Volume XVIII, Number 14 Monday, October 17, 2011

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

Forecast: Tough Fee Cuts Are in Labs' Future

EVERY CLINICAL LABORATORY AND ANATOMIC PATHOLOGY GROUP PRACTICE in the United States should prepare for some big-time financial belt-tightening during the next 36 months. That certainly is the message coming from intense budget battles unfolding in Washington, DC, this fall.

Most of you reading this probably know that the Medicare patient lab test co-pay/co-insurance proposal is back on the table. Whether it is the Congressional Super Committee looking to specify $1.2 trillion in reduced spending over 10 years or the Senate and House finance committees seeking sources of Medicare funding cutbacks just to get through the 2012 budget cycle, restoring the lab test co-pay requirement looks mighty attractive. That is particularly true when the co-pay is projected to generate up to $16 billion in savings over 10 years.

But that is not the only bad news. I doubt many of you know about the MedPAC proposal. It was issued last month and suggested that cutbacks in funding of Medicare lab testing could be used to provide the money needed to apply to physician fees, per the SGR (sustainable growth rate) formula. According to our Washington connections, MedPAC's initial proposal targeted $22 billion in lab test funding cutbacks over 10 years!

You will read more details about these proposals on pages 3-6. THE DARK REPORT is the first lab industry news source to provide information about the entire range of unwelcome ideas circulating around Congress. I agree with our editor that, for 2012, the lab industry's biggest strategic issue is how to ameliorate the impact of major budget cuts to Medicare and healthcare in general. Of course, clinical laboratories are not being singled out for such deep funding cuts. All classes of providers will be lobbying legislators until the 2012 budget process concludes.

If you agree with me that funding for lab testing is at high risk in coming months, then I recommend that you join us for a special audio conference on October 26 that will delve into the current legislative situation. We've arranged for Alan Mertz, President of the **American Clinical Laboratory Association**, and Peter Kazon, Senior Counsel in the Washington, DC, office of **Alston & Bird** to give you an insider's perspective of the situation.

We think there is still time for a united lab testing industry to step forward and educate lawmakers about the value of clinical lab testing. Plan to join us for this important audio conference and get the knowledge you need to help steer your lab to financial stability in the coming years. TDR

Congress Likely to Pass Deep Cuts in Lab Test Fees

Reinstituting Medicare patient co-pay is one of three proposals to cut lab test reimbursement

CEO SUMMARY: All signs point to a potentially dismal financial outcome for the clinical lab testing industry as Congress tries to trim spending by $1.2 trillion over the next 10 years. At least three proposals to significantly cut lab test reimbursement are in active debate by federal lawmakers. One proposal calls for reinstituting the Medicare patient 20% lab test co-pay. Other credible proposals would reduce lab testing fees by between $11 billion and $20 billion over 10 years.

MOVING INTO 2012, the clinical lab industry faces unprecedented funding cutbacks as Congress wrestles with intractable budget problems.

The news is bad. At least three different proposals to impose significant reductions in reimbursement for clinical lab testing are in play in Congress. It is also possible that other unknown ideas to further control spending on laboratory tests are being evaluated.

Although the **Clinical Laboratory Coalition** and a number of lab industry leaders are aware of these important developments, most lab administrators and pathologists do not know the full range of threats to lab test reimbursement. Nor do many in the profession realize how deeply these proposals would slash existing levels of reimbursement.

"Every clinical laboratory and pathology group has reason to be concerned about what is unfolding in Washington this year," stated Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA). "There are more threats to the financial stability of lab testing from more directions than has ever been seen in the past."

Each of the three biggest proposals to cut lab test funding now under consideration will dwarf the ongoing Medicare Part B fee reductions that were mandated by the Patient Protection and Accountable Care Act (PPACA) passed in 2010. Moreover, these proposals will leave those scheduled multi-year fee cuts in place.

The most immediate action will come from the bipartisan, 12-member Super Committee that was created last summer

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.)**

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

as a result of the debt limit legislation. The Super Committee is tasked to find $1.2 trillion in budgetary savings over 10 years, from spending cuts or tax revenue.

Major Cuts In Medicare

"Medicare is at the top of the list of possible spending cuts that the Super Committee will propose," noted Mertz. "It's difficult to know exactly what they're considering because this is a different process than ever before used by Congress. The process is not at all transparent. Further, the committee members are inaccessible and that means we can't speak to them.

"We are talking with some of their staff members, but that's not the same as meeting with the committee members," he added. "Plus, the committee is on a very fast time track and will not conduct any public hearings. The process is about as controlled and opaque as any I've ever seen in Congress. All we keep hearing is that everything is on the table.

"But, by meeting with other members of Congress, we do know that the lab cost-sharing [patient co-pay] idea is being considered, and possibly another proposal to implement an additional cut in the lab test fee schedule," Mertz commented. "Beyond that, we really don't know.

"To achieve the goal of cutting at least $1.2 trillion over 10 years, the committee members feel they can't get there without substantial Medicare cuts," he explained. "That is why everything is on the table. By law, the Super Committee must vote on its plan by November 23. That plan next goes to the full House and Senate in December and the resulting bill can neither be amended nor filibustered.

An Opaque Process

"In the past, when there was an ill-advised proposal on the table, we would work with Congress to revise the proposal to make it less destructive to labs and patients," he said. "But this Super Committee's process is so unusual that we can't even discuss the ideas with the committee members. And this committee's work is just the first of the threats now facing the lab testing industry.

"The second threat is related to the first one because, if the Super Committee can't agree on cuts that total $1.2 trillion in federal spending, there would be an automatic 'sequestration,' or cut in Medicare provider reimbursement of 2%. In addition, the formula Medicare uses for the physician fee schedule will expire at the end of the year," Mertz added. "That formula is called the sustainable growth rate (SGR).

"When it expires, Congress will need to extend it and find a way to pay for it," he stated. "Lab funding cuts could again be on the table to help get the funds to pay for the physician fee schedule update.

"The third threat comes from MedPAC, which is an independent group that advises Congress on Medicare issues," he added. "Last month, MedPAC proposed to permanently repeal the SGR and replace it with a formula in which they would pick and choose which specialties would get funded and which ones would be cut.

Cuts To Pathologist Fees

"Under this plan," continued Mertz, "the payment rate for primary care physicians would be frozen for 10 years and all the other specialties, including pathology presumably, would get annual cuts of 5.9% in three consecutive years. After that, the payment rate would be frozen.

"The problem with this idea is that it would cost Medicare about $235 billion over 10 years," he noted. "That means Congress would have to cut payments to other providers over 10 years—meaning drug companies, health plans, equipment companies, and everyone else. So, this idea could hurt clinical labs as well.

"Originally, MedPAC proposed $22 billion in cuts to lab testing reimbursement, but we strongly opposed this cut as well as pointed out an error in their calcu-

Any New Lab Fee Reductions To Be Added To Cuts Already in Health Reform Law

AS CONGRESS CONSIDERS NEW AND DEEPER cuts to clinical lab payments, Mark S. Birenbaum, Ph.D., pointed out that the healthcare reform law of 2010 already has lab fee cuts built into it.

"The Affordable Care Act (ACA) called for five annual cuts in lab fees under the Medicare Part B fee schedule of 1.75% each year," said Birenbaum, the Administrator of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) in St. Louis, Missouri.

"This year, the first cut of 1.75% was implemented and the second cut will take effect next year," he said. "Those two cuts already total 3.5% and three more cuts are coming for a total reduction of lab fees of 8.75% over five years.

"This is happening even as a number of law suits question the constitutionality of that law," added Birenbaum. "The constitutionality issue is expected to be addressed by the Supreme Court next year. But, meanwhile, labs have already taken the hit.

"In addition, we know that the Super Committee may cut lab test fees even more," he continued. "Should they not reach $1.2 trillion in spending cuts, there would be an across-the-board cut that equals about 2% of Medicare spending. Thus, if the super committee members do nothing, that 2% Medicare cut goes into effect next year, and gets tacked on to the 3.5% cuts mandated by the ACA legislation.

"On October 5, our members visited Capitol Hill and conducted more than 50 meetings with members of Congress about how these cumulative cuts will affect clinical labs," said Birenbaum. "We explained that many community laboratories have profit margins of 5% and 6%. These labs cannot continue absorbing cuts of 2% and 3% each year and remain in business.

"Our concern is that, once these funding cutbacks get to a certain point, labs will just have to close up shop," he said. "Clearly, the level of funding cuts now under consideration threatens the financial viability of many labs."

lations," explained Mertz. "They ended up proposing $11 billion in cuts to the clinical lab fee schedule. While that is not as bad as $22 billion, labs should not be cut at all given how much they have been cut in recent years. Keep in mind that there would still be the cut to pathology under the physician fee schedule of 5.9%.

"It may be optimistic to think that Congress would not approve MedPAC's proposal on the physician fee schedule," commented Mertz. "However, the Super Committee could look at MedPAC's ideas and use them as an alternative to the lab co-pay idea. If that happens, the total cuts to lab testing fees could be 10% each year over 10 years. That is something clinical laboratories could ill afford.

"Among all these ideas, I'm most worried about cost sharing [patient co-pay] or the cuts to the clinical lab fee schedule," Mertz commented. "Even if neither were enacted right now, one proposal could be passed and the other could happen soon after as part of some worst-case scenario, such as another deficit-reduction negotiation."

Mertz is careful to point out that the lab test funding can be negatively impacted from other activities unfolding now in Washington, DC. "In addition to these budget considerations, there are other proposals that could affect lab payments," he noted.

Regulating Home Brew Tests

"For example, the FDA continues to consider issuing guidance to regulate laboratory-developed tests (LDTs, also called home brew tests) as FDA devices," stated Mertz. "We are very concerned about that because it could stifle innovation and the ability of laboratories to introduce new LDTs that are essential to patient care.

"Therefore, we are very supportive of ideas the House Energy and Commerce Committee has about taking a different approach to this issue," he explained. "We prefer that Congress address this matter legislatively such that FDA does not regulate LDTs as medical devices.

CLIA And LDTs

"The best way to achieve this would be to enhance CLIA in ways that would allow it to address the clinical validity of LDTs," he added. "That is a much better way to deal with this issue, and some legislators are in favor of this idea.

"Another proposal that concerns us relates to the issue of code stacking," he said. "The AMA has proposed moving some codes related to molecular tests from the clinical lab fee schedule to the physician fee schedule. So far, this proposal has not moved forward very fast.

"The problem is that the physician fee schedule increases by only a small amount each year while the clinical lab fee schedule has no volume limit built into it," observed Mertz. "Plus, there is a 20% co-payment in the physician fee schedule and that co-pay is not part of the clinical lab test fee schedule—at least not now. Therefore, the lab profession doesn't want to move molecular test codes to a fee schedule that is so limited and that requires a patient 20% co-pay.

Lab Professionals Respond

"While all of these proposals have the potential to cripple labs, there has been one promising aspect of this effort," he continued. "That is the advocacy work on the part of labs and the grassroots efforts by laboratorians.

"Lab administrators and lab staffs have been phenomenal. I've never seen anything like it," said Mertz. "The entire lab testing community has been doing a great job to get the message out to members of Congress. The **American Association of Bioanalysts** (AAB) and the **National Independent Laboratory Association** (NILA) have been instrumental in getting their members to participate, as has the Clinical Lab Coalition and ACLA."

Mertz urged laboratory professionals to respond to these Congressional proposals. "Right now, we don't need to do anything any differently," he added. "What is needed is for more lab professionals to step forward and voice their views to their congressmen and Senators. Tell them the importance of the work that labs do.

"We have encouraged our members, meaning the CEOs and lab directors, to meet with their congressmen or senators or at least schedule a phone call with them," Mertz said. "When you have the top people calling members of Congress, that's called 'grass tops.' And when you have employees contacting members of Congress, that's called 'grass roots.'"

Special Audio Conference

Because of the unprecedented nature of the reimbursement-slashing proposals facing the lab testing industry, THE DARK REPORT has scheduled a special audio conference with Alan Mertz and Peter Kazon, who is Senior Counsel in the Washington, DC, office of **Alston & Bird**.

It is titled, "Washington Puts Lab-Test Cost-Cutting on the Table for 2012: Devastating Fee Cuts plus Other Congressional Proposals and How Your Lab Can Prevent Them." It takes place on Wednesday, October 26.

Details and registration to the audio conference are at *www.darkdaily.com*. Mertz and Kazon will provide an insider's perspective of how Congress is responding to these proposals to cut lab test funding, along with actions labs can take now to educate lawmakers on these issues. **TDR**

Contact Alan Mertz at 202-637-9466 or amertz@clinical-labs.org; Mark Birenbaum at aab@aab.org or 314-241-1445.

In Massachusetts, AG Targets Drug Testing Labs

Inducements and kickbacks are associated with urine drug screens offered by some labs

CEO SUMMARY: Since taking office in 2007, Massachusetts Attorney General Martha Coakley has aggressively pursued civil charges against drug testing labs. Last month, Coakley announced a criminal arrest in one ongoing investigation after a grand jury indicted a physician in a kickback scheme involving lab testing. In four years, Coakley has reached settlements with four independent clinical lab companies and each of these labs has agreed to make repayments and establish compliance programs.

In Massachusetts, Attorney General **Martha Coakley** has aggressively pursued civil charges against drug testing laboratories since taking office in 2007. Last month, Coakley announced a criminal arrest in one ongoing investigation after a grand jury indicted a physician in a kickback scheme that involved lab testing services.

On September 30, Coakley announced that a grand jury in Suffolk County Superior Court returned indictments against Punyamurtula Kishore, M.D., of Brookline, Massachusetts, and three other defendants. Kishore owns and manages **Preventive Medicine Associates, Inc.** (PMA), and allegedly runs a kickback scheme and has fraudulently billed **MassHealth** (the state Medicaid program) nearly $3.8 million, Coakley said.

PMA has 29 medical branches in the state and some include physician office laboratories (POLs), the AG's office said. Kishore allegedly used bribes or kickbacks to induce owners of sober houses for alcoholics and drug abusers to require their residents to submit to urine drug screens performed by PMA's POLs at least three times a week, the office said. Kishore and PMA were charged with eight counts related to receiving kickbacks and eight counts related to filing false claims.

Medicaid Fraud Cases

This and similar cases in Massachusetts since 2007 may prove interesting to lab administrators and pathologists for two reasons. First, in recent years, Coakley has brought Medicaid fraud charges against at least five other clinical laboratory companies alleging Medicaid fraud associated with claims submitted for urine drug screens. Thus, the current prosecution of Kishore is the Attorney General's latest warning shot for labs serving the urine drug testing market in Massachusetts.

Second, Coakley's prosecution of Kishore could shed light on a sector of lab testing that some consider a gray area. Questions have been raised about the clinical appropriateness of urine screens offered to physicians by laboratories; or urine screens performed by physicians in clinics; in tandem with the aggressive coding, billing, and reimbursement practices associated with this testing.

Massachusetts AG's Case Against Executives Of Calloway Laboratories Remains Unsettled

AMONG THE CASES THAT Massachusetts Attorney General Martha Coakley has pursued is one announced last year that remains unsettled.

In July 2010, a grand jury in Middlesex County returned 42 indictments against a laboratory in Woburn, two of its principals (CEO Arthur Levitan and COO Patrick Cavanaugh), and two employees of a sober house for allegedly orchestrating a Medicaid fraud and kickback scheme using "straw companies" and overcharging the state's Medicaid program, Coakley said.

In the indictments, state officials alleged that **Calloway Laboratories** of Woburn, Levitan, and Cavanaugh engaged in a kickback scheme involving two straw companies that funneled kickbacks to sober houses and paid middlemen and a medical office to illegally obtain urine drug screening business paid for by MassHealth. Coakley alleged that MassHealth paid in excess of $10.6 million for urine drug screen business obtained by Calloway as a result of these illegal kickbacks.

Calloway was charged with three counts of filing Medicaid false claims, 16 counts related to Medicaid kickback, and two counts of larceny over $250. Levitan was charged with 12 counts related to Medicaid kickbacks, Cavanaugh was charged with five counts related to Medicaid kickbacks and one count related to corruption of a witness. Two other defendants were charged with three counts related to Medicaid kickbacks.

Physicians who prescribe pain medications often use urine screens provided by outside laboratories or perform this testing on-site. Recognizing that some pain-management drugs can be addictive and that some patients will obtain prescriptions for these drugs so they can resell them on the street, prescribing physicians have legitimate reasons to monitor patients' use of these drugs.

To do so, these physicians use appropriate lab tests to monitor patient care and to help manage liability by having lab test results that show each patient was taking the pain medications as prescribed.

Kickbacks To Induce Testing

The cases Coakley has brought since 2007 against different laboratory companies involve kickbacks to induce test ordering and tests that were not ordered by an authorized prescriber.

In the PMA case, Kishore was arrested September 20 at his home in Brookline. In court, he pleaded not guilty to one count related to Medicaid kickbacks. When announcing Kishore's arrest, Coakley said that Kishore allegedly manipulated PMA's business relationships to bill MassHealth for tens of thousands of urine drug screen tests of Medicaid-eligible residents.

In connection with this case, the grand jury also returned indictments against three men who run sober houses. Each was charged with one count of receiving Medicaid kickbacks. Kishore's arrest is a criminal complaint and Coakley has negotiated settlement agreements with four state diagnostic laboratories since 2007. Here are the details of the other cases.

On August 19 of this year, Coakley announced that **Diagnostic Laboratory Medicine, Inc.**, (DLM) in Bedford paid $153,780 to settle Medicaid fraud charges. The settlement resolved allegations that, from 2005 until this year, DLM billed Medicaid for urine drug tests that were not properly ordered by a doctor or other authorized prescriber, that DLM overcharged MassHealth for urine tests by failing to give the program its best price, and that it failed to comply with record keep-

ing requirements, Coakley said. As a result, Medicaid made significant overpayments to DLM.

Resolving Allegations

In September 2010, **Clinical Science Laboratory, Inc.**, of Mansfield, agreed to pay $525,000 to resolve allegations it billed Medicaid for urine drug tests which were not properly ordered by a doctor or other provider and were ordered for purposes not covered by Medicaid, the office said. Between 2004 and 2009, Clinical Science billed Medicaid for unauthorized urine drug tests, the AG said.

In February 2010, Coakley reached a settlement with System Coordinated Services, Inc., doing business as **Life Laboratories**, a clinical laboratory in Springfield. Under the settlement, the laboratory has agreed to reimburse $450,000 to MassHealth.

Between 2004 and 2009, Life Laboratories and an unspecified number of other labs billed MassHealth for urine drug and alcohol tests that were not properly ordered by a doctor or authorized prescriber, and were inappropriately ordered for non-medical purposes, such as residential sobriety monitoring, the AG's office said. Also, Life Laboratories overcharged MassHealth for the urine drug and alcohol tests by failing to give it the best price, the office said.

False Claims Violations

In July 2009, Coakley reached an agreement with **Boston Clinical Laboratories, Inc.**, in Waltham, to settle Medicaid false claims violations. Boston Clinical agreed to pay $615,000 to MassHealth and $14,000 to the federal Medicare program. In October 2007, Coakley alleged that Boston Clinical intentionally filed claims and received payment for urine drug screens that were improperly ordered. From January 2000 through October 2007, Boston Clinical submitted more than 66,000 claims for urine drug screens to Medicaid and many of these claims were not properly ordered by an authorized prescriber or were ordered for non-medical purposes, the AG's office said.

In September 2007, Coakley reached an agreement with **Willow Street Medical Laboratory, LLC**, in Lynn, settling allegations of overpayment and inappropriate referrals. Under the agreement, the company (also known as Willow Laboratories and Medical Center, Inc.) agreed to pay $8.15 million to the commonwealth.

Willow Street Laboratories had billed Medicaid for urine drug and alcohol tests which were not properly ordered by a doctor or other authorized prescriber, the AG's office said. The tests were often inappropriately ordered for non-medical purposes, such as probation, parole, or residential sobriety monitoring.

Inappropriate Payments

Further, the AG's office stated that Willow Street Laboratories had made inappropriate payments to a third-party to obtain additional Medicaid business. It had also made payments to some substance abuse treatment programs, halfway houses, shelters and sober houses, in the form of free urine drug screen services.

In addition to making these payments to the state, the labs involved in these settlements all agreed to institute compliance programs, Coakley said.

At the federal level, a whistleblower case against **Ameritox, Ltd.**, of Baltimore, Maryland, was settled in 2010 for $15.5 million. Ameritox was alleged to have "made cash payments to its physician clients... to induce the referral of drug testing services. It also resolves claims arising from the offer by Ameritox of free collector personnel to its physician clientele... in order to induce the referral of Medicare business," according to the U.S. Attorney's office.

Collectively, these cases demonstrate that certain lab testing companies continue to be willing to induce business in ways that violate state and federal laws. TDR

Lab Compliance Watch

In-Practice Histology Lab Splits Biopsies; ID's Patient with DNA

In response to continuing requests by clients and readers of **THE DARK REPORT,** this issue institutes a new feature titled "Lab Fraud Watch." It will provide information about activities in the medical laboratory testing marketplace which could be interpreted as violating federal and state fraud and abuse laws.

It is the belief of many lab executives and pathologists that, in the absence of more aggressive enforcement and regulatory guidance by federal and state agencies, the incidence of non-compliant marketing practices and financial arrangements seen in the lab marketplace has become more common in recent years.

Clients and readers regularly tell us that they would like more "market intelligence" about the types of schemes used by some lab firms to skirt both the letter and the intent of laws governing fraud and abuse. It should be recognized that any description of these practices generally come to us as second-hand information. For that reason, important facts may be unknown which would be material in deciding whether the alleged practice would be in violation of federal and state laws.

—Editor

IN THE NORTHEAST, IT WAS REPORTED TO US that a urology group which operates an in-clinic anatomic pathology laboratory has begun handling selected tissue biopsies in the following ways.

First, after harvesting certain biopsy specimens, it then cuts them in half. Each half goes into a separate specimen container and is then sent to the urology group's in-practice histology laboratory.

There, each biopsy specimen is tested. Our source assumes that the urology practice then bills the payer for each technical component service and each professional component service on the two halves of what would typically be handled as a single biopsy specimen by most pathology laboratories.

DNA Testing For Patient ID

What adds interest to this situation is another procedure which is done by this urology group. At the time the biopsy specimens are collected from the patient, a buccal swab is also collected. The purpose of this buccal swab is to establish positive patient identification of the tissue specimen and the slides when handled by the histology laboratory and the pathologist(s). The urology group's anatomic pathology laboratory will run the DNA from the buccal swab and similarly test the DNA of the patient's biopsy tissue to verify a match.

Our source tells us that the urology group then bills the payers for the DNA testing and payers will reimburse these DNA tests as part of patient safety and positive patient ID practices.

As represented above, the practice of dividing a single biopsy specimen into two specimen containers, if done only to maximize payer reimbursement, would violate certain state and federal laws. TDR

Contact editor Robert Michel in confidence to discuss lab market practices that may violate state and federal law: 512-264-7103 or labletter@aol.com.

Hospital Lab Uses HIE To Win Outreach Clients

In Cincinnati, Mercy Lab Services quadrupled outreach test volume while holding costs constant

CEO SUMMARY: Health information exchanges (HIEs) are operating nationwide, but few handle lab test orders and results with ease the way HealthBridge does. This long-established HIE in Cincinnati, Ohio, allows physicians to send lab test orders from their electronic health record systems (EHRs) and to receive matched lab test results back in their EHRs. One lab taking full advantage of this HIE is Mercy Lab Services, which has boosted its outreach volume four-fold and experienced 53% growth last year.

ACROSS THE NATION, a growing number of health information exchanges (HIE) are becoming operational. As they do, local lab companies and hospital laboratory outreach programs are leveraging these HIEs to gain competitive advantage and increase their market share of tests referred by office-based physicians.

This is a significant development. Savvy hospital lab outreach programs are seizing the opportunity to use their region's HIE as a tool to help win new outreach clients while holding down costs, particularly the cost of providing the electronic links needed to interface their laboratory information systems (LIS) with the EMR (electronic medical record) systems of their office-based physician clients.

In Cincinnati, Ohio, **Mercy Laboratory Services** (MLS) has proved masterful at using **HealthBridge**, the region's HIE, to expand its lab testing outreach business. "Over the past five years, our lab has quadrupled test volume while keeping costs stable," stated Tony Bull, Sales and Operations Manager for Mercy Lab Services. His laboratory serves **Mercy Health**, an integrated delivery system of seven hospitals with 2,954 beds in the Greater Cincinnati metro area.

"We kept costs stable as outreach testing volumes increased and our average cost-per-test declined significantly," explained Bull. "By holding other important cost factors at a constant level, our lab increased its per-test revenue during this time period, posting growth of 53% in the last year alone! Such growth and stable costs are particularly important in a slow economy."

Serving 50 Hospitals

Bull says that one key to Mercy Lab's success is its partnership with HealthBridge, one of the nation's largest and most advanced HIEs. Established in 1997, it serves 50 hospitals, 800 physician practices, and 7,500 physicians in five communities in Ohio, Northern Kentucky, and Eastern Indiana.

HealthBridge uses its secure electronic network to transmit roughly 3.2 million

Outreach Labs at Three Large Hospitals Gain Advantages by Working Together with HealthBridge

ONE UNUSUAL ASPECT of HealthBridge of Greater Cincinnati, a health information exchange (HIE), is that it allows three competing hospital lab outreach programs to work together in a collaborative manner.

Mercy Laboratory Services, which serves Mercy Health, an integrated delivery system of seven hospitals with 2,954 beds in Cincinnati, is working with labs from two other large hospital systems in order to get a volume discount from the HIE, said Tony Bull, Sales and Operations Manager for Mercy Lab Services.

"We have the laboratories from three health systems collaborating in our relationship with HealthBridge," noted Bull. "HealthBridge gives us a volume discount based on the number of lab test orders we put through. It's a cost advantage for us because of the combined volume our three lab outreach programs generate."

Along with Mercy Lab Services, the other two participating health systems are **TriHealth**, an integrated health care system in Cincinnati that includes **Good Samaritan Hospital** (460 adult and 130 newborn beds) and **Bethesda Hospital, Inc.**, (360 adult and 60 newborn beds), and **St. Elizabeth Healthcare**, a large integrated delivery system in nearby Covington, Kentucky. This system has six hospitals with 1,187 beds.

The three hospital systems are similar in that they each run outreach programs in the Cincinnati metro area and each one competes with the other.

HealthBridge assesses a per-click charge based on the number of orders each hospital sends through the system. HealthBridge bills each hospital separately at the end of each month. The hospital lab organizations do not share any information with each other. "It's an arms-length relationship," Bull explained. "But it is one more way that HealthBridge helps each of our respective outreach programs to compete more effectively against the national labs."

electronic messages each month. This includes clinical lab test orders and lab test results. Other clinical data handled by HealthBridge include radiology reports, discharge summaries, and other information on more than 2.5 million patients.

There are several ways that participating with HealthBridge helps Mercy Laboratory Services win new office-based physician clients and retain their business. "Our relationship with HealthBridge allows us to compete on a level playing field with the national laboratories," observed Bull.

Speedy EMR Interfaces

"We regularly encounter situations with potential clients where the question is asked, 'Can you interface your lab with our electronic health record (EHR) system?' And by working closely with HealthBridge, we can answer, 'Yes, absolutely!'" he noted.

"Plus, we can establish these interfaces relatively quickly, which is another way that HealthBridge helps us level the playing field," continued Bull. "The national labs have been connecting physicians to their information systems for several years and so they can do it relatively quickly.

"Most physicians want to connect to their laboratory provider within a month or two," he commented. "Without HealthBridge, it would have taken us a great deal longer than that, plus the added expense of writing the interface between our LIS and each client's EMR.

"But now that HealthBridge is part of how our lab connects to physicians' offices, it has helped our sales efforts," he added. "It

allows us to offer all the services that any other lab can offer, including the national labs. For our existing clients, we can work with nearly any EHR system now.

"This is equally true for those physicians trying to establish meaningful use," said Bull. "Our lab can support meaningful use with the interfaces we establish to their EMRs.

Connecting To Physicians

"The reason working with HealthBridge facilitates connections to physicians is that the HIE has been establishing connections among all providers in Greater Cincinnati for 10 years," stated Stacey Potts, the HealthBridge Product Manager, Community Order Entry. An expert in how labs and physicians exchange lab orders and test results, Potts worked in the lab industry for 12 years before coming to HealthBridge in 2005.

"The reason this whole system works is that for physicians, we have one connection to HealthBridge," Potts explained. "Once the physician's EMR is connected to HealthBridge, that EMR is then able to access data from multiple hospitals and multiple labs. We now connect to the EMR products of 26 different vendors."

"Such simplicity is significant for physicians, added Bull. "Physicians appreciate the fact that one connection to HealthBridge eliminates the need to establish multiple interfaces with their EMR and each different ancillary service provider that serves their practice. It also greatly shortens the time needed by any new lab to connect with their EMR.

Less Cost For Interfaces

"Because HealthBridge eliminates the thousands of dollars typically required to create an interface between a lab's LIS and the physician's EMR, this greatly reduces our lab's cost to connect to the EMRs of our clients," he said. "To connect to HealthBridge, the medical practices typically pay as little as $25 per physician per month for the EHR interface. Plus, HealthBridge has a level of expertise in informatics that we don't have, which means we don't have to devote our internal resources to getting physicians up and running." TDR

Contact Tony Bull at 513-853-5165 or LABull@health-partners.org; Stacey Potts at 513-469-7222 or info@healthbridge.org.

Doctors Can Speak To Local Pathologists

HEALTHBRIDGE MAKES IT EASY for local pathologists to work with local physicians practicing throughout the Cincinnati metropolitan area.

"Working with the labs here in Cincinnati, I've found that the physicians want to pick up the phone and talk with a local pathologist." observed Stacey Potts, the HealthBridge Product Manager, Community Order Entry. "Physicians value the customer service that local labs can offer. Helping local labs and other providers leverage our HIE to serve our physicians and hospitals was part of the vision when the chief information officers of the city's hospitals started HealthBridge in 1997.

"While there is friendly competition among these hospitals, they put patient care first," she said. "One problem they wanted to solve was delivering lab test results to physicians. And now, 10 years later, we have a portal that allows physicians to access any of their hospital applications directly—even while working outside the physical hospital.

"We also have a clinical messaging system that delivers patient lab results; radiology reports; patient admission, discharge, and transfer reports; and transcription reports into a clinical messaging in-box," noted Potts. "This system allows physicians to read their patients' results from all content providers in one place and they can forward this information to their EMRs."

Letter to the Editor

Why Pathologists Benefit From Growth of In-Office Path Labs

Dear Editor:

Your article on the trend of office-based physicians building in-clinic anatomic pathology laboratories was fascinating, but in my opinion, it was off the mark.

In the article, "AP Labs in Doc's Clinics Now an Established Fact" (See TDR, September 6, 2011), you wrote that the growth of in-clinic pathology labs is disrupting community hospital-based pathology groups. Yes, this trend is disruptive because, as you correctly point out, in-office anatomic pathology laboratories do capture lab test volume from community pathology practices. While it may appear that this trend is bad for pathologists, in fact, the opposite is true.

Perhaps you believe the tales of woe coming from some pathology associations and large specialty pathology firms such as AmeriPath, GI Pathology, and Aurora Diagnostics. If so, you may be interested to learn that the real story is a bit more complex than they say.

In reality, local hospital-based pathologists have been taking it on the chin for many years because urologists, gastroenterologists, and other specialists have left hospitals to open ambulatory surgery centers (ASCs) that compete directly with hospitals. Seeing an opportunity, entrepreneurs jumped on this trend and started specialty pathology labs to process specimens from these ASCs. The early entrants to this field were AmeriPath and Bostwick Labs.

National lab companies like these were nimble new entrants into specialty pathology. Hospital-based pathologists were left out because they lacked sales teams, data systems, and couriers. Instead, they were often stuck inside the hospital—unable to respond to the needs of these potential clients. Plus, hospital administrators had little interest in serving non-patients just to keep pathologists happy.

But then local physicians started in-office pathology labs, and a new opportunity was born. I would assert that the specialist physician owners of these in-office labs were not the only the big winners. Local hospital-based pathologists also benefit because the national specialty pathology labs cannot compete in this market. They cannot make money providing a local pathologist who will work part time at an in-office lab. Instead, the money specialty pathology labs once made on the technical component (TC) of anatomic pathology is now flowing to in-office pathology labs and it is the national specialty labs who howl in pain.

Hospital Pathologists Benefit

Local hospital-based pathologists are benefiting from this trend because they can go to work for these in-office pathology labs and bill for the professional component (PC). In a hospital, they get none of the billed TC. At most in-office pathology labs, pathologists are paid essentially the Medicare professional fee less the practice expense portion of that fee because they did not build the lab. The volumes are significant, there is no competition, and the in-office labs pay the pathologists directly. The pathologists avoid the billing expense and have flexible hours.

All this is good news for the local pathologists working in these in-office labs. That's the trend that was left out of your story and it's one that many of your readers would be glad to discuss with you.

Yours truly,
Joe Plandowski

Editor: Joe Plandowski is one of the founders of In-Office Pathology (www.iopathology.com) in Lake Forest, Illinois. Contact him at 800-280-3785 or iopath@bex.net.

Are Prosecutors Afraid of Big and Little Lab Firms?

Lab execs in California express puzzlement about the settlement terms in major *qui tam* case

CEO SUMMARY: Settlements in the big whistleblower suits involving major lab companies typically generate national headlines. But seldom do the views of the "quiet majority" of lab owners and lab executives get much attention. These are the majority of lab professionals working hard to follow compliance laws and requirements. They want to meet both the letter and the intent of the law. What follows is a sampling of the sentiments expressed by such individuals since settlement of the Medi-Cal qui tam lawsuit.

By Robert L. Michel

IT'S BEEN JUST SEVEN WEEKS since the nation's second largest clinical laboratory company settled its whistleblower lawsuit in California that alleged violations of the state's Medi-Cal billing laws.

During that time, the offices of THE DARK REPORT have fielded an interesting range of comments from executives, pathologists, and clinical laboratory managers about the outcomes of this *qui tam* lawsuit. Collectively, these individuals—most working in California—say they are puzzled about important aspects of this settlement.

Their questions and comments center around two themes. First, if, in fact, the State of California believed that the plaintiff laboratories had violated state laws on how to price services to the Medi-Cal program, why didn't the Attorney General more vigorously press the defendant laboratory companies, even to the point of going to trial?

Further, they observe that, if state prosecutors were confident about their interpretation of these laws, what rebuttal arguments did the defendants put forth so that they avoided having to repay the full amount of the alleged overcharges, plus a penalty amount that would be significant and painful to the plaintiff labs? "Wouldn't such full financial restitution and a hefty penalty send precisely the unmistakable message to the entire clinical laboratory industry that is wanted by state regulators?" they ask.

Interpreting State Law

In fact, that question ties into the second theme. These lab professionals bemoan the lack of a clear set of guidelines as to how the state will interpret and enforce these laws from this point in time. Those who have read the settlement agreements made public by the California Attorney General (AG) recognize how the language in the settlement specifies that each party reserves all its rights to assert its respective position in the future.

Thus, there is a general sentiment among more than a few of the owners and executives of independent laboratory companies that there is no language in the settlement agreement upon which they might base their compliance policies relative to applicable state laws. These executives universally express that they would like reason-

able confidence that the compliance policies of their laboratory are on the right side of the law.

The famous adage "You can fool some of the people all the time, and all of the people some of the time, but you cannot fool all of the people all the time," was mentioned by one lab executive. It was his view that there is something wrong with a legal system that can extract $300 million in payments from defendant laboratories to resolve certain allegations that they violated the law, and at the same time not end up with language in the settlement that brings useful clarity to the law and how it will be interpreted and enforced by regulators and prosecutors in the state.

The Language Of 51510(a)

This brings me to the point where I would like to offer some observations. At the heart of these concerns is the California Code of Regulations (CCR), Title 22, section 51501(a), which states in part:

> *Notwithstanding any other provisions of these regulations, no provider shall charge [Medi-Cal] for any service or any article more than would have been charged for the same service or article to other purchasers of comparable services or articles under comparable circumstances...*

This language is an important element in the whistleblower case that was concluded with the recent settlements between the California AG and the defendant laboratories. You can decide for yourself how you would interpret this language and how you would align your lab's sales and marketing practices to comply with your interpretation.

In the case of whistleblower and lab company owner Chris Riedel, his response was to file a whistleblower lawsuit that sought to recover money for the California Medicaid program. It was the absence of enforcement action and appropriate regulatory guidance by state officials which made such a *qui tam* lawsuit feasible.

So now, after six years of litigation and payments of approximately $300 million by the defendant laboratories, whistleblower Riedel has his vindication. Or does he? In the coming months, lab executives and lab owners in the Golden State will be watching to see what changes in the discount pricing schemes will be made by the defendant lab companies.

Great Frustration

As all of these comments demonstrate, the feedback we hear in our office is that there is great frustration out there by many laboratory administrators and clinical lab managers who earnestly want to do the right thing. But they consistently see lab companies in the marketplace willing to continually push the interpretation of state and federal compliance requirements in ways that give their lab organization clear competitive advantage.

It would be accurate to say that these lab professionals—who represent the hard-working, law-abiding citizens who support order and the rule of law—are disgusted with all the state and federal agencies where bureaucrats shy away from confronting so many of these compliance violations. "It seems regulators are afraid of taking on any lab, large or small," noted one recent caller. "I find this to be a mystery, since we all know how much power a government agency has whenever it decides to enforce the law."

Taking Personal Initiative

Maybe the lesson to be learned by these recent events is that it may be up to the lab industry to police itself, using the power of *qui tam* suits. Certainly the examples of C. Jack Dowden (**National Health Labs**, 1992, $111 million), Robert Merena (**SmithKline Beecham PLC**, 1997, $325 million), Thomas Cantor (**Quest Diagnostics** and **Nichols Institute Diagnostics**, 2009, $302 million), and now Chris Riedel (seven labs, $300 million, 2011), demonstrate that a common sense reading of compliance laws and regulations can lead to a successful enforcement action. TDR

Lab Briefs

ROSETTA GENOMICS TO LAY OFF 35 EMPLOYEES

TO CUT EXPENSES AND SHIFT MORE FUNDING toward sales of its proprietary molecular tests, **Rosetta Genomics** says it will eliminate 35 jobs. The company, based in Israel, operates a clinical laboratory in Philadelphia, Pennsylvania.

The Philadelphia laboratory employs eight people, but Rosetta did not disclose whether staff layoffs would happen at this location. The company is selling diagnostic tests that use microRNA technology and has a sales force to develop use of its proprietary tests in oncology.

"We have begun to see a significant increase in demand for our tests since the launch of our dedicated oncology sales team," noted Kenneth A. Berlin, CEO and President of Rosetta Genomics. "As expected, there is the usual lag between generating demand and getting paid for these tests by the applicable payers. We recently submitted our first claims to payers."

AUREON BIOSCIENCES CLOSES ITS DOORS, LAYS OFF 95 EMPLOYEES

IN WHAT WAS A SURPRISE ANNOUNCEMENT TO ITS EMPLOYEES, **Aureon Biosciences, Inc.**, of Yonkers, New York, suddenly closed its laboratory on October 7 and laid off 95 employees. This news was reported by *Westfair Business Publications*, in White Plains, New York.

The company offered two proprietary tissue-based tests for prostate cancer that provided prognostic information to physicians and their patients. The company was founded in 2002.

"The decision was made, for reasons unclear, to pull the funding from the company and put the company's intellectual property up for sale," stated Michael Oates, President and CEO of the **Hudson Valley Economic Development Corp.** (HVEDC), in an interview published by *Westfaironlin.com*.

Aureon's diagnostic technology had attracted several prominent laboratory industry executives. Kevin Johnson, formerly CEO of **Dianon Systems, Inc.**, prior to its sale to **Laboratory Corporation of America**, has served as its Chairman since 2003. Vijay Aggarwal, Ph.D., was CEO and President through 2009. Aggarwal previously held executive positions at **Quest Diagnostics Incorporated** and **SmithKline Beecham Clinical Laboratories**.

Aureon's current CEO and President is Robert Shovlin. He had come to Aureon from Quest Diagnostics and had earlier held a sales management position at Dianon Systems.

PLUS DIAGNOSTICS, ATHEROTECH, SEQUENOM EACH ANNOUNCE PLANS TO BUILD NEW LABS

DESPITE A TEPID ECONOMY, three laboratory companies are expanding by building new clinical laboratory facilities. The companies are **PLUS Diagnostics**, **Sequenom, Inc.**, and **Atherotech Diagnostics Lab**.

Earlier this month, PLUS Diagnostics, with headquarters in Union, New Jersey, revealed plans to open a new laboratory facility in Houston, Texas. The lab is expected to become operational by the end of the year.

The company said that this lab will provide anatomic pathology services to gastroenterologists and urologists in Texas and the greater Southwest region. Plus Diagnostics indicated that the Houston lab may later serve dermatologists and women's health.

The Houston lab will be the third facility PLUS Diagnostics has built in the past two years. In 2009, the company

opened a new facility in Union, as well as a laboratory in Irvine, California. The lab in Irvine was its first on the West Coast.

On October 12, the office of North Carolina Governor Bev Purdue released news that Sequenom, based in San Diego, California, was planning to build a molecular diagnostics clinical laboratory in the state. The new lab facility is expected to be located in the Research Triangle Park area.

According to *The Herald-Sun* of Raleigh, Sequenom was awarded a $2.3 million grant from the state and the new laboratory is expected to employ 242 people. The availability of medical technologists apparently played a role in Sequenom's decision to establish a laboratory in North Carolina.

"In finding trained lab technicians who can do these very complex tests, many of the other states we looked at just didn't have that workforce available," stated Paul Maier, Sequenom's Chief Financial Officer, in *The Herald-Sun* story. "We have that workforce available in North Carolina."

Research Triangle Park is where **Laboratory Corporation of America** has based much of its advanced molecular and genetic testing since establishing its Center for Molecular Biology and Pathology there in the late 1980s. That is one reason why Sequenom believes it will have a pool of experienced medical technologists from which it can recruit.

Sequenom is still negotiating a lease on a property. It said that it expects the new lab facility will become operational in the second half of 2012.

It was October 3 when Atherotech Diagnostics Lab of Birmingham, Alabama, announced that it would expand its main laboratory facility by 30%. Atherotech markets a proprietary diagnostic test it calls VAP (Vertical Auto Profile). This assay measures cholesterol markers associated with heart disease. It also has other clinical laboratory services.

In a press release, Atherotech CEO Michael Mullen said that the company's staff had already grown by 30% during 2011. He predicted that another 40% increase in staff would take place during 2012. Work to expand the lab facility is expected to be completed in 2012.

NATIONAL QUALITY FORUM ADDS TWO SERIOUS ADVERSE EVENTS FOR LABS

MANY LAB ADMINISTRATORS may not have noticed that the recently-updated list of "never events" includes two items that directly apply to clinical laboratories.

When the **National Quality Forum** (NQF), in Washington, DC, updated its list of serious reportable events (SREs) earlier this year, it added four new SREs. Two of the new SREs related to lab testing activities.

The first SRE is: "Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen." The NQF committee that considered this SRE said serious injury could result from progress of an undiagnosed disease or the threat of disease that changes the patient's risk status for life.

The second SRE is: "Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results." The committee members acknowledged that failure to follow up or communicate significantly raises the risk of death or serious injury.

The NQF Board of Directors approved the 29 SREs listed in its report, *Serious Reportable Events in Healthcare–2011 Update: A Consensus Report*.

"This newly expanded list of serious reportable events across multiple settings provides a critical opportunity to learn from mistakes and take swift action to improve patient safety," said Janet Corrigan, NQF's President and CEO. The first NQF-endorsed list of SREs was released in 2002. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Have you ever heard the term "digital PCR" (Polymerase Chain Reaction)? That technology was of such interest to **Bio-Rad Laboratories, Inc.**, that it just paid $162 million to acquire **QuantaLife, Inc.**, the company that developed this digital PCR technology. The deal was announced on October 5. In the press release, it was noted that, "QuantaLife has developed an innovative digital PCR system that provides quantification of target molecules with unprecedented precision and sensitivity... Digital PCR provides researchers with a new tool for the detection of rare mutations including distinguishing rare sequences in tumors, precise measurement of copy number variation, and absolute quantification of gene expression."

MORE ON: *Digital PCR*

Financial analysts commenting on the acquisition said that digital PCR may be a $100 million per year market in the next three years. The worldwide research market for PCR is estimated to be about $2.5 billion per year. Bio-Rad is estimated to hold a 10% share of that market.

TRANSITIONS

• **Lifepoint Informatics, Inc.**, of Glen Rock, New Jersey, appointed Lee Barnard to the position of Chief Business Development Officer last month. Barnard has held executive positions with **Centrex Clinical Laboratories**, **eCast Corporation**, **DocSite, LLC**, and **Laboratory Corporation of America**.

• Julie Pantalone was hired to be the Vice President of Sales, Medical Division, for **Atlas Development Corporation**, based in Calabasa, California. She previously spent more than a decade in sales and business development at **William Beaumont Hospital**. Prior to that, she held positions at **Quest Diagnostics Incorporated**.

• Brian Ward was appointed as Chief Executive Officer for **diaDexus, Inc.**, of South San Francisco, California. His executive positions include stints at **On-Q-ity, Inc.**, **Genomic Health, Inc.**, **Myriad Genetics, Inc.**, and **Genyzme Genetics**.

• Martin Madaus is the new CEO for **Quanterix, Corp.**, based in Cambridge, Massachusetts. Madaus is the former CEO of **Millipore Corp.**, and was also CEO of **Roche Diagnostics**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the acquisition of the anatomic pathology business of **Caris Life Sciences, Inc.** by the Japanese company **Miraca Holdings, Inc.**, for a hefty sales price of $725 million.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 7, 2011.