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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Expanding Lab Market Share in a Recession

IT IS UNCHARTED TERRITORY FOR CLINICAL LABS AND PATHOLOGY GROUPS. A recession now officially exists in the United States. The last time this nation experienced an extended and painful economic recession was between July 1981 and November 1982, according to *wikipedia.com*.

That means it has been more than 26 years since anyone has managed a clinical laboratory during an economic recession! Few of us old-timers are still around to share the experience and wisdom gained during those challenging years. That means an entire new crop of laboratory managers and pathologists are about to undergo their trial by fire. To cope with the poor business environment, they will need good business strategies to keep their laboratories financially solvent and profitable.

Of course, the immediate pressure is to reduce operational costs in the face of slackening test volume, payer reluctance to settle claims in a timely fashion (since they want to hang on to the money), and the inability or unwillingness of larger numbers of patients to promptly and fully pay their bills to their lab test and pathology providers. Fortunately, clients and long-time readers of THE DARK REPORT know that quality management methods, including Lean and Six Sigma, are highly-effective tools to eliminate unnecessary costs while improving productivity and quality.

That covers the cost/operations side of the ledger. The other way to sustain financial stability is to grow the laboratory business in a cost-effective manner. This means expanding lab outreach market share. In speaking to laboratory executives across the country, there is a consistent message: in most regions, well-managed laboratories continue to see strong rates of growth in new client accounts, additional specimen referrals, and net revenue.

Two public laboratory companies offer proof that a well-executed sales strategy still produces good results. **Bio-Reference Laboratories, Inc.** (BRLI) reported its first quarter of fiscal year 2009 on March 5. It enjoyed a net revenue increase of 13%. Specialty test provider **Clarient, Inc.** reported its fourth quarter 2008 earnings on March 11. Clarient saw a net revenue increase of 76.4%, along with an increase in specimen volume of 39%.

These two examples should inspire hospital lab outreach programs and pathology groups. Even in a tough economy, a well-executed sales/marketing program can produce growth, along with increased profits! TDR

Attorney General Brown Sues Seven Calif. Labs

He joins whistleblower lawsuit, claims labs did not give Medi-Cal program their lowest prices

CEO SUMMARY: California Attorney General Jerry Brown made a big splash last month by accusing seven lab firms of committing "massive fraud and kickbacks" under state Medicaid laws. However, he is relying on a legal theory that has not prevailed in some prior court cases involving discounted billing for laboratory testing. Nonetheless, it appears that a multi-year legal battle is now under way, with the substantial resources of the California Attorney General arrayed against the seven defendant lab companies.

HOLDING A NEWS CONFERENCE last month to announce "massive fraud and kickbacks," California Attorney General Edmund G. Brown Jr. made it sound like the lawsuit filed against seven California labs was going to be a prosecutorial slam dunk.

On March 20, Brown joined the whistleblower lawsuit against seven private laboratories that seeks to recover what Brown described as hundreds of millions of dollars in illegal overcharges to Medi-Cal, the state's medicaid aid program for the poor.

In the legal action pending in San Mateo Superior Court, Brown contended that seven medical laboratory companies in California systematically overcharged the Medi-Cal program during the past 15 years. The labs did so by failing to offer Medi-Cal the lowest price for lab tests that they had negotiated with physicians, Brown said.

News of this development rippled across the laboratory industry because of the press conference conducted by California Attorney General Brown. But many lab industry veterans consider this an "old news" event, because similar claims have not prevailed in either state or federal courts.

Despite these court precedents, the whistleblower action can be considered another roll of the lawsuit dice. A decision against the seven laboratory companies named as defendants could roil the status quo that allows deeply discounted client billing and physician-markup arrangements (in states where this practice is legal), even as labs bill the Medicare and Medicaid programs at the maximum allowed by their respective fee-for-service rates.

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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).

Lab executives and pathologists should evaluate the implications of this story only after: 1) learning about the basic facts of this whistleblower case; and, 2) understanding that there are a series of court decisions over the past two decades that support the widespread practice of laboratories offering different prices to different healthcare providers, which, in some cases, may be lower prices than what these labs charge Medicare and Medicaid.

Medi-Cal Fraud & Kickbacks

Here are the facts of the case as Brown outlined them in the news conference. "In the face of declining state revenues, these [seven] medical labs have siphoned off hundreds of millions of dollars from programs intended for the most vulnerable California families," Brown said. "Such a pattern of massive Medi-Cal fraud and kickbacks cannot be tolerated, and I will take every action the law allows to recover what is owed."

As a whistleblower under California's False Claims Act, the original lawsuit was filed under seal in 2005 by Chris Riedel, CEO and owner of **Hunter Laboratories, Inc.**, in Campbell, California. While Riedel's suit seeks to recover at least $100 million, one of Riedel's attorneys, Joe Cotchett, of **Cotchett, Pitre & McCarthy**, in San Francisco, said Medi-Cal losses might total more than $1 billion.

Case Filed Under Seal

In his suit, Riedel claims Hunter Laboratories discovered that it could not compete in a significant segment of the marketplace due to price discounting practices that violate California State law. During the press conference, Brown explained that Riedel's lawsuit details how many major laboratory competitors offered referring doctors, hospitals, and clinics far lower rates than they charged Medi-Cal. After the filing in 2005, the state Bureau of Medi-Cal Fraud and Elder Abuse investigated the allegations and Attorney General Brown intervened. The case was unsealed in March.

In the lawsuit, Riedel claimed the following labs overcharged the Medi-Cal program over 15 years:

- **Quest Diagnostics Incorporated**, based in Madison, New Jersey; with its affiliate **Specialty Laboratories, Inc.**, based in Valencia, California; and four Quest affiliates.
- **Laboratory Corporation of America**, based in Burlington, North Carolina.
- **Health Line Clinical Laboratories, Inc.**, now known as **Taurus West, Inc.**, in Burbank.
- **Westcliff Medical Laboratories, Inc.**, based in Santa Ana.
- **Physicians Immunodiagnostic Laboratory, Inc.**, in Burbank.
- **Whitefield Medical Laboratory, Inc.**, based in Pomona, California.
- **Seacliff Diagnostics Medical Group**, based in Monterey Park, California.

Niall McCarthy, another attorney with Cotchett, Pitre & McCarthy, explained that the labs are required under California law to bill Medi-Cal the lowest prices they charge to any other purchaser under similar circumstances. "Instead, the lawsuit alleges that since at least 1995, defendants have systematically billed Medi-Cal the highest prices possible, resulting in overpayments totaling in the hundreds of millions of dollars," McCarthy said.

"In some cases," he continued, "the labs charged Medi-Cal rates for exams that were 500% higher than what they charged others. For example, one lab company billed Medi-Cal $8.59 to perform a blood test. It charged a person with private insurance $1.43 for the same test, amounting to a 501% rate increase [to Medi-Cal]."

Riedel was said to be on vacation last week and could not be reached for comment. In a press release, Brown quoted Riedel explaining why he filed the case. "I confirmed with the California Department of Health Care Services that these practices were illegal," Riedel said. "We [Hunter Laboratories] then had a

California Attorney General Jerry Brown Outlines His Case Against Seven Laboratory Companies

IN HIS PRESS CONFERENCE, California Attorney General Edmund G. Brown Jr. outlined the facts of what he called a case of fraud perpetrated against Medi-Cal. Brown stated that the seven lab firms routinely overcharged Medi-Cal by granting discounts to physicians and not giving Medi-Cal the lowest rate it negotiated with others.

For example, Brown alleged that Quest Diagnostics charged Medi-Cal $8.59 to perform a complete blood count test, while it charged some of its other customers $1.43 for the exact same test. "This is one of the most frequently requested blood tests," he added.

Laboratory Corporation of America charged Medi-Cal $30.09 to perform a Hepatitis C Antibody screening, while it charged some of its other customers only $6.44 for the test, Brown said.

Health Line Clinical Laboratories charged Medi-Cal $12.65 to perform an HIV Antibody screening, while charging some of its other customers $1.75 for the test, he added.

"These are not isolated examples," Brown continued. "They are part of a pattern of fraudulent overcharging and kickbacks that developed over the past decade. Here's how it worked: The defendant labs provided deep discounts when they were being paid directly by doctors, patients, or hospitals. Prices were often below the lab's cost and sometimes free.

"In exchange for these steep discounts, the defendants expected its customers to refer all of their other patients (where the lab was paid by an insurance company, Medicare, and Medi-Cal) to its lab," he said. "Under California law, this amounted to providing an illegal kickback. These sharply reduced prices, however, were not made available to Medi-Cal. Instead of charging the discounted prices, the defendants charged Medi-Cal up to six times more than the defendant charged others for the same tests. In effect, defendants shifted the costs of doing business from the private sector to Medi-Cal.

"Additionally, defendants offered their clients who paid them directly (not through Medi-Cal or other insurance) deeper and deeper discounts in order to get a larger share of the lab testing business," Brown said. "This created an unfair playing field, and laboratories that followed the law could not effectively compete. These law-abiding companies were sometimes forced to sell or go out of business completely."

choice—either join the other labs in violating the law or be unable to compete for business. We chose to suffer the financial consequence, and follow the law."

Under California law, Brown explained, "'…no provider shall charge [Medi-Cal] for any service…more than would have been charged for the same service…to other purchasers of comparable services…under comparable circumstances.' Yet, the medical laboratories charged Medi-Cal as much as six times more than they charged some other providers for the same tests," he noted.

The crux of this issue is whether those laboratories which offer deeply-discounted prices to private health insurers, hospitals, physicians, and other categories of providers, failed to offer California's Medicaid program—known as Medi-Cal—their lowest prices, in conformance with California Medi-Cal statutes.

To a casual observer, Brown made this lawsuit look like a potential easy win for the prosecution. But the facts show a more complex legal picture. An attorney familiar with laboratory billing issues observed that earlier court cases in California have involved clinical laboratories initially believed to be acting in a fraudulent manner. However, courts have found this not to be so.

"In fact, courts have ruled in favor of laboratories that did charge different rates to different payers," said Patric Hooper, a lawyer with **Hooper, Lundy & Bookman,**

Inc., in Los Angeles. "The courts have ruled previously that there is nothing wrong with a laboratory giving discounts to physicians to get other business. As a matter of fact, it is probably good public policy for laboratories to give discounts because it can lower costs for Medi-Cal and HMOs."

Prior California Case Law

For this reason, the current whistleblower lawsuit may prove to be much more complex than how Brown explained it during his announcement to the press. While making his claims about the seven defendant laboratories, Brown did not discuss earlier California case law on this issue.

"There is one case, the Physicians and Surgeons case, upon which California is relying—and it is one of several cases I litigated!" said Hooper whose firm had been involved in the whistleblower case earlier when it represented four of the defendant labs but was disqualified due to an alleged conflict, a ruling that the firm is appealing. "However, at his press conference, the attorney general ignored the more recent court of appeals decision in *People v Duz-Mor Diagnostic Laboratory Inc.*

"I litigated that case and many others like it," he continued. "In the *Duz-Mor* case, a 1998 California Court of Appeals ruling specifically held that there is nothing wrong with a laboratory giving discounts to physicians to get other business. In that ruling the court wrote that it is probably good public policy to give discounts because it can lower costs overall. As all labs know, in California, state law prevents doctors from marking up laboratory tests.

Long-Standing Issue

"The issue has been around for more than 30 years," he added. "Congress knows all about dual pricing, and the State of California knows about it. While I cannot talk about the specifics of this particular case at this time other than to mention what is stated in the complaint, I can confirm that the subject of dual pricing or discounts has been litigated over and over again since as early as 1983.

"When some labs give discounts, it looks bad when the attorney general says, 'These labs are not giving Medi-Cal the same breaks they are giving to others.'

"But in *Duz-Mor*," explained Hooper, "the court said, 'In our view, the practice of negotiating discounts for the physicians' private pay patients benefits healthcare consumers. The lower prices are by law passed on to consumers. The evidence in *Duz-More* established that if discounts were not negotiated, private pay patients would pay more for services than Medi-Cal pays for beneficiaries or than HMOs pay on behalf of their members.' The court could find no public policy benefit in ruling against *Duz-More.*

"Because Medicare and Medi-Cal know all about dual pricing, they have historically dealt with it in rate setting," Hooper explained. "Every time Medicare or Medi-Cal set rates, they knock down reimbursement by another X%. They say, 'We know you labs are lowering your rates.' So, in essence, they have chosen to deal with it through rate making and not through court cases filed under the False Claims Act. In some selected cases, state Medi-Cal auditors have also conducted audits when the circumstances of a particular case may trigger an overpayment."

Element of "Lawsuit Lottery"

Despite the facts Hooper laid out concerning earlier case law on this legal issue, there remains an element of "lawsuit lottery" in this ongoing legal action. Plus, now that the California Attorney General has joined Riedel's whistleblower lawsuit and unsealed the details to the public, he's got the vast resources of the California Attorney General's office to support this case as it moves through the courts. Expect a tough, multi-year battle with several appeals. TDR

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Patient Safety Update

Diagnostic Errors Get Attention As Next Patient Safety Goal

Errors in diagnosis estimated to be responsible for between 40,000 and 90,000 deaths yearly

PHYSICIAN LEADERS IN PATIENT SAFETY are turning up the heat on doctors to reduce the incidence of diagnostic errors. This is a topic few dared to openly discuss until recently. It is directly linked to Medicare and private payer efforts to crack down on medical errors.

This development has profound consequences for pathologists and laboratory executives. As physicians come under pressure to reduce errors in diagnosis, they will need more sophisticated support from their clinical laboratory. In turn, this will bring pathologists closer to treatment settings as valued consultants in diagnosis.

Admittedly, the campaign to make reduction of diagnostic errors is in its infancy. For example, a supplement to the May 2008 issue of *The American Journal of Medicine* (AJM) first opened this delicate subject with a compilation of papers discussing why the sensitive issue of diagnostic errors is rarely discussed, as well as why it has been understudied.

Writing in AJM, guest editors Mark L. Graber, M.D., a faculty member at **SUNY Stony Book**, and Eta S. Berner, Ed.D., faculty member in the School of Health Professions at the **University of Alabama at Birmingham**, noted that, on a basic level, physicians tend to be overly confident about their own skills and are complacent because they fail to recognize the prevalence of the problems.

"The fact that most of their diagnoses are correct, and that effective feedback regarding their errors is lacking, reinforces this inclination," they said. "When directly questioned, many clinicians find it inconceivable that their own error rate could be as high as the literature demonstrates."

Graber and Berner further explained, "They [physicians] acknowledge that diagnostic errors exist [in their own practice], but believe their rate is very low, and that any errors are made by others who are less skillful or less careful."

Call For Immediate Action

Now two respected physician leaders in the patient safety movement have called for immediate action in an op-ed article, published in the March 11, 2009, issue of *Journal of the America Medical Association* (JAMA). From **Johns Hopkins School of Medicine**, David Newman-Toker, M.D., Ph.D., and Peter Pronovost, M.D., Ph.D., emphasized that the problems caused by errors in diagnosis are much bigger in terms of deaths than more popular targets, like medication errors and wrong-site surgeries.

Diagnostic errors—including missed, wrong, or delayed diagnoses—account for an estimated 40,000 to 90,000 deaths a year. Diagnostic errors trigger nearly twice as many tort claims as medication errors and also subject patients to medical complications, as well as the discomfort and cost of medical tests they don't need.

Papers published in the May 2008 supplement of AJM confirm the extent of diagnostic errors. These authors suggested

improvement will best come by developing systems to provide physicians with better feedback on their own errors.

According to the AJM papers, the diagnostic error rate is generally less than 5% in the perceptual specialties, such as pathology, radiology, and dermatology. However, the diagnostic error rate can reach as high as 10% to 15% in medical specialties.

These papers also pointed out that medical practitioners do not utilize systems designed to aid in diagnostic decisions. "In my view, diagnostic error will be reduced only if physicians have a more realistic understanding of the amount of diagnostic errors they personally make," contended Paul Mongerson, a retired engineer.

In 1980, as a patient facing an apparent diagnosis of pancreatic cancer, Mongerson created a matrix chart of his symptoms and test results to assess the probability that his doctors were right. He didn't think so and did not undergo surgey. Mongerson later created a foundation to promote computer-based and other strategies to reduce diagnostic errors.

At Johns Hopkins, Newman-Toker and Pronovost recommended moving beyond blaming doctors, which hasn't produced any solutions. They asserted that reducing diagnostic errors will require a focus on larger "system" failures that affect the practice of medicine overall. This is similar to the approach to reducing medication and other treatment errors.

Improve Diagnostic Accuracy

"Moving away from a model that chastises individual physicians to one that focuses on improving the medical system as a whole could offer big payoffs for improving diagnostic accuracy, as well as the cost effectiveness of care," said Newman-Toker, Assistant Professor of Neurology, Otolaryngology, Health Sciences Informatics, Epidemiology and Health Policy and Management at Johns Hopkins School of Medicine and Johns Hopkins Bloomberg School of Public Health.

The Johns Hopkins team recommended systematically adopting tools like checklists to help physicians remember critical diagnoses. They noted that hospitals successfully reduced bloodstream infections in intensive care patients by requiring physicians to follow a procedural checklist that emphasizes sterile techniques when inserting medical catheters in these patients.

They also recommended making computers with diagnostic-decision support systems available to assist physicians in calculating the level of risk for patients with certain diseases.

Realign Resources

"Right now, there is often a mismatch between who gets advanced diagnostic testing and who needs it, leading to worse outcomes and higher costs," Newman-Toker said. "Realigning resources with needs would improve outcomes at a lower cost."

He explained, for example, that triage protocols in emergency departments often lump patients with typically benign symptoms like headache into the "low-risk" category, even though headache can be indicative of serious conditions like a bleeding brain aneurysm. Newman-Toker suggested that one systemic fix to decrease diagnostic errors would be to create different triage rules for "low-risk" and "high-risk" patients presenting with a headache. There would be detailed criteria for distinguishing between the two categories.

The Johns Hopkins physicians said that health systems could further decrease diagnostic errors with time-tested, low-tech tools such as independent second looks at X-rays and CT scans or by rapidly directing patients with unusual symptoms to diagnostic experts. Pathologists obviously would be among diagnostic consultants in high demand, advising physicians about the most appropriate laboratory tests to perform, helping to interpret results, and to select treatment options. TDR

—Patricia Kirk

Warning: Three-Fold Rise In EMR Adoption Predicted

Stimulus plan sets aside $20 billion for physicians who install certified EMRs

CEO SUMMARY: Doctors are responding to news that up to $20 billion in federal funding is now available to help pay for their adoption of electronic medical record (EMR) systems. Demand for EMRs is expected to increase three-fold in the coming years. That means clinical labs and pathology groups must step up their EMR interface capabilities—or lose clients as physicians move their business to laboratories who do a better job of interfacing with physicians' EMRs.

IT IS PREDICTED THAT the American Recovery and Reinvestment Act of 2009 (ARRA) may trigger a three-fold increase in the number of physicians installing electronic medical record (EMR) systems over the next 10 years. If that happens, hospital laboratory outreach programs will face an unprecedented demand from physicians to install LIS-to-EMR interfaces.

"Prior to passage of ARRA, an average of 12,000 physicians per year would transition to use of an EMR in their practices," observed Pat Wolfram, Vice President of Marketing and Customer Services for **Ignis Systems Corporation**, a firm in Portland, Oregon, that integrates EMRs to laboratories. "ARRA is the game-changer because it mandates federal spending of $20 billion over the next five to six years to spur adoption of EMRs and to reimburse physicians for much of the EMR's installation cost.

"At a recent users' group meeting, we spent three days with 400 advanced EMR users," he continued. "The hottest topic was ARRA's funding for 'meaningful use' of EMRs. Among the other high-interest topics was EMR interoperability, including links to labs.

"ARRA calls for investing $20 billion to foster private-sector investments in healthcare information technology (HIT), and ARRA has a goal of 90% EMR adoption by 2019," commented Wolfram. "Some interpretations show an even more aggressive goal. To meet that goal of 90% adoption, EMRs must be installed at the rate of 40,000 physicians per year over the next 10 years. That's over three times the current rate of 12,000 physicians per year who adopt EMRs!

Economic Stimulus for HIT

"As a company that specializes in working with physicians to integrate EMRs with laboratories, we are working with our lab partners now to scale up our capacity by three times," Wolfram added. "In fact, every EMR vendor and every lab that connects to EMRs similarly must prepare a plan to handle physician demand that may be three-fold higher than current EMR adoption rates."

In a recent conference call conducted by the **Medical Group Management Association** (MGMA) in Englewood, Colorado, its President and CEO, William Jesse, M.D. explained how ARRA will

stimulate HIT adoption in group practices. The carrot is that ARRA will reimburse physicians who install certified EMRs within the next five years. There is also reimbursement for physicians who have already installed certified EMRs. The stick is that, for physicians who do not install certified EMRs within the next five years, Medicare will reduce the rate it pays to treat Medicare beneficiaries.

Reimbursement for EMRs

During the conference call, Jesse stated that "The two main incentive opportunities are through the Medicare program and separately through the Medicaid program," he added. "A physician can dip from either pocket—but cannot dip from both.

"Under the Medicare incentives, eligible physicians are defined as physicians (both M.D.s and D.O.s), dentists, podiatrists, optometrists, and chiropractors," Jesse said. "Because there is a separate pool of money for hospital incentives, hospital-based physicians such as pathologists, anesthesiologists, emergency physicians, or hospitalists—whose sole site of practice is the hospital—are *not* eligible for the Medicare incentives." In the case of pathologists and other hospital-based physicians, Jesse noted that they may receive support for EMR adoption through the hospital incentives but cannot receive funding directly through Medicare.

Five Years To Adopt EMRs

"Under ARRA, Medicare will reimburse physicians $15,000 to $18,000 in 2011 or 2012 and then less for each year after that for five years up to a maximum of $44,000," Jesse said. "This is the carrot and stick approach. You get the carrot at the front end, and the size of the carrot gets smaller if you delay. If you decide not to do this until the fourth year, then the amount of the incentive is only $4,000 to $6,000.

"And if you haven't implemented an electronic health record by the fifth year, which is 2015, then the stick comes out," explained Jesse. "The stick affects your Medicare payment rate. Under ARRA, Medicare payment rates to physicians who are not using EMRs will drop by these factors: 1% less in 2015; 2% less in 2016; 3% less in 2017; and up to 5% less in 2019. Clearly, this is a system designed to get physicians to implement EMRs early on."

During the conference call, Jesse also explained that physician reimbursement for EMR adoption is also available under the Medicaid provisions in ARRA for physicians who have 30% of their patients in the Medicaid program. "States are authorized to make payments to Medicaid providers that total no more than 85% of their net average allowable costs for certified EMR technology," Jesse said. "So, in essence, about 85% of what a physician spends to acquire an EMR—up to a maximum of $63,750, can be paid by the state Medicaid program.

Medicaid Funds Up To 85%

"That includes the cost of purchasing hardware and software plus the cost of support services including maintenance and training," noted Jesse. "The Medicaid provider is then responsible for paying the remaining 15% of the net allowable costs. So a physician does have to spend some money out of pocket, but in essence 85% of EMR adoption costs—up to that maximum of $63,750, will be paid by Medicaid."

Wolfram's observation that physician adoption of EMRs is about to jump threefold in coming months represents a timely warning for clinical laboratories and pathology group practices. It means that many of every labs' bread-and-butter clients will be moving to EMRs—and will want their laboratory provider to provide an electronic interface to enable lab test results to automatically populate the patient record in the EMR.

That is why lab administrators and pathologists should be developing strategies and lining up the resources needed to meet these new needs of their client physicians. Failure to act in a timely manner could result in lost client accounts. TDR

Contact Pat Wolfram at 888-806-0309 x502, or pat.wolfram@IgnisSystems.com.

Buy Your EMR from Wal-Mart? Don't Laugh! Sam's Club Teams Up with Dell, eClinicalWorks

IMAGINE BUYING AN electronic medical record (EMR) system at Wal-Mart! Don't laugh because about 200,000 healthcare providers—mostly doctors—are already members of the Sam's Club division of Wal-Mart Stores, which will offer Dell computers and eClinicalWorks software to physicians in small offices seeking electronic health record systems.

Recognizing that the government will spend an estimated $20 billion over the next five years to get physicians to install electronic medical record (EMR) systems, Sam's Club, Dell, and eClinicalWorks are working to make technology more accessible and affordable for physicians in smaller practice settings. That was reported by the *New York Times*, which also said that Sam's Club, Dell, and eClinicalWorks expect their prices will undercut health information technology suppliers by as much as half!

Wal-Mart will offer physicians hardware, software, installation, maintenance, and training for $25,000 for the first physician in a practice, and about $10,000 for each additional doctor in the group. Sam's Club estimates that, after the installation and training, continuing annual costs for maintenance and support of the EMR system will run between $4,000 to $6,500 annually.

Wal-Mart/Sam's Club is shrewd to target physicians in small-group settings. EMR penetration in this tier 3 category is estimated to be only about 3% to 4%. Because of the new federal financial incentives for EMR adoption, demand from these physicians is expected to skyrocket.

In Florida, a regional initiative is organizing to take advantage of the federal stimulus funding. It is **PaperFree Tampa Bay**, a public-private partnership. Last month, the group said its goal is to convert all physicians in the Tampa Bay area from paper prescriptions—known to be the cause of costly medical errors—to electronic prescribing.

Partners in the Tampa program include **University of South Florida (USF) Health** and **Allscripts**, which will work together to help 3,200 physicians in Hillsborough County to implement EMRs. Later, program officials plan to expand the effort to the entire 10-county Tampa Bay region, including the counties of DeSoto, Hardee, Hernando, Highlands, Manatee, Pasco, Pinellas, Polk, and Sarasota.

The $20 billion dollar federal honey pot for EMR funding has already upped demand for EMRS by physicians in small practice settings. Writing in *For the Record* (*http://www.fortherecordmag.com/*), John E. O'Keefe, in a story called "EMRs at the Tipping Point," observed that:

According to a recent report by healthcare market research firm Kalorama Information, the EMR market is expected to grow by 14.1% annually through 2012. With the tier 1 market segment (large hospitals) approaching full saturation—approximately 80% already employ EMRs—and tier 2 (large medical groups) adoption slowing, much of that growth will be coming from the bottom up.

A segment of the healthcare industry that as recently as the summer of 2006 recorded only a 3% to 4% EMR adoption rate, tier 3 providers (smaller private practices) are now clamoring to implement the systems. This is no small thing. According to U.S. Census reports, of the physicians at work in the United States, some 60% are small to midsized practice providers.

In some cases, physician-initiated EMR implementation inquiries actually increased more than twentyfold in December 2008 alone compared with the previous six-month period. And 2009 looks to continue, if not significantly expand, that trend.

Lab Briefs

INVERNESS ACQUIRES TEST BUSINESS FROM ACON

WITH A STRATEGY OF BECOMING DOMINANT in the consumer testing market and point-of-care (POC) testing sector, **Inverness Medical Innovations, Inc.**, of Waltham, Massachusetts, has actively acquired companies and technologies in these fields.

Its latest move was to pay $200 million to purchase the remaining parts of **ACON** that it did not own. Inverness will end up with ACON's lateral flow immunoassay diagnostics kits designed for consumers, laboratories, and point-of-care applications. ACON, a diagnostics products company in San Diego, California, generated about $45 million in sales annually from this product line.

The acquired assets include tests sold within Inverness' areas of infectious disease, cardiology, drugs of abuse, and women's health. ACON will retain its other worldwide *in vitro* diagnostics businesses, including diabetes, clinical chemistry, and immunoassay products. The acquisition is expected to close by end April 30, 2009.

Inverness has used acquisitions as a path to growth. With annual revenue of $1.7 billion, it has become a sizeable enterprise by exploiting different market niches in diagnostic testing.

MAKING LAB DATA "LIQUID" FOR ALL USERS

OVER AT *WWW.LABSOFTNEWS.COM*, our friend and blogger Bruce Friedman, M.D. has identified another confirming example of the importance of laboratory test data.

Friedman, who is a Professor Emeritus of Pathology at **University of Michigan Medical Center**, recently had an expert in PHRs (patient health records) speak at his LabInfoTech conference in Las Vegas, Nevada last month. John Moore, who blogs for **Chilmark**, described his experience with PHR at **Kaiser Permanente**. Friedman quotes Moore thusly:

> *Friedman...asked me to update the audience on the PHR market and more broadly, what are the implications, either implied or explicit of trends in PHRs to pathology labs. It took me some time to think this one through, but finally a light-bulb went off in my head!*
>
> *What are Kaiser Permanente (KP) members most enthralled with in how they use the KP PHR? It is getting their lab results quickly, online, and with background information on what those results mean to take appropriate action(s).*
>
> *Then, if one were to look at RHIOs & HIEs, what types of data are the first to move within these exchanges? It was lab data and meds! Stepping into ER, what does an ER doc most want to see when a patient presents in ER? Labs, meds, and allergies. [I recognized that] the need to make lab data "liquid" was everywhere.*
>
> *This "aha moment" led to the creation of a presentation,... that folds in our previous research on PHRs, more recent research on Cloud Computing in healthcare—some even more recent work on RHIOs and HIEs—with what all this means to the lab market.*

Friedman perceptively picked up on Moore's use of the term "liquid" to characterize the way laboratory test data needs to flow effortlessly to all authorized users, including the patient. THE DARK REPORT observes that Moore has another equally important insight. Kaiser Permanente, which is among the nation's leaders in measuring patient satisfaction, has learned that patients place great value on having timely and complete access, not only to their laboratory test results, but to additional information about the clinical meaning of those results. Labs should act on these insights by enriching their laboratory informatics capabilities. TDR

Gene Testing

Navigenics Buys Clinical Lab From Affymetrix Last Month

Direct-to-consumer genetics testing vendor now has in-house laboratory testing capabilities

IF **NAVIGENICS INC.** HAD A SLOGAN to match its business model, it might be, "Damn the torpedoes. Full speed ahead!" Last month the personal genomics testing company acquired a clinical testing laboratory.

In a deal with **Affymetrix, Inc.**, Navigenics purchased the **Affymetrix Clinical Services Laboratory**, a CLIA-certified testing facility in Sacramento, California. This lab provides molecular genome scanning using the Affymetrix GeneChip microarray platform. The purchase of this lab means Navigenics now can offer fully integrated genome screening and analysis under one roof.

Genetic Testing Service

As a direct-to-consumer company offering genetic tests to the public, it was just last year that Navigenics received a cease and desist order from the California Department of Health. The order said Navigenics was in violation of the California Business and Professions Code requirements that the company perform its tests in a clinically licensed facility, and that all of its lab test orders must be referred by either a physician or surgeon. It responded to the order by saying it did not actually test patients' genomes; rather it analyzed them, according to *Wired* magazine. *(See TDR, July 7, 2008.)*

At the time, *Wired* reported that Navigenics was claiming it therefore should not be regulated as a clinical laboratory under California state law, arguing that it merely applies algorithms to DNA data it receives from tests performed by a third-party, a licensed laboratory.

It seems that Navigenics has adopted the philosophy of "it is better to join them than fight them." The acquisition of Affymetrix' clinical laboratory helps Navigenics comply with the California Department of Health letter.

Moreover, Navigenics had another motive to purchase a clinical laboratory. According to a report by *GenoneWeb Daily News*, Navigenics has experienced an increase in the volume of orders for its genetic screening services.

It recently began offering a less expensive genetics service. Also, Navigenics has a marketing partnership with **MDVIP**. This physician group, based in Boca Raton, Florida, runs a national network of individual physicians who practice preventive and personalized healthcare.

Business seems to be good for Navigenics. It has a research collaboration with **The Scripps Translational Science Institute**, Affymetrix, and **Microsoft** to genetically screen 10,000 participants. It will also continue to provide DNA scanning for Affymetrix customers, using the clinical laboratory it acquired from Affymetrix.

Navigenics is an example of a lab testing company developed outside of the traditional laboratory medicine estalishment. It represents a new sector in lab testing that is not controlled by pathologists. TDR

Hey Doc! How Do You Rate With Zagat Health Survey?

➤Zagat Health Survey designed to help WellPoint's patients select their physicians

➤➤CEO SUMMARY: Once patients become involved in managing their healthcare, they actively seek information that can help them make informed decisions. Health insurers are providing tools to help make this job easier. WellPoint teamed up with Zagat Survey to create the Zagat Health Survey. This unique tool offers consumers a snapshot of a physician from the patient point of view. It is available exclusively to members of WellPoint's affiliated plans and other participating Blues Plan members.

OVER THE PAST FIVE YEARS, one trend in healthcare has been to encourage consumers to take a greater role in choosing their doctors, hospitals, and other providers—even as they are required to pay more money out of pocket. Two elements are required for this trend to succeed.

First, consumers must have easy access to the actual prices charged by different physicians, hospitals, laboratories, and other providers. Second, consumers need a way to determine the quality and service differences among these different providers. These dynamics lie at the heart of CDHPs, (consumer-directed health plans) and HDHPs (high-deductible health plans), including HSAs (health savings accounts) and HRAs (health reimbursement accounts).

➤Shopping For Doctors

As consumers assume responsibility for managing their own healthcare, they are shopping the Internet for doctors and—much like choosing a hairdresser or restaurant—are making decisions based in part on consumer reviews.

No one in the medical community gave this consumer-driven phenomenon much thought until **WellPoint, Inc.**, the nation's largest insurer, enlisted **Zagat Survey, LLC**, a trusted resource of consumer information, to create a consumer satisfaction survey exclusively for its members.

Beginning early last year, WellPoint rolled out the Zagat Health Survey in Southern California, Ohio, and Connecticut. WellPoint plans to eventually expand the tool to all 34.2 million Blues plan members in 14 states. **Blue Cross Blue Shield of North Carolina**, which is not affiliated with WellPoint, also recently contracted with WellPoint to extend the program to its members statewide.

With WellPoint actively promoting the tool online and via direct mail, survey information is building quickly. According to Eric Fennel, Wellpoint Vice President for Innovation, over the last few quarters the volume of consumer feedback on providers has increased exponentially.

In launching the survey, he says the Zagat/WellPoint team involved the medical community market-by-market,

including state medical societies. "Some were concerned the survey would only attract the negative, but we were confident that if we positioned it the right way, consumers would respond positively—and they have!" Fennel noted. Consistent with Zagat's approach in other survey tools, the consumers' ratings and comments are allowed to speak for themselves. So far WellPoint is pleased with the results.

"The feedback that consumers are sharing with each other has been thoughtful and constructive," observed Fennel, who noted that more than 75% of patients post comments. Within that total, 85% of patients who post recommend their doctor.

Despite the early evidence that patients are even-handed in their assessments, the idea of being rated by a consumer guide like Zagat has some doctors' knickers in a bunch. "It is curious that they [WellPoint] would go to a company that had no experience in health care to try to find out how good a doctor is," said William Handelman, M.D., a kidney specialist in Torrington, Connecticut, to the *New York Times*. "It certainly is very subjective."

"As If Preparing A Meal"

Angelo S. Carrabba, M.D., an obstetrician in Rocky Hill, Connecticut, declared that WellPoint's **Anthem Blue Cross and Blue Shield** is "treating medical care provided by dedicated and caring physicians as if we were preparing a meal."

Another sceptic is Arthur Caplan, Director of the Center for Bioethics at the **University of Pennsylvania**. He is distrustful of open forums for evaluating physician quality. "There is no correlation between a doctor being an inept danger to the patient and his popularity," declared Caplan, who contended that patient reviews of doctors are "a recipe for disaster."

The fact that insurers are attempting to rate doctor quality has raised a red flag with some state governments, which are concerned about the motive. Attorney generals and the **American Medical Association** warn that these programs could direct patients to the cheapest—rather than the best—physicians. *The Wall Street Journal* reported last fall that the New York Attorney General ordered health plans, including WellPoint's **Empire Blue Cross Blue Shield**, to halt or provide more details on their doctor-ranking programs.

Rating Consumer Experience

With regard to the Zagat Health Survey, WellPoint's Fennel stressed, "This tool looks at consumer experience, not clinical quality." He suggested that physicians could use the information constructively to make service improvements in their practice.

"The Zagat Health Survey is just one response by Wellpoint to overall consumer desire for greater transparency in healthcare," observed Fennel. "People value other people's opinions, but that by itself is not the whole story." He points out that research indicates consumer surveys are helpful and that the categories surveyed—Trust, Communication, Availability and Environment—are elements of the experience that consumers are uniquely positioned to evaluate.

The Zagat Health Survey is just one part of the consumer transparency effort at WellPoint. It also has a program to provide its members access to the prices charged by different providers. WellPoint's Anthem Care Blue Cross Blue Shield enables its members to compare costs and outcomes for procedures performed at local hospitals and outpatient facilities.

Cost Comparison Tool

The Anthem Care Comparison tool estimates the cost for the full spectrum of services associated with the procedure at each facility in the region that has a contract with Anthem Care. "The data reflects our actual cost, but doesn't yet reflect the patient out-of-pocket," said Fennel. "The goal is to provide consumers with an upfront understanding of the overall costs they are likely to incur. The cost is dis-

played alongside quality information for each facility, including: frequency or number of procedures, complications, mortality rate and length of stay."

"WellPoint is also developing a similar member tool for physician quality," he said. "Ultimately the various types of provider information will be integrated into one display context that consumers use to manage their healthcare.

"The objective is to provide information to members so they understand all the factors needed to make an informed decision about their healthcare and their choice of providers," stated Fennel. "We want members to be engaged in the healthcare process, and we want to be an objective source of information to support those decisions."

Useful Conclusions

Lab directors and pathologists can draw several useful conclusions from WellPoint's efforts to provide more transparency to consumers on provider pricing, provider quality, and patient satisfaction with a specific provider's service. First, it is now in the second year of working with Zagat on the physician health survey. Consumer response is so positive that WellPoint intends to roll this out to other health plans within its system.

Next, consumers using WellPoint's Zagat health survey like it. It is another example of how and why the Internet is a great marketing resource. For that reason, clinical labs and pathology groups should be expanding their Web presence and introducing patient-friendly services.

Finally, good or bad, consumers will tell other consumers about their experience, and once posted on the Internet, the critique stays there for a very long time. That is another reason why laboratories should pay attention to patient satisfaction. **TDR**

—Patricia Kirk

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How WellPoint Works With Zagat Health Survey

TO HELP CONSUMERS MAKE INFORMED DECISIONS when selecting their doctors, WellPoint engaged the help of Zagat Survey to design and operate what is called the Zagat Health Survey.

The survey tool leverages the familiar Zagat-brand display. It is accessed via WellPoint's on-line provider directory and at related points. WellPoint members are asked to rate their physicians on four criteria. Members are also asked if they would recommend this doctor to other people. The survey invites members to write comments about their experience and/or explain their physician rating.

Zagat collects and organizes the information. To avoid skewing data, a published doctor rating requires a minimum of 10 submissions. Consumers are only allowed one submission per physician. Each review is screened and inappropriate comments are removed.

The rating scale is 0 to 3, with 3 being excellent; 2 very good; 1 good; and, 0 fair-poor. Consumer scores for a physician are averaged and multiplied by 10 to create the familiar Zagat 0-30-number ratings. The four criteria include:

- **TRUST**—Is the patient confident in the physician's approach, integrity and recommendations?
- **COMMUNICATION**—What about the physician's bedside manner, responsiveness and rapport?
- **AVAILABILITY**—Was it easy to make an appointment, was the doctor on time, or the patient kept waiting for hours?
- **OFFICE ENVIRONMENT**—What's the condition of the doctor's office/waiting area, is there reading material, a children's play area, separate area for sick and well children, and does the staff have a helpful and pleasant attitude?

Medically Unlikely Edits Are Back–and a Problem!

CMS instituted 100 new MUEs on January 1, then carriers began rejecting laboratory claims

CEO SUMMARY: On January 1, 2009, CMS implemented Phase VIII of its policy on medically unlikely edits (MUEs) involving about 100 laboratory CPT Codes. It also began to deny whole claims, not just the "medically unlikely" parts of claims. After hearing of the problem in early March, ACLA, CAP, and other lab groups stepped in to work closely with CMS officials to resolve the problem. Claims are expected to be paid in full until new revisions to MUE rules are implemented.

UNUSUALLY HIGH RATES of Medicare claim denials have been experienced by some labs since the first of this year. The cause is the implementation of as many as 100 MUEs (Medically Unlikely Edits) involving laboratory CPT codes.

"It was on January 1 that the federal **Centers for Medicare & Medicaid Services** (CMS) instituted Phase VIII MUEs," stated Alan Mertz, CEO of the **American Clinical Laboratory Association** (ACLA) in Washington, DC. "This resulted in denials for claims that incorporate any of 100 laboratory CPT codes. In particular, our member labs noticed MUEs related to claims for fluorescence *in situ* hybridization (FISH), flow cytometry, and immunohistochemistry (IHC)."

Resolution Takes Weeks

As this pattern of unexpected claims denials was recognized, professional lab organizations, including ACLA, worked closely with CMS officials to resolve this issue. "ACLA learned on March 13 that CMS would no longer deny the laboratory-related MUEs in question," noted Mertz. "From that date, it would take about two weeks for all Medicare contractors to begin paying these claims normally again. That doesn't change the fact that some labs will have experienced an unusually high rate of denials for about three months—from January 1 through the end of March."

While the current MUE problem may be ended for the moment, pathologists and lab directors are well aware of the potential for inappropriate MUEs to cause havoc. Back in early 2006, THE DARK REPORT was first in the lab industry to call attention to the CMS proposal to limit CPT 88305 (Level IV—Surgical Pathology, Gross and Microscopic Exam) to two units of service per day. At that time, a Medicare contractor had developed a list of MUEs that targeted 1,100 laboratory CPT codes for restriction of service! *(See TDR, January 16, 2006, and June 12, 2006.)*

Since that time, officials from laboratory organizations, including ACLA and the **College of American Pathologists** (CAP) have worked with CMS to institute an MUE program that is fair to labs, while allowing CMS to use electronic claims

editing systems that flag medically unlikely events, such as a hysterectomy involving a male patient.

"The most recent snag developed when some lab directors noticed higher than usual claim denials in the first three months of the year," said Mertz. "Many labs did not know the extent of the problem at first because the CMS contractors did not explain the denials."

No Prior Announcement

"There was no opportunity to meet with CMS before this big batch of MUEs hit in January," Mertz explained. "So, it was not until late February and early March before our members notified us that, not only were the Medicare carriers denying payment for the units of service in excess of the MUE, but the carriers were actually denying whole line items in the claims if the claim had exceeded the MUE!

"We asked our members to quickly survey about one month's worth of claims," he added. "In a single month, we had eight laboratories report about $1 million in denials. These centered around 23 codes, particularly claims for FISH, flow cytometry, and IHC tests.

"Fortunately, during a conference call about this matter, CMS agreed to suspend the implementation of Phase VIII MUEs until we have an opportunity to meet with them to discuss what went wrong and identify ways to rectify this problem," Mertz stated. "It will take CMS about two weeks to implement suspension of these MUE denials, which they did pledge to do until this can be resolved."

During the conference call, those representing the labs raised a number of issues in addition to the denial of claims, said David A. Mongillo, ACLA's Vice President for Policy and Medical Affairs. "Labs were concerned about a lack of transparency, the criteria used for establishing the MUEs, and the processes CMS followed in implementing the Phase VIII revisions," he said. "CMS' positive response is welcome and we will continue to work with CMS to resolve these issues." TDR

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Recent MUE Implementation Meant Entire Claim Was Denied

Medicare's policy of having carriers follow a procedure to deny the entire claim for tests subject to medically unlikely edits (MUEs), was clearly unjustified, said Alan Mertz, CEO, of the American Clinical Laboratory Association (ACLA).

"The federal Centers for Medicare & Medicaid Services (CMS) could have limited the denial to those units of service that exceed the MUE," Mertz observed. "But to deny the entire claim was arbitrary and capricious. It was also harmful to both patients and providers.

"The tests at issue," he continued, "including but not limited to procedures in flow cytometry, histology, immunohistochemistry, and fluorescent *in situ* hybridization, are medically necessary and supported by appropriate diagnosis codes. These tests are being ordered by physicians to determine treatment for Medicare beneficiaries who are often critically ill."

"Further, CMS exacerbated the effect of such denials on patients and providers by not publishing the exact number of approved MUEs, and by not disclosing this information to ACLA and other laboratory organizations," stated Mertz.

"This new and unsubstantiated policy runs counter to the multitude of input on full disclosure of the MUEs," added Mertz. "The laboratory or pathologist performs those tests deemed medically necessary by a provider but have no idea whether they will be paid at all for the markers or stains deemed medically necessary. This is an untenable position for the laboratory community."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Effective May, 1, 2009, **Laboratory Corporation of America** will no longer be a contract provider for **Regence BlueShield**, headquartered in Seattle, Washington. Regence notified physicians that it was ending its relationship with LabCorp "as a result of rising costs of care provided in our markets and LabCorp's refusal to accept market level reimbursement. ...Regence is committed to maintaining our laboratory network service at an affordable cost." This network change shows that health insurers are still willing to disrupt the contract status quo in their region to achieve the combination of pricing and value added laboratory testing services that advance their interests.

MORE ON: Regence

Regence BlueShield is the largest health insurer in Washington, with 840,000 beneficiaries. Thus, LabCorp loses network status for an important payer in the Pacific Northwest.

CLARIENT LINES UP NEW INVESTOR IN A $50 MILLION DEAL

On March 26, 2009, **Clarient, Inc.**, of Aliso Viejo, California, announced a private convertible preferred stock placement with **Oak Partners**. Totaling $50 million, Oak Partners has already funded $29.1 million and will fund an additional $10.9 million by June 26. Clarient is using this new capital to "retire Clarient's existing debt obligations, pay transaction expenses, and provide working capital." Clarient has experienced steady growth in revenue and specimen volume over the past three years. It describes itself as an "anatomic pathology and molecular testing services resource." Clarient ended fiscal 2008 with revenue of $73.7 million. That was an increase of 71.8% over 2007 revenue of $43.0 million.

TRANSITIONS

• Steve Gutman, M.D., has taken a position as Professor of Pathology at the **University of Central Florida** in Orlando, Florida. He was formerly Director of the Office of In Vitro Diagnostics (OIVD) at the **Food and Drug Administration** (FDA). After many years of service, Gutman left the agency earlier this year.

• Don St. Pierre is now the Acting Director of the Office of In Vitro Diagnostics at the FDA. He has served in the OIVD office for more than seven years.

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