Volume XIV, Number 12 Monday, August 27, 2007

*From the Desk of R. Lewis Dark...*

# THE DARK REPORT

**RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs**

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# COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

## EMR Links as Labs' Next Competitive Advantage

WE ARE CAREFULLY TRACKING THE ACCEPTANCE AND USE of electronic medical record (EMR) systems by office-based physicians. It is an important trend, one that is both an opportunity and a threat for regional laboratories.

As you will read on pages 3-6, once physicians install and begin to use EMR in their daily practice, literally the first ancillary service they want is a direct electronic feed of laboratory test results into the EMR. Then, as physicians grow familiar with working with the EMR, they next want the ability to electronically order tests from their EMR.

It is no surprise, then, that independent labs and hospital laboratory outreach programs are beginning to spend money to create electronic interface gateways between their laboratory information system (LIS) and the EMRs of their physician-clients. The depth and breadth of this trend was confirmed at the special LIS-EMR Interface Gateway program at the *Executive War College* last May in Miami.

This presents an opportunity for regional labs. As clients implement an EMR, the laboratory provider must be ready to create the electronic bridge that allows the seamless transmission of laboratory orders and lab test results back and forth between the EMR and the LIS. As labs succeed in this, they have a strengthened relationship with each client—a relationship that adds value to the physician and makes it tougher for competing labs to win that account.

The threat is simple. Failure by regional labs to respond to clients' needs for direct EMR-LIS ordering and results reporting will cause the client to seek another laboratory which can provide such electronic interface gateways.

There are two labs in the United States which understand this fundamental strategic shift: **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**. As one software wonk told us, "The two national labs are all over this right now—integrating their LISs to EMRs." In fact, this is a perfect example of how economies of scale and national reach provide the two blood brothers with competitive advantage. Each national lab has ample resources to invest in writing the code to connect their informatics systems to every major EMR vendor's product. Regional labs should pay heed to this strategic shift in the marketplace. Because the largest medical groups are first to implement EMRs, it is the regional labs' biggest clients who will be first to ask for direct LIS-EMR lab ordering and results reporting. TDR

# Getting Connected: Labs Find Value in EMR Links

## Early adopter labs are using LIS-EMR links to forge tight business relationships with clients

***CEO SUMMARY: As physicians deploy electronic medical record (EMR) systems, they quickly ask their laboratory for electronic results reporting directly into the EMR. Later, these doctors will ask for electronic test orders from their EMR. Savvy labs are using this opportunity to develop closer business relationships with their clients. Two experts in the EMR field offer insights about how to succeed with this strategy.***

PHYSICIAN ADOPTION of electronic medical record (EMR) systems is changing the way many doctors order their laboratory tests and receive lab test results. A new company is ready to exploit this fast-moving trend by linking physician EMRs with their laboratory providers.

The new company is **Ignis Systems Corporation**, based in Portland, Oregon. Its founders are Pat Wolfram, Vice President of Marketing and Customer Services, and Ken Willett, President and Chief Technologist. The goal of their company is to help independent labs and hospital laboratory outreach programs achieve bi-directional electronic test ordering and lab test reporting that is fully integrated within the EMR workflow of physician-clients and their staff.

Before joining Ignis Systems, Wolfram was the Global Product Manager for EMR Interoperability at **GE HealthCare Information Technologies** in Beaverton, Oregon. An expert in EMRs, Wolfram told THE DARK REPORT'S *Executive War College* in May that about 60,000 to 70,000 physicians have EMRs installed today. He also predicted that, "in the coming years, EMR adoption will proceed steadily so that about 200,000 physicians will have them installed by 2011."

Wolfram's participation at the *Executive War College's* full-day session on creating interface gateways between the laboratory information system (LIS) and the physicians' EMR led directly to the current strategy of Ignis Systems. "There were 250 lab directors in attendance and presentations were made by most of the software companies installing interface gateways between

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

physicians' EMRs and their laboratory provider," observed Wolfram. "It made us realize the business opportunities that already exist to help physicians and labs enable real time lab test ordering and reporting through the use of electronic links between the EMR and the LIS."

In recent years, Willett has written interconnect software for the GE Centricity EMR to enable the system to place orders and accept results from ancillary service providers, particularly laboratories. "That EMR interface gateway seminar at the *Executive War College* inspired us to join forces at Ignis Systems," stated Willett. "We already have a working interface gateway for this EMR product, which is currently used by more than 20,000 physicians. We are making swift progress on a more universal electronic interface gateway that will enable hospital laboratories to connect their LIS to the physicians' EMR for direct lab test ordering and lab test reporting."

Because Wolfram and Willett have actively worked inside an EMR company and helped physicians implement and operate their EMR system, THE DARK REPORT asked them to share their insights about how physician use of EMRs changes the daily relationship a doctor's office has with its laboratory provider.

## ➤ Meeting Clients' Needs

"For pathologists and lab directors interested in developing interface gateways between their LIS and the EMR systems of their physician clients, three key elements are required to succeed," said Wolfram. "First, physicians who have made the substantial investment in EMRs use the EMR as their cockpit for managing all aspects of patient care. The EMR facilitates clinical staff workflows, manages medications, trends vital signs, maintains family history, reviews lab/radiology/cardiology reports, and orders tests and treatment plans. Since labs account for such a large part of a patient's clinical profile, physicians expect lab tests to be orderable and reportable within their EMR cockpit.

"Second, labs must understand the IT (information technology) strategy of their clients," Wolfram added. "Every year, new surveys confirm that almost every physician group in the United States is thinking about an EMR strategy or is in some stage of deploying such systems.

"Here is where regional laboratories and hospital lab outreach programs will find plenty of opportunity," he continued. "Every physician in the United States has either: 1) deployed an EMR already; 2) is deploying an EMR; 3) is budgeting for an EMR deployment; 4) or is creating a plan for EMR acquisition and use.

"A lab should approach its biggest clients and determine where they are on the EMR adoption curve," Wolfram added. "Use this information to develop a proactive strategy to work with these clients on their EMR deployment. Become part of their EMR strategy

## ➤ Look For Existing Interfaces

"Third, leverage your hospital's IT infrastructure," he said. "Your hospital outreach strategy is so much more appealing to a physician group if you show them a roadmap that shows their EMR integrated to your lab services, followed later by access to your hospital's radiology services (images and interpretations), cardiology ECGs, echocardiograms, perinatal discharge summaries, and so on.

"In your discussions with the hospital's IT leadership, the lab should determine which EMR vendors are already capable of interfacing directly with the hospital's IT system and with your laboratory's LIS," Wolfram advised.

"Specifically, which EMR vendors are able to connect via the HL7 protocols? Which EMR vendors can already interface electronically with other clinical departments in the hospital? HL7 refers to **Health Level Seven, Inc.** [*www.HL7.org*], a nonprofit, standards developing organization that facilitates the exchange of health care data," Wolfram said. "In that same

vein, determine if the EMR vendors are active in improving and adopting interoperability standards. Complementing HL7 are IHE, ELINCS, and other standards bodies that will make the hospital integration challenge less foreboding."

Wolfram and Willett next discussed how physicians want to use EMRs in their daily medical practice. "What physicians value is having results on screen alongside the patient's medications, allergies, diagnoses, and vital signs," noted Willett. "They want their EMR systems to be much like the paper charts they have used for years. Moreover, physicians insist that EMRs support the way they see and interact with patients. It is a work flow issue. The EMR must function in ways that are consistent with the physician's personal work style.

"When physicians see patients, they want to view all the diagnostic information they have on those patients," said Willett. "They tell us they want the historical data, their notes, the images on each patient, and they want to see all this information at once. They sometimes spread a patient's paper chart across the desk to get a complete view of the information. Of course, physicians want their EMRs to allow them to view the patient's chart in the same way."

"When physicians implement an EMR into their practice, the first outside clinical information they want to flow electronically into the EMR is laboratory test results," observed Wolfram. "In my work with physicians, electronic reporting of lab test results into the EMR consistently tops the list as the major priority.

"I would estimate that 90% of the deployed EMR systems in this country today get lab test results through an electronic interface," Wolfram observed. "It demonstrates the high value that physicians place on receiving and viewing lab results in their EMR.

"However, this is just one of two EMR integration phases that engage labs," he continued. "The first phase involves viewing results directly within the EMR. The second integration phase involves ordering electronically. This is a win-win for the lab and for the physician. For the lab, tests placed electronically create a complete and accurate test request. When the EMR

## Existing LIS-EMR Solution For Hospital Lab Outreach

**IGNIS SYSTEMS CORPORATION** of Portland, Oregon, launched its business with a unique advantage. It is already a specialist in integrating GE's ambulatory EMR within hospitals.

It has done this many times and is experienced in adapting this EMR to conform to the requirements of dozens of hospital environments. The principals of Ignis also have extensive experience with large reference labs which complements the work they have done for hospital laboratories.

The company's product is called EMR-Link and it integrates within GE HealthCare's Centricity EMR. It verifies lab orders for Medicare medical necessity, generates advance beneficiary notice forms, forwards electronic lab orders using HL7, and automates the closing of the EMR's open lab orders. EMR-Link's ability to handle medical necessity helps laboratories get reimbursed for lab work requested by the physician through the EMR.

"Hospital lab directors and pathologists will be interested to know that EMR-Link, by design, is tailored to be a natural extension of their physician clients' EMR workflow," explained Pat Wolfram, Vice President of Marketing and Customer Services for Ignis Systems. "At the same time, EMR-Link can be extended to connect the physicians' EMR to other services in the hospital. As they learn about this capability, many hospital administrators want to first use EMR-Link to connect their hospitals' LIS to the EMR of client physicians. Once that is accomplished, EMR-Link then becomes an integration interface for other clinical services between their hospitals and the physicians' EMR."

is the source of the data that populates the test request, it has the patient ID, the ordering provider's ID, and other required information needed by the lab to perform the test and evaluate the results.

"For the physician, an electronic lab order creates a much better lab result, facilitating a guaranteed match to the patient's chart, immediate notification to the ordering physician's desktop, and the ability to automatically update the test order status from 'in process' to 'closed,' an important CLIA requirement," Wolfram added. "Ignis' goal is to make the orders phase as easy to deploy as the results phase, so you'll see them both in phase one EMR deployments.

"The second stage of EMR-to-lab interoperability is about to commence because many physicians see the value that electronic orders bring to their EMR charts and to their staff workflow," he added. "They're ready to change their workflow once again to incorporate electronic lab ordering.

"When pathologists and lab directors think about services that will make them competitive and help them win business and retain business from physician clinics, they might put themselves in the shoes of that physician," Wolfram continued. "It's been our experience in working with physicians and labs on these types of interface gateways that collaboration between the lab and clinic staff in building the interoperability leads to stronger business relationships between the client and the lab," stated Wolfram. "It also contributes to a tighter, more successful integration of the lab ordering and the lab resulting function between the EMR and the LIS."

## Resistance to Change

Willett warned that laboratories need to constantly maintain the physicians' perspective on how the EMR supports existing workflow. "Remember a great truth about medical groups and doctor's offices," he advised. "Existing workflow has been optimized for the physician! That means if your lab offers a solution that disrupts a physician's workflow, there will be resistance to that change," he said.

"Office managers and staff tell us they will only make changes to workflow when they see a clear benefit from doing so," noted Willett. "They weigh the cost of additional training, as well as how staff levels might change. That is why they evaluate thoroughly any EMR or new EMR modules that change the physician's workflow."

## Still Using Paper Lab Orders

Wolfram agreed, saying, "To date, the majority of orders that physicians submit today are on paper. An order placed through an EMR must be as fast as using a pre-printed test requisition and checking boxes to order a CBC and a chemistry panel, then circling a diagnosis. Workflow is paramount to them. Electronic lab ordering must be fast, productive, and consistent with existing workflow in the physician's office.

"Lab order entry in the GE EMR, complemented by our EMR-Link system, doesn't require physicians to do anything differently from what they do already," Wolfram added. "They click one additional button to check for medical necessity, then the order moves to the phlebotomist or nurse at the draw station. If the draw station activity is managed by another lab application, the order information (such as the patient ID, insurance, order codes, and diagnoses) is pulled by EMR-Link from the EMR and passed directly to that application in the format needed by that application. We have development projects underway supporting this workflow with lab ordering vendors such as **Atlas Medical** and **Orchard Software.**"

Lab directors and pathologists will want to track the uptake of EMRs by office-based physicians. This major trend promises deep changes to the daily working relationships between physician clients and their laboratory providers. TDR

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# Michigan Derm Convicted On 31 Fraud Charges

## At trial, federal prosecutor opts not to pursue 35 counts relating to fraudulent billing of lab tests

***CEO SUMMARY: Last year, dermatologist Robert W. Stokes, D.O., of Grand Rapids, Michigan, was indicted by the federal government for 72 counts relating to various offenses, including upcoding, and improper coding. Of this total, 35 counts against Stokes involved his billing payers for laboratory tests he did not perform and laboratory services that he did not render, in violation of Title 18, United States Code, Section 1347.***

FEDERAL PROSECUTORS HAVE INDICTED, TRIED, AND CONVICTED a dermatologist in Michigan. The dermatologist faced 72 counts of billing fraud, including 35 counts of improper billing for laboratory testing services. Today, the dermatologist awaits sentencing after being convicted on 31 counts of billing fraud in April.

In an indictment filed last year in the U.S. District Court for the Western District of Michigan, Southern Division, federal prosecutors said the defendant Robert W. Stokes, D.O., a dermatologist in Grand Rapids, Michigan, had fraudulently billed for services he did not perform. The government originally sought a judgment of $1.04 million, representing the amount Stokes obtained fraudulently, according to the indictment.

Since the indictment was handed up, THE DARK REPORT has tracked this story because of the 35 criminal counts relating to improper billing of lab tests by Stokes. However, principles in the case have refused to discuss the details, making it difficult to develop a legal analysis of the federal prosecutor's case and Stokes' defense. Even following the conviction, few details of the case have been made public.

The federal indictments and the successful conviction of Stokes by the U.S. Attorney in the Western District of Michigan are important developments for both the laboratory industry and physicians involved in discounted billing (client billing) arrangements for laboratory tests. It shows both laboratories and the physicians they serve that billing arrangements that fall outside the law can subject the participants to criminal action.

### Stokes Convicted in April

Stokes was indicted on June 27, 2006. His trial took place in April, when it was announced by U.S. Attorney Charles R. Gross that, after one day of deliberation, a jury had convicted Stokes, age 55, on 31 counts of health care fraud. Although the specific counts under which Stokes was convicted have not been made public, THE DARK REPORT has learned that during the trial, the federal prosecutor chose not to pursue the laboratory billing fraud charges.

Nevertheless, because of his conviction on the 31 other fraud charges, Stokes faces a

maximum penalty of 10 years in prison and a $250,000 fine for each count. Sentencing is scheduled for October 24, 2007. Currently Stokes is free on bond. He has also agreed to cease the practice of medicine.

## Feds Are Willing To Indict

The case is significant to pathologists and lab directors. First, it demonstrates that federal prosecutors are willing to indict a physician for violations of federal law in how laboratory tests are marked up and billed to payers. Second, laboratory test reports played an important role in identifying for federal investigators how Stokes violated the law and how he improperly coded and billed for his professional services.

According to the 72-count indictment, Stokes is a board-certified dermatologist who submitted claims to **Medicare**, **Blue Cross Blue Shield of Michigan** (BCBSM), **Tricare**, and **Aetna** between August 2001 and December 2004. The indictment says Stokes billed for services he did not perform, including laboratory services that he did not render.

"Defendant Stokes also executed his scheme and artifice by billing BCBSM, Aetna, and Tricare for laboratory services that he did not render," the indictment says. "In order to receive reimbursement for a service, a participating provider, such as Stokes, must certify that he personally performed the service and that the service was performed at this office. Stokes routinely billed BCBSM, Aetna, and Tricare for laboratory services that were rendered by independent outside laboratory facilities and then billed to Stokes. Moreover, Stokes not only billed for the services that he did not perform, but he inflated the cost of the services by adding a 'mark up' to his costs."

At the same time that Stokes was marking up and filing claims for laboratory tests, he was also routinely upcoding office surgical procedures. The indictment notes that this meant Stokes submitted claims for a more complex level of treatment than he performed, thus earning a higher level of reimbursement.

There were instances when Stokes billed for what the indictment calls an "adjacent tissue transfer" when, in fact, he performed a less complex procedure. Billing for this service caused him to receive a higher level of reimbursement than what he should have received. An adjacent tissue transfer involves creating a flap of skin to cover a defect created by removing a lesion.

Stokes also upcoded claims for doing lesion removals. CPT codes for lesion removals are based on size, thickness, and the nature of the lesion removed. The indictment says Stokes received more reimbursement than he should have been entitled to by billing for the removal of large lesions when in fact he had removed smaller lesions.

Stokes billed BCBSM, Medicare, and other insurers for office visits that were not separately reimbursable, the indictment says. "When providers bill insurance companies for office surgical procedures, the reimbursement they receive for the procedure includes the office visit," the indictment says. "A provider was entitled to separate reimbursement for the office visit if, and only if, the provider indicated on the claim that the office visit was for a significant, separately identifiable evaluation performed on the same day as the procedure."

## Private Payers, Not Medicare

THE DARK REPORT observes that the Stokes case is noteworthy because a U.S. attorney was willing to investigate and indict this physician for an ongoing pattern of billing violations, including filing improper claims for laboratory services. Moreover, the 35 counts of laboratory billing fraud do not involve the Medicare program. Stokes was indicted for filing fraudulent lab testing claims against Blue Cross Blue Shield of Michigan, Aetna, and TriCare. These indictments against Stokes may be relevant as an indication of the current thinking among federal investigators.

Despite the unwillingness of the prosecution and the defense to publicly discuss

# Pathology Reports Help FBI Agents Build Case Against Stokes for Fraudulent Claims

**ONE DEPOSITION FILED** in the federal criminal case against dermatologist Robert W. Stokes, D.O., of Grand Rapids, Michigan, reveals how pathology reports were used by the FBI as evidence of the fraudulent claims filed by Stokes.

In his deposition, FBI Special Agent Mark Squeteri said that the investigation into Stokes began after the FBI received complaints from Medicare patients. Squeteri and his colleagues set about to review the billing and pathology records of patients treated by Stokes.

Squeteri reported that Stokes had been investigated earlier. In 1998, Stokes was the subject of a Medicare administrative hearing on whether he had properly billed for removal of lesions based on the actual size of the lesion. The hearing officer in this earlier case found that, in every instance where size could be determined, Stokes had billed for a lesion larger than the lesion that was removed. The hearing officer ruled that Stokes was responsible for repaying overpayments from Medicare.

## Fraudulent Claims

Squeteri also reported that he had received complaints from BCBSM's anti-fraud hotline, alleging that Stokes had billed for services not rendered and for removing malignant lesions, which according to pathology reports, were benign. Squeteri described an instance where one complainant reported that Stokes had removed a spot from her hand and told her she had skin cancer. When the complainant sought a second opinion, she learned the spots on her hand were age spots. The second physician obtained a copy of the pathologist's report and found the lesion Stokes had removed was benign, even though Stokes had billed for the removal of a malignant lesion.

Squeteri reviewed Stokes' Medicare billing records between 1999 and 2001. He found that Stokes routinely billed for removing malignant lesions and for removing the largest sized tumors, thus generating the largest payments.

During his investigation, Squeteri found that Stokes was referring the biopsies he removed to **Hilbrich Dermatopathology Laboratory, Inc.**, in Garden City, Michigan, for independent examination. FBI Agent Squeteri pulled 51 claims randomly from Stokes' office. He compared the insurance claims submitted by Stokes against the pathology reports issued by Hilbrich Dermatopathology Laboratory.

"In each of the 51 cases, Stokes billed for the removal of a lesion larger in size than the lesson that was removed," wrote Squeteri. "Also, in about one-third of the instances in which Stokes billed for removing a malignant lesion, the pathology report identified the specimens as benign. These misrepresentations caused Medicare and BCBSM to pay Stokes more than he was entitled to receive."

It is an interesting aspect to this federal criminal case that the FBI used the original pathology reports as evidence to demonstrate that Stokes was filing fraudulent claims. It is a reminder that laboratory test data is a primary source of objective information about the patient's condition and can be used as a way to confirm that the physician made the proper diagnosis and followed appropriate guidelines to treat the patient.

the specific details of this federal case and the resulting conviction of Stokes, that does not alter a key fact. A significant part of this criminal case was built upon fraudulent billing by an office-based physician for laboratory tests he did not perform, under some type of client billing arrangement with his lab provider. This aspect of the case is analyzed in the intelligence briefing that follows. TDR

# Lab Billing Indictments Underscore Docs' Risks

## ➤Dermatologist's federal indictment and court trial for fraudulent lab billing is another warning

***➤➤CEO SUMMARY: Physicians should consider the precedent established recently when the U.S. Attorney for the Western District of Michigan obtained a 72-count indictment against a local dermatologist, including 35 counts of submitting fraudulent claims for lab tests he did not perform, as well as laboratory services he did not render. One legal expert considers this federal indictment to be a significant development.***

"EACH TIME FEDERAL PROSECUTORS obtain an indictment for healthcare fraud and go to trial against the defendents, it helps us gain insight into the enforcement mindset of the federal establishment," stated Jane Pine Wood, an attorney with **McDonald Hopkins** of Cleveland, Ohio.

Wood was referring to the recent indictment and trial of Robert W. Stokes, D.O., a dermatologist practicing in Grand Rapids, Michigan. Stokes was indicted on 72 counts of fraudulent billing, ranging from upcoding to billing for professional services not performed. In the indictment, 35 counts specifically involved laboratory testing, alleging that Stokes submitted fraudulent claims for laboratory tests he did not perform and for laboratory services that he did not render.

At his jury trial in April, Stokes was convicted on 31 counts. He will be sentenced on October 24, 2007. Stokes is currently free on bail and has agreed not to practice medicine. There has been little public discussion of the details of the trial by the court, the federal prosecutor, or the defense counsel.

However, THE DARK REPORT has learned that, at the opening of the trial, the federal prosecutor was ready to pursue a conviction on all 72 counts against Stokes. Then, as the trial proceeded, the prosecution decided to emphasize Stokes' fraudulent billing for his professional services and not pursue the 35 counts involving Stokes' fraudulent billing for lab testing services.

### ➤Jury Convicts Stokes

The prosecutor's strategy succeeded. The jury convicted Stokes on 31 counts of fraudulent billing for professional services. These cases represented the bulk of the $1.04 million in restitution that the federal government was seeking as part of its case against Stokes. It is likely that the restitution amounts involved in the fraudulent laboratory testing claims were a small amount of that total, another reason the federal attorney did not more aggressively pursue these counts at trial.

Attorney Wood advised that pathologists, laboratory directors, and physicians who refer specimens to laboratories should not read too much into the fact

that the federal attorney did not pursue the fraudulent lab billing counts at the trial. "Clearly the federal attorney had evidence to support indicting Stokes on 35 counts of fraudulent billing for lab tests," observed Wood. "He also took these counts to trial. However, it appears he did not pursue them to finality at trial.

"There are many legal strategies and reasons why, at trial, a prosecutor may choose to emphasize certain counts against a defendant over others," continued Wood. "Until we know more, we won't understand how events at Stokes' trial caused the counts on lab billing fraud to take a back seat to other counts.

"None of this should distract from the primary lesson here," she declared. "Physicians involved in billing for laboratory test services want to avoid the indictment itself! This case is a reminder to physicians and laboratories that U.S. attorneys will prosecute physicians who fraudulently bill for laboratory testing services."

## Discounted Billing

Wood noted that, as explained in the indictment, it was likely that Stokes had a discounted billing/client billing arrangement with his laboratory providers. "The indictment alleges that Stokes submitted claims for laboratory testing services he did not perform," said Wood. "In addition, it says that he was account billing to some insurers. He probably knew that he couldn't account bill for Medicare because the laboratory that performs tests for Medicare must directly bill Medicare. It's possible that Stokes was not aware that Tricare is a government payer just as Medicare is." Tricare is an agency of the U.S. Department of Defense that administers healthcare for the uniformed services, retirees, and their families. It insures more than 9.1 million eligible beneficiaries worldwide.

"In this case, the prosecutor was probably concerned that the defendant was account billing for lab tests when, in theory, at least the payer agreements would generally require the doctor to perform the services in order to bill," Wood explained. "I am speculating here, but it may be that the payer contracts were not as clear or the payers were not able to provide sufficient evidence that the activity was fraudulent. Therefore, the prosecutor would have had a more difficult time when pursuing the facts behind those charges during the trial.

## Indictment Under USC 1347

"The key to the case was the indictment under United States Code 1347, which is for obtaining money under false pretenses," Wood explained. "USC 1347 is the general healthcare fraud statute that the government uses in such cases. This statute includes violations involving upcoding, miscoding, and filing claims for services not rendered.

"To me, the most important issue in this case is not necessarily what happened at trial, but that a prosecutor was willing to indict a physician in those situations where the payer contracts would have requested certification that he provided the service," Wood continued. "Of course, it would have been nice to have a clear legal decision on the lab fraud charges, but it's not as though those counts were dismissed. To the contrary, it's just that they were not pursued.

## Indicted And Convicted

"That is an important distinction because the defendant can't claim the government lost its case on those counts," Wood explained. "If the prosecution had any reservations about pursuing those charges and winning a conviction, it certainly did not have reservations about the other charges and so pursued those charges. Thus, the government got what it wanted out of its case against Stokes: an indictment and a conviction." TDR

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# Path Group Responds to FBI Visits in Stokes Case

## ➤Dermatopathology lab chooses to cease deeply discounted client billing after FBI visits

***➤➤CEO SUMMARY: As the FBI launched its investigation of fraudulent billing by Michigan dermatologist Robert W. Stokes, D.O., two years ago, staff at several pathology labs found themselves "up close and personal" with federal healthcare fraud prosecutors. One pathology lab, based on what it learned, decided to revamp its compliance program. It ceased deep discounts on client bill accounts and moved its prices closer to Medicare fees.***

DURING THE FBI'S INVESTIGATION of fraudulent billing by Michigan dermatologist Robert W. Stokes, D.O., pathology laboratories doing business with Stokes were visited. In one case, interaction with federal fraud investigators led pathologists to cease offering deeply discounted client bill pricing to dermatologists and other physician clients.

FBI Special Agent Mark Squeteri visited pathology laboratories that maintained accounts with Stokes, seeking evidence against the dermatologist. In his deposition described in the sidebar on page 9, agent Squeteri described how he had reviewed the lab testing records of **Hilbrich Dermatopathology Laboratory, Inc.**, in Garden City, Michigan. Squeteri used those records when building the federal case against Stokes. The investigation led directly to his conviction.

In THE DARK REPORT'S own research about the Stokes case and what it means for federal enforcement of various statutes that govern laboratory billing, it uncovered another Midwest pathology laboratory that provided lab testing services to Stokes during the time he submitted fraudulent lab test claims identified in the indictment.

Staff at this laboratory told THE DARK REPORT, off the record, that it had cooperated fully with the FBI investigation and that at least one of its employees was deposed and subpoenaed to testify at Stokes' criminal trial last April.

### ➤FBI Investigates Stokes

These FBI inquiries took place starting about two years ago. "We were implicated by [our business] association [with Stokes], but there were no criminal charges," stated one pathologist at this laboratory. "The FBI was here, met with one of our staffers, and asked a lot of questions about lab billing. Of course, this staff member was represented by attorneys from our lab's law firm.

"Since that time, we have closely followed the subject of lab discounts to client bill physicians and physician mark-ups on ancillary services," he continued. "Since our laboratory provides testing services across state lines, we are now well-informed about how compliance laws and enforcement practices can vary from state to state. At the

same time, it seems every laboratory company we compete with has a different legal interpretation about compliance, client billing policies, and price discounting.

## Basing Fees On Medicare

"Even though prices offered by competing laboratories vary greatly, and compliance requirements are different from state to state, our laboratory decided it would be best for us to cease offering deep discounts from the Medicare fee schedule," continued the pathologist. "We raised our rates to be closer to Medicare fee schedules.

"At the time, informed about many details about the Stokes case and how the FBI and federal attorney were proceeding, we considered this to be a prudent decision," he added. "However, this was a decision that came with a lot of financial pain. As we announced our new pricing policy to clients, we lost about a third of our volume, which, of course, represented a lot of revenue."

This pathology laboratory has survived its new pricing policy. "Financially, we are doing okay today," noted the pathologist. "Because our fee schedule is in the same range as the Medicare fee schedule, we have a high confidence factor in our compliance program. There is peace of mind in that. Having watched the Stokes case unfold, from investigation to indictment to jury trial and conviction, we probably know more about how federal prosecutors put together a laboratory billing fraud case than any other pathology laboratory in this country.

## Lab Competitors

"On the other hand, over the past two years, since the investigation started in the Stokes case, we have not seen any competing laboratories cease deep discounting for client bill accounts and move their prices up to a level close to Medicare fees," observed the pathologist.

"In following the issue of labs offering discounted prices to physician-clients, we thought the federal Office of the Inspector General (OIG) was going to look at whether labs were discounting their rates," he said. "We've been disappointed that the OIG has not done more on this issue."

That situation may soon change. On July 2, the **Centers for Medicare and Medicaid Services** (CMS) published its proposed rules as part of the 2008 Medicare Physician Fee Schedule. A number of proposed rules specifically address physician mark ups on ancillary services. *(See pages 15-18 for more on the proposed rules.)*

In the meantime, the investigation, indictment, jury trial, and criminal conviction of dermatologist Robert W. Stokes, D.O., is a reminder that federal healthcare investigators remain willing to pursue provable cases of fraudulent billing, including claims for lab testing. There is still risk for laboratories and physicians to push the boundaries of compliance in these matters.

## Threat Of Indictment

Federal authorities, of course, continue to hold the ultimate hammer: the threat of indictment. In the case of Stokes, the big news for the laboratory industry was the indictment itself. Of the 72 counts of fraud issued against Stokes, 35 involved fraudulent claims for lab tests. As the indictment states, Stokes "routinely billed ...for laboratory services that were rendered by outside laboratory facilities and then billed to Stokes. Moreover, Stokes not only billed for services he did not perform, but he inflated the cost of the service by adding a 'mark-up' to his costs."

Pathologists and laboratory directors should reflect on the decision by the Midwest pathology laboratory, following its interaction with the FBI and a U.S. attorney's office, to cease deeply discounted billing and raise client bill pricing closer to the level of Medicare fees. Based on its intimate interaction with these federal officials, it was willing to endure a 30% decline in business to revamp and tighten its compliance policies to be consistent with what it had learned from federal prosecutors during the Stokes investigation. TDR

# Are Feds Ready to Strike at TC/PC Arrangements?

## ➤CMS proposes new rules for comment and sends a message on ancillary services schemes

***➤➤CEO SUMMARY: Pathologists and laboratory directors will want to pay attention to the proposed rules published by the Centers for Medicare and Medicaid Services on July 2, 2007. The document is a grab bag of proposals and rules that would significantly curb many common ancillary services arrangements now used by physicians to capture revenue. Diagnostic testing, including both radiology and pathology services, were the subject of several of the proposed new rules.***

RECENT ACTIONS BY FEDERAL REGULATORS and the Medicare program show that officials are taking a broad swipe at a range of activities. In particular, proposed language in the latest rulemaking process targets how referring physicians participate in programs designed to generate ancillary revenue.

The ancillary services of anatomic pathology and radiology seem to be a primary focus for federal attention. On July 2, 2007, the **Centers for Medicare and Medicaid Services** (CMS) published its proposed rules as part of the 2008 Medicare Physician Fee Schedule. This document included many proposed rules that could restrict how physicians generate revenue from ancillary services.

### ➤Knockout Punch By Feds

One attorney was direct and blunt about how these proposals could kill a number of popular ways that physicians use to capture ancillary service revenue generated by their patients. "CMS outlined 11 proposals or initiatives that could provide the necessary 1-2-3 punch to knock out many existing arrangements," wrote Bruce A. Johnson, attorney with **Faegre & Benson** in Denver, Colorado. "One proposal would impose new limits on reimbursement for diagnostic testing services. A second group of proposals—with seemingly minor wording changes to the Stark final rule—would have major practical implications, and a third set would emphasize the enforcement environment."

THE DARK REPORT believes that, with the publication of these proposed rules and certain other events in the regulatory domain, federal health program officials are signaling their intent to curb behavior and activities they deem to be counter to the spirit and purpose of the Medicare and Medicaid programs. Because some of these proposed rules will affect diagnostic testing services—both in pathology and radiology—pathologists and laboratory directors will want to stay informed about these issues.

Proposed rules that expand anti-markup restrictions are probably the most prominent issue that directly affects today's anatomic pathology marketplace. Essentially, these rules will prohibit physicians and medical groups from profiting

from the professional component (PC) unless the interpreting physician is a full-time employee.

## Public Comment Period

With the publication of these proposed rules by CMS on July 2, the public is invited to comment. Pathologists and other parties have until August 31 and, in some cases, until the end of the first week in September to make comments on the proposals.

To get context and understanding about these federal proposals, THE DARK REPORT caught up with Rick L. Hindmand and Richard S. Cooper, two attorneys at **McDonald Hopkins** with extensive legal expertise in pathology and clinical laboratory matters.

"Probably the single most significant proposal in the July 2 document is a further restriction on anti-markup regulations," observed Hindmand. "There is a proposed rule that would revise payment policies next year for the Medicare Physician Fee Schedule and payment policies under Medicare Part B. This particular proposal has significant implications for pathologists and laboratories, independent diagnostic testing facilities (IDTFs) such as imaging centers, and physicians who provide ancillary services.

## Payment Policies Reviewed

"Essentially, CMS proposes to extend the restrictions that currently exist on purchased diagnostic tests and apply these same restrictions to certain reassigned professional diagnostic interpretations," explained Hindmand. "This would be a major change in how physicians can bill professional component services (PC) to Medicare.

"If a physician or group practice accepts reassignment from a pathologist for the professional interpretation of a pathology service, under the new proposal, the billing physician or medical group would be restricted from marking up the price paid to the pathologist," said Hindmand, "The billing physician or medical group would also be required to identify the interpreting pathologist in that claim it submits to Medicare.

"The group also must indicate the amount paid for the interpretation, *unless the interpreting pathologist is a full-time employee of the billing physician or medical group*," he stressed. "If the interpreting pathologist is a part-time employee, a full-time independent contractor, or a part-time independent contractor, then the physician or group could not mark up the amount paid to the interpreting pathologist in the claim to Medicare for the professional component (PC)."

## Anti-Markup Provision

"It should be noted, however," interjected Cooper, "that this anti-markup provision would not apply to independent laboratories that provide the technical component (TC) and purchase the PC."

"Yes, and there is more," added Hindmand. "The CMS is proposing rules that would extend these same restrictions to the technical component (TC) service performed by personnel who are not full-time employees of the billing entity. It is unclear, however, how this standard would be interpreted and applied, in cases where a medical practice with its own laboratory uses histotechnologists who are not full-time employees."

"If the anti-markup rule is enforced as proposed, a medical group practice that retains a pathologist part time would be restricted in terms of what it could bill," Hindmand explained. "The group could not bill Medicare more than the amount that it paid to the pathologist for the professional component."

Cooper explained how this changes the financial motives for specialist physicians to participate in TC/PC (Technical Component/Professional Component) arrangements. "In essence, the incentive to bill for the PC goes away. If CMS implements this proposed rule, this is likely to

*(continued on page17.)*

# CMS Issues List of Proposed Rules in July, Hoping to Curb Ancillary Arrangements

Following a careful reading of the CMS proposed rules, published on July 2, 2007, one healthcare attorney believes significant changes will soon reshape how physicians are able to profit from ancillary services.

"If the proposals are implemented, many ancillary service arrangements would be weakened and some knocked out entirely," declared Attorney Bruce A. Johnson of Faegre & Benson in Denver, Colorado. "CMS would effectively direct providers to retreat to their respective corners and [their] historical involvement with ancillary services—even though the healthcare delivery environment continues to change dramatically."

Johnson discussed the CMS language dealing with diagnostic tests, saying that "the first major proposal in the 2008 PFS (Physician Fee Schedule) addresses diagnostic tests and revisits issues first raised in 2007 when CMS proposed to modify the 'contractual arrangements' exception to Medicare's prohibition on reassignment, impose anti-markup prohibitions on 'purchased diagnostic tests,' and restrict what constitutes a 'centralized building' under the Stark Law. These proposals were directed at perceived abusive arrangements such as 'condo' anatomical pathology laboratories which were rejected in OIG Advisory Opinion 04-17, and similar 'contractual joint venture' arrangements which were the subject of an April 2003 OIG Special Advisory Bulletin.

## Significant Concerns

"CMS didn't implement its 2007 proposals," continued Johnson, "but based on the 2008 PFS, the agency continues to have significant concerns regarding 'condo' path labs and similar arrangements.

"Tellingly, CMS declined to propose any specific changes to the in-office ancillary services exception in the PFS, but it clearly has its eye on the exception, and changes may be in the works," he said. "In the PFS, CMS solicited comments on whether certain services should be permitted under the exception (including, for example, physical therapy services that are not furnished incident to a physician's services, ancillary services that are not required to assist in patient diagnosis or developing a plan of treatment, and certain complex laboratory services). It also requested comments regarding potential changes to the exception's "building" requirements, and others that would help curtail program or patient abuse.

## More Expansive Solution

"In the 2008 proposal, CMS appears to have crafted a simpler, but more expansive solution by proposing an anti-markup provision on both the professional and technical components of diagnostic tests performed by 'outside suppliers' who CMS would define as anyone other than a full-time employee of the physician or medical group billing for diagnostic services.

"The proposals clearly convey the agency's concerns with the variety of ancillary service and related ventures that have been developed—despite the presence of the Stark Law," stated Johnson. "...if the proposals are implemented, the size and shape of providers who remain active in the provision of ancillary health care services is likely to change. Providers that are likely to be able to continue to furnish such services include hospitals, large multispecialty physician groups, large single specialty "network" practices focusing on defined disease states (e.g., cancer care, cardiovascular care, neuro/musculoskeletal care), integrated delivery systems and niche service providers.

"Absent persuasive comments, the projected massive cuts in reimbursement under the 2008 PFS, combined with the significant changes suggested in the proposed rules, could very well constitute the knock-out punch for many providers and existing service arrangements," concluded Johnson.

*(continued from page15.)*

have a positive result for pathologists," predicted Cooper.

"Further, this could have an impact that extends beyond the Medicare and Medicaid programs," continued Cooper. "It is increasingly common for private health insurers to adopt Medicare coverage and reimbursement policies without major modifications. If CMS adopts this policy, I would assume pathologists and the lab community would begin lobbying commercial and private payers to adopt similar provisions."

Hindmand agreed that implementation of the proposed rule would definitely affect many existing ancillary service arrangements. "The proposal would affect a group practice that operates an office laboratory and has part-time laboratory staff members," Hindmand said. "The way the proposal is drafted, the group would have to have full-time employees if they are going to perform the technical component without being subject to the anti-markup restriction. If the group can't mark up the amount it paid, then it can't make any profit at all. Furthermore, in order to bill for the technical component, the group would be required to directly perform the professional component."

## Ancillary Service Models

During the past four years, specialist physicians have developed several ancillary service models for anatomic pathology (AP) that allow them to profit from AP services provided to their patients. *(See TDR, July 3, 2006.)* One model is for the specialist physicians to establish an in-house laboratory and hire their own histotechnologists and bring in a pathologist as a partner or full time employee. A second model used by specialist physicians is to establish an in-house laboratory (TC) and contract out the pathology professional component (PC).

A third approach is to use an outside laboratory for the technical component, then contract with a pathologist to perform professional component services.

A fourth approach is the anatomic pathology laboratory condominium complex (pod lab). In a single building of 10 to 15 rooms, each room is a fully equipped histology laboratory. Each laboratory is owned by a different specialist group practice. During the day, histologists and pathologists move from one laboratory to the next to perform the work. These histologists are often either: 1) part-time employees of each of the different groups that own labs; or, 2) are contracted on a part-time basis by each group that owns a lab to perform the TC and the PC services. *(See TDRs, July 19, 2004, and August 9, 2004.)*

## A Significant Effect on Profit

According to Cooper, the goal of CMS is not to restrict or constrain a common contracting arrangement in pathology. "It is a long-established practice that hospitals can contract with pathologists for services that may range from full-time to part-time, including only a few days per week," noted Cooper. "Consequently, a number of individual pathologists will spend time providing services at several hospitals each day and each week. It is not the intent of CMS to change these long-standing arrangements between hospitals and pathologists.

"In fact, this proposal appears to be aimed at restricting how specialist physicians can profit from ancillary services," he explained. "A pathologist working for a number of hospitals doesn't seem to raise the same concerns.

"These proposed rules have triggered another question," continued Cooper. "Does this particular proposal affect those pathologists who work in a centralized building in a condo lab/pod lab business model? Would this proposed language remove the PC markup capability from the condo/pod lab concept?

"Unless the pathologist is a full-time employee or partner in the specialist medical group that owns the condo laboratory, the specialist group can only bill for the actual cost of the PC service it paid," observed Cooper. "Weigh that against that the negative effects of the increased liability

## Feds Solicit Comments on In-Office Ancillary Exception

**IN RESPONSE TO THE PUBLICATION OF PROPOSED RULES** in the 2008 Medicare Physician Fee Schedule, **Hall, Render, Killian, Heath & Lyman**, a law firm with offices in Michigan, Indiana, Kentucky, and Wisconsin, issued a Health Law Alert.

Hall Render noted that the OIG was soliciting comments on potential changes to the in-office ancillary services exception. It quoted the federal language on this point: "At the time of enactment, a typical in-office ancillary services arrangement might have involved a clinical laboratory owned by physicians located on one floor of a small medical office building. Under such an arrangement, a staff member would take a urine or blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited."

Hall Render next wrote that "CMS believes that, today, services furnished pursuant to the exception are not so closely connected to the physician practice. For example, a group practice provides pathology services furnished in a centralized building that is not physically close to any of the group's other offices and, in some cases, the technical component of such services is furnished by laboratory technologists who are employed by an entity unrelated to the group. The professional component of the pathology services may be furnished by contractor pathologists who have virtually no relationship to the group practice. CMS states that, 'in sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS.' Even when ancillary services are furnished in the same building as the group practice's office, CMS is concerned that there may be little interaction between the physicians who are treating patients and the staff that provide the ancillary services."

Hall Render concluded by writing that "CMS specifically seeks comments on: (1) whether certain services should not qualify for the exception (for example, therapy services that are not provided on an incident-to basis, services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, and complex laboratory services); (2) whether, and, if so, how the definitions of 'same building' and 'centralized building' should be changed; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse."

risk associated with a pathologist delivering professional component (PC) services in a condo/pod lab model, along with the licensure, insurance, and liability issues. If a markup is prohibited on PC, it may cause some of these condo/pod lab owners to rethink the clinical and business justification for maintaining an off-site laboratory operation like this."

Hindmand agreed, saying, "The anti-markup proposal wouldn't prohibit this kind of business operation, but it would limit the amount of reimbursement the group could receive. That probably removes the business incentive to do it."

THE DARK REPORT observes that Medicare officials and private payers have been concerned for several years about the rapid increase in the number of physicians establishing arrangements that allow them to file claims for ancillary services, particularly in radiology and pathology. The number and scope of the proposed rules is a sign that federal policymakers are ready to act with some energy to curb and redirect certain forms of these arrangements. **TDR**

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# INTELLIGENCE

## LATE & LATENT

*Items too late to print, too early to report*

Something different is happening when the **Associated Press** does a story about how the **American Clinical Laboratory Association** (ACLA), a lab industry trade group, has spent money lobbying Congress. The Associated Press used federal records to confirm that ACLA, paid $140,000 to **Alston & Bird LLP**, a law firm with offices in Washington, D.C., and other cities, to lobby Congress between January 1 and June 30, 2007. On behalf of ACLA, Alston & Bird lobbied both houses of Congress and the **Food and Drug Administration** (FDA) on direct-to-consumer issues, the federal records show. This lobbying activity reflects increased activity on bills and regulatory issues affecting laboratories, as well as ACLA's strategy of taking a higher profile on behalf of its laboratory members.

### PREDICTIVE MARKER DISCOVERED FOR PROSTATE CANCER

Researchers at the **Mayo Clinic** in Rochester, Minnesota, have identified an immune molecule that appears to affect the development of prostate cancer. Known as B7-H3, this biomarker could help predict cancer recurrence and progression after surgery. Timothy Roth, M.D., a urology resident at Mayo and lead author of the study, noted that this discovery can help physicians develop individualized treatment plans for prostate cancer patients. The findings were published in *Cancer Research on* August 15.

### MORE ON: Prostate Biomarker

Researchers are optimistic that B7-H3 will prove useful as a diagnostic, prognostic, and therapeutic tool. Tumor cells display B7-H3 as prostate cancers develop. The marker can still be identified even after anti-hormone therapy commences. Researchers believe that B7-H3 kills or paralyzes immune cells trying to attack the cancer. This new biomarker is an example of how molecular discoveries are providing clinicians with the ability to understand more about prostate cancer, giving them the ability differentiate cancer types, then identify the best treatment protocol for the patient.

### UPDATE ON ROCHE BID FOR VENTANA

As of press time, the $3 billion hostile take-over offer by **Roche Holding AG** for **Ventana Medical Systems, Inc.**, was still unfolding. Last week, Roche won a federal court injunction to stop Ventana from using an Arizona state law to oppose the Roche offer. Roche then extended its offer to buy Ventana shares for another 30 days, through September 20.

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***That's all the insider intelligence for this report. Look for the next briefing on Monday, September 17, 2007.***

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**PREVIEW #4**

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# UPCOMING...

- ***More on Proposed Anti-Markup Rules for Pathology Professional Services and TC/PC Deals.***
- ***Overlooked Laboratory Superstars Share Secrets of Fast Growth, High Profits.***
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