adequate assurance of clinical validity. FDA also alleged that there had been quality problems with some LDTs. However, FDA has provided only a handful of examples to support this rationale. Another reason given was that there was an "uneven playing field" between LDTs and FDA-regulated diagnostic products.

While some of these arguments can be sharply contested, one other factor cannot be disputed: that LDTs play a much more important role in health care today than they did years ago. Yet the argument cuts both ways, for there is considerable apprehension that FDA regulation would handicap a dynamic, innovative industry that is constantly introducing tests that would otherwise be unavailable if the device regulatory regime applied to them.

If adopted, the Framework would result in the regulation of virtually all LDTs. FDA would no longer exercise "enforcement discretion"; rather, LDTs would be regulated essentially the same as distributed in vitro diagnostics (IVDs).

The level and timing of the regulation of an LDT would largely be a function of risk. Under the Framework, all LDTs, with the exception of those for forensic use and certain LDTs for transplantation, would be subject to basic device requirements such as adverse event reporting. In addition, many LDTs would be subject to FDA premarket review. LDTs sub-

ject to premarket review would be divided into two categories: high risk and moderate risk. The high-risk category would itself be subdivided into highest-risk LDTs, such as companion diagnostics. The laboratory would need to submit a premarket approval application (PMA) for these LDTs within one year of finalization of the Framework. Other high-risk devices would get a longer reprieve: Some PMAs could be deferred for up to five years. For moderate-risk tests, the deadline for submitting 510(k) notices would extend out as far as nine years. The Framework is short on specifics on exactly how tests will be assigned their deadlines for PMA or 510(k) submission.

While it is uncertain where FDA will draw the line, it is certain that some commenters will be unhappy with whatever FDA chooses.

To minimize disruption, the proposed Framework authorizes grandfathering for high-risk tests: existing high-risk tests could remain on the market as long as an application is submitted in a timely manner. FDA officials have stated that they would offer a similar grandfathering approach for moderate-risk LDTs, although this is not explicitly stated in the Framework draft guidance. Thus, if rumors were to spread of the impending release of a final guidance, it would not be surprising if many laboratories accelerated the release of their LDTs.

Yet even this seemingly straightforward technical element—grandfathering of marketed LDTs—illustrates the gaps in the draft Framework. What conduct would constitute marketing? Advertising the test? Running at least one sample? An even more significant foreseeable question is how static must the test be that is grandfathered. Could the laboratory change its pre-analytic steps? Could it modify the test to add a mutation? Replace an analyzer? (Some LDTs that have been reviewed by FDA specify not only the type of equipment but the serial number.)

Another aspect of the LDT Framework—which has received far more attention than grandfathering—is neither technical nor seemingly straightforward: tests for rare diseases. There is agreement that imposing the full rigor of device regulation on LDTs for rare conditions would have an unduly adverse effect on access. Therefore, FDA has proposed a much reduced regulatory regime for these assays if they qualify for an exception.

FDA's proposal, however, essentially vitiated the exception. FDA applied a cut-off of 4,000 tests. This is unworkable; for example, some tests in neonates will have a prevalence of less than 1 in 10,000. FDA has indicated that the 4,000 tests limit does need to be raised. The question, then, is what is the appropriate level? FDA has heard a diversity of views, both in written comments and at a January 8-9, 2015 public meeting. While it is uncertain where FDA will draw the line, it is certain that some commenters will be unhappy with whatever FDA chooses. And the question of where to draw the line for rare diseases is just one of the many controversial issues that has arisen.

New Developments and Next Steps

Subsequent to the closing of the comment period, FDA and the Centers for Medicare & Medicaid Services (CMS)—the part of HHS responsible for implementing CLIA—announced a Joint Task Force. One of the primary goals was to address "stakeholder confusion about the roles of the two agencies." The task force's objectives include improving inter-agency collaboration, identifying similar regulatory requirements under FDA's and

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CLIA's regulations, and outreach. The impact of this initiative remains to be seen. While greater FDA-CMS collaboration may be helpful, it is unlikely to assuage fundamental concerns over LDT regulation by FDA.

Ultimately, discontent among stakeholders would almost surely be the fate of any final LDT Framework FDA releases. Given the sharply divergent perspectives, ranging from LDTs are dangerous and stifle IVD development to LDTs are essential and must be unregulated, dissatisfaction with a final Framework is inevitable.

Releasing a final document will not be simple. FDA received over 200 written comments to its proposal. It also heard many competing perspectives at its January meeting, as well as additional comments from groups that have met with FDA. These comments provide an array of ideas, suggestions, views, and criticisms. Presumably, if FDA does move forward, it will elect to make at least some major substantive changes to address the comments. Yet FDA may feel somewhat constrained: dramatic modifications could result in a chorus of complaints that there was no opportunity to comment on the revisions.

Congress is currently working on legislation that would substantially revamp FDA regulation in a myriad of ways.

FDA's revised draft final Framework would then need to be reviewed by HHS. HHS is bound to be heavily lobbied by various interest groups. OMB review would be next. Again, the lobbying would likely be intense. And the clock is ticking. If a final guidance is not released by the end of the Obama administration, a new president will be pressed to put the LDT Framework on hold.

However, even if the final Framework runs this gauntlet and beats the clock—an outcome FDA has pushed for—FDA may not have the final word. ACLA has made no secret that it would be prepared to sue. While FDA believes it would be on solid legal ground, there are vulnerabilities. First, it is not certain that LDTs are even "devices" within the meaning of the law. Second, it is far from clear that Congress authorized FDA to regulate LDTs. In enacting CLIA, Congress made no mention of FDA's authority over labs. (FDA's explanation is basically that FDA's authority was so well known in 1988 that no mention was needed.)

Third, FDA would be upending the regulatory regime for LDTs through guidance documents, rather than by issuing a regulation. FDA's decision to bypass rulemaking opens the agency up to a strong charge that it has violated the Administrative Procedure Act (APA). FDA's primary response appears to be that because it had the authority to regulate LDTs, issuing a regulation was not necessary. How this litigation would play out is far from clear. In my view, FDA's successful defense is not assured, particularly on the APA argument.

Potential Alternatives to FDA Framework

Conceivably, though, neither FDA not the courts will have the final word. Congress could enact legislation which would supersede any FDA proposal. Congress is currently working on legislation that would substantially revamp FDA regulation in a myriad of ways. The House Energy & Commerce Committee has released a discussion draft which covers IVD regulation. If adopted, it would substantially revise FDA's regulation of IVDs, including LDTs. Under the proposal, LDTs would be regulated by FDA, albeit at a lower level

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Latest Fraud Takedown and CMS Fraud Detection Strategies Yield Big Returns, *from page 1*

"This record-setting takedown sends a message to would-be perpetrators that health care fraud is a risky way to line your pockets," said HHS-OIG Inspector General Daniel R. Levinson in the release. "Our agents and our law enforcement partners stand ready to protect these vital programs and ensure that those who would steal from federal health care programs ultimately pay for their crimes."

The Affordable Care Act is credited with providing new enforcement resources and $350 million in funding that financed additional prosecutors and expanded Strike Force activities, enabling enforcement initiatives such as this takedown. Assistant Attorney General Leslie R. Caldwell also explained in the release how the Department of Justice has become "more strategic" in finding and prosecuting fraud: "We obtain and analyze billing data in real time. We target hot spots—areas of the country and the types of health care services where the billing data shows the potential for a high volume of fraud—and we are speeding up our investigations." For further discussion of new strategies for fighting fraud and tips for improving compliance, see page 4.

OIG Evaluates Use of Analytics to Detect Fraud

The Department of Health and Human Services' (HHS) Office of Inspector General was charged with certifying the savings achieved under the Fraud Prevention System (FPS) and determining the return on investment. An OIG report released this month reviewed whether HHS properly reported savings from the use of analytics and whether use of the FPS should be continued, expanded or changed. That report indicates the system yielded more than $133 million in adjusted actual and projected savings for Medicare—$85 million from FPS-initiated administrative actions and $47 million from administrative actions in which an FPS lead "contributed to the existing investigation." Adjusted saving is the amount of identified savings that can actually be achieved. Administrative actions include payment suspension, referral to law enforcement, overpayment recovery, prepayment edits, automatic denials or rejections and even revocation of Medicare billing privileges. The OIG calculated a $2.84 return on investment for each dollar spent.

The OIG's 2015 report on the third year of the system's operation concluded that use of FPS does "enhance[] and should continue to enhance its efforts to prevent fraud, waste and abuse in the Medicare Fee-for-Service program" and it achieved a positive return on investment. However, the report indicates that HHS didn't find it "cost-effective and feasible, at this time" to expand use of predictive analytics in all 50 states "because of policy differences among programs" information technology readiness, resources and data availability. The OIG also recommended that Medicare contractors be better informed about how to attribute FPS savings and document the impact of FPS leads on administrative actions.

The allegations in this takedown include anti-kickback violations, money laundering and aggravated identity theft relating to home health care, psychotherapy, physical and occupational therapy, durable medical equipment and prescription drugs. The government alleges that the individuals charged billed for equipment, care and services not actually provided. While the cases involve allegations only at this point and must be proved in court, with these new charges, the Department of Justice said national takedown operations to date have yielded charges for over 900 individuals and involved more than $2.5 billion in billings. This latest takedown emphasizes the increased attention and resources devoted to health care fraud enforcement efforts and prosecution of physicians and other individuals in addition to large organizations.

FPS Use of Analytics Proactively Fights Fraud

The takedown also comes at the same time that the Centers for Medicare and Medicaid Services announced its Fraud Prevention System (FPS), an "advanced analytics system," has uncovered $820 million in inappropriate payments. The system uses state of the art techniques similar to those alluded to in comments regarding the Strike Force takedown. The FPS employs "predictive modeling and other analytics technologies to find and avoid payment of improper Medicare claims." Using analytics in much the same way credit card companies do, the system finds "troublesome billing patterns and outlier claims." CMS indicated in a press release that

"The third year results of the Fraud Prevention System demonstrate our commitment to high-yield prevention activities, and our progress in moving beyond the 'pay and chase' model."

—Dr. Shantanu Agrawal, CMS Deputy Administrator

it intends to use the system not just to identify and prosecute fraud but also to ferret out potential payment issues that are not necessarily the result of illegal intentions but could be "better served by education or data transparency interventions."

"We are proving that in a modern health care system you can both fight fraud and avoid creating hassles for the vast majority of physicians who simply want to get paid for services rendered. The key is data," Acting CMS Administrator Andy Slavitt said in a press release. Referring to the system's identification in 2014 of $454 million in improper payments, Slavitt declared: "Very few investments have a 10:1 return on taxpayer money."

CMS explains that the analytics help spot potentially improper billing patterns and use information about past billing practices to find fraud. CMS says these "predictive models" helped it identify questionable payments to a podiatrist and ambulance provider. CMS Deputy Administrator and Director of the Center for Program Integrity Dr. Shantanu Agrawal emphasized the system's ability to facilitate a more proactive approach to fighting fraud: "The third year results of the Fraud Prevention System demonstrate our commitment to high-yield prevention activities, and our progress in moving beyond the 'pay and chase' model."

Takeaway: New technologies and use of data analytics give enforcement efforts a boost and aid in not only detecting fraud but finding and preventing potential for improper payments as well. G2

G2 Compliance Corner

Don't Overlook Free Resources When Preparing Your Laboratory for ICD-10

The transition to ICD-10 is approaching fast and laboratories need to ensure they are prepared. While the Centers for Medicare and Medicaid Services (CMS) has indicated in answers to Frequently Asked Questions that Medicare contractors won't deny physician or other provider claims billed under the Part B physician fee schedule based solely on the specificity of the ICD-10 diagnosis code as long as a valid code from the right family is used, valid ICD-10 codes are needed after Oct. 1, 2015. You also shouldn't count on that grace period and instead get your laboratory up to speed before the deadline. To help you, CMS and the American Medical Association recently highlighted some free educational resources that can help providers prepare for the new codes.

Among the resources CMS has provided to help physicians adjust to ICD-10:

- "Road to 10" – a web-based resource for small physician practices that includes a quick start guide, an interactive case study tool that quizzes providers on coding specific clinical scenarios—with new scenarios added weekly, specialty-specific tools, webcasts, videos and assistance in building an action plan for the transition.
- Training videos.
- Frequently Asked Questions that indicate there will be some flexibility to account for errors in coding under the new ICD-10 system.

CMS also plans to establish an ICD-10 Ombudsman to assist providers in the transition as well as a communication and collaboration center to monitor implementation. The agency promised guidance explaining how to submit issues and concerns to the Ombudsman.

Note too that CMS has provided You Tube videos titled "ICD-10 Coding Basics" and "Coding for ICD-10-CM: More of the Basics," both of which specifically include laboratories in the target audience listed. CMS highlighted the "More of the Basics" video in a recent MLN Matters article regarding CLIA-Waived tests. The video includes presentations from American Health Information Management Association and American Hospital Association representatives and offers an introduction to ICD-10 coding and its unique characteristics as well as a comparison to ICD-9 coding.

OIG Enforcement for First Half of Fiscal 2015, *from page 4*

- Adequate funding and resources for compliance staff.
- Adequate funding and resources for internal investigations.
- Periodic review of "compliance policies and practices" and updating as necessary to meeting changing risks.
- "[E]ffective system for confidential, internal reporting of compliance violations."
- Enforcement mechanisms, incentives for compliant conduct and discipline for noncompliant conduct.
- Holding third parties with which the organization works accountable for their compliance.

> ***"A company should not expect to receive cooperation credit for just producing documents in response to a grand jury subpoena. To the contrary, compliance with lawful process is a legal requirement, not voluntary cooperation."***
>
> **—Leslie R. Caldwell, Assistant Attorney General**

Truly Cooperate with Investigations

Discussing prosecution of corporate entities, Caldwell explained the value of corporate cooperation. Caldwell explained that entities seeking to benefit from alleged cooperation must "conduct a thorough internal investigation and turn over all available evidence of wrongdoing to our prosecutors in a timely and complete way" and identify culpable individuals, even if evidence points toward high level executives. "A company should not expect to receive cooperation credit for just producing documents in response to a grand jury subpoena," said Caldwell. "To the contrary, compliance with lawful process is a legal requirement, not voluntary cooperation."

In discussing the criminal division's collaboration with the Civil Division on parallel prosecutions, Caldwell noted that prosecutors consider the severity and pervasiveness of the alleged activity and the culpability of individuals, among other factors, when deciding whether to bring criminal prosecution.

Takeaway: Fraud enforcement in the laboratory sector isn't abating any time soon as the Department of Justice names laboratory services as one focus of its efforts. So consider tips the Assistant AG highlights for effective compliance programs and cooperation during investigations. G2

Compliance Perspectives: Outcome of LDT Regulation Controversy Defies Forecasting, *from page 8*

than what FDA has proposed. IVD regulation would generally be reduced from its current level. Whether this legislation will be enacted and, if so, in what form, remains entirely unclear. The 21st Century Cures legislation adopted by the House did not address LDTs. In the meantime, a group of labs and IVD companies called the Diagnostic Test Working Group have tried to craft their own legislative solution.

The current unpredictability seems fitting for LDTs. For over two decades, the topic has defied forecasting. It is possible that in the relatively near future, a new regulatory regime will be established, either by congressional legislation, or by FDA administrative action that survives the internal review process and judicial review. Or, these efforts may come to naught, leaving the story of FDA regulation of LDTs without an ending. G2

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News at a Glance

Medicare Celebrates 50th Birthday. This month, Medicare and Medicaid reached a milestone birthday. On July 30, 1965, President Lyndon B. Johnson signed legislation establishing those federal health insurance programs. The Centers for Medicare and Medicaid Services (CMS) reports that there are currently 55 million Americans benefitting from Medicare and that "in any given month" over 70 million benefit from Medicaid. "As we take a moment to reflect on the past five decades, we must also look to the future and explore ways to strengthen and improve health care for future generations," said Andy Slavitt, acting administrator of the CMS, in a statement. CMS also announced this month that a Medicare Trustees Report indicates the trust fund supporting Medicare hospital insurance coverage is still projected to remain solvent until 2030 and that cost growth continues to be low. Medicare spending growth per enrollee has been averaging 1.3 per cent during the last five years, according to a CMS press release announcing the report. "Growth in per-Medicare enrollee costs continues to be historically low even as the economy continues to rebound. While this is good news, we cannot be complacent as the number of Medicare beneficiaries continues to grow," said Slavitt in the release. "That's why we must continue to transform our health care system into one that delivers better care and spends our dollars in a smarter way for beneficiaries so Medicare can continue to meet the needs of our beneficiaries for the next 50 years and beyond."

Lengthy Sentence for Physician in Lab Referral Case. Yet another physician has been sentenced in connection with the Biodiagnostic Laboratory Services (BLS) case, receiving one of the longer sentences in the matter. Frank Santangelo, of Boonton, New Jersey was sentenced to over five years in prison after pleading guilty to Travel Act violations, money laundering and failing to file tax returns. In addition to prison, he also received three years supervised release and a $6,250 fine and $1.8 million forfeiture pursuant to his plea agreement. The government alleged Santangelo received over $1.8 million in bribes in exchange for referrals and BLS gained over $6 million in Medicare and private insurance payments relating to the referrals. A second physician was also sentenced this month to 21 months in prison for his involvement in the BLS case. Anthony DelPiano, of Monmouth Junction, had pleaded guilty to one count of accepting bribes. He also received one year supervised release, a $10,000 fine and must forfeit $207,500. So far, 38 people including 26 physicians, have pleaded guilty in connection with the BLS investigation.

FDA Approves Theranos Assay. California-based Theranos announced it received FDA approval for its herpes simplex virus-1 (HSV-1) IgG assay. The FDA decision, issued July 2 through the 510(k) process, clears for sale the Theranos HSV-1 IgG assay, which Theranos offers for $9.07. The laboratory-developed test (LDT), an enzyme-linked immunosorbent assay, is cleared for use on the company's automated, proprietary platform with venous blood and fingerstick blood. "FDA review is a uniquely rigorous process we undertook voluntarily because we remain deeply committed to ensuring that our systems and all of our laboratory developed tests are of the highest quality, and that patients and their physicians have access to the most accurate information about their health," said Holmes in a statement issued by the company. Meanwhile, as we reported in the April issue of *G2 Compliance Advisor*, the bill that Theranos lobbied into Arizona law took effect this month allowing Arizona residents to order any laboratory test they want without a doctor's authorization. G2

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