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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

Does Anyone Know the Law in California?

WHAT IS THE LAW IN CALIFORNIA THAT DEFINES PROVIDER PRICING and how Medi-Cal should be billed? You probably think that question would be rather easy to answer after you read one of the state statutes that governs pricing relative to Medi-Cal claims. Popularly known among the lab industry as 51501(a), it requires that "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 law is commonly referred to as a "best price" statute. In force for more than four decades, it is familiar to lab executives, managers, and lab sales representatives in the Golden State. During all this time, to my knowledge, every hospital in California that operated a laboratory outreach program in competition with commercial lab companies was careful never to bill Medi-Cal at a price higher than what it charged any single client. But a number of the larger independent lab companies in California commonly extended deeply-discounted lab test prices to selected providers while submitting claims to Medi-Cal at a higher price for these assays.

Then came the whistleblower lawsuit filed back in 2005 by **Hunter Laboratories, Inc.**, and Chris Riedel. It alleged that the lab test pricing practices of seven lab companies violated 51501(a) and related state and federal laws. That was certainly a disruption to the status quo. Now, six years later, the California Attorney General (AG) has entered into settlement agreements with two defendants—**Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, and released those agreements to the public.

Together, the two lab companies are paying $290.5 million to resolve the *qui tam* case, while explictly denying that their deep discount lab test pricing practices were in violation of 51501(a) and the related laws. Moreover, each lab has language in its respective "Settlement Agreement and Release" that appears to allow it to extend lower prices to some providers than the prices at which it submits claims to Medi-Cal, at least through February 1, 2014.

Thus, I think it is fair to ask this question: "Does anyone in California know the law?" Given that all citizens should have equal standing before the law, will the two blood brothers gain competitive advantage from these settlement agreements during the next few years? If anyone knows the answer to this question, I'd like to hear from him or her! TDR

LabCorp Inks Agreement In Medi-Cal Pricing Case

Although the settlement resolves this *qui tam* case, it remains unclear how California interprets 51501(a)

CEO SUMMARY: In its "Settlement Agreement and Release" with the California Attorney General (AG), Laboratory Corporation of America has negotiated terms that essentially match the agreement that exists between Quest Diagnostics Incorporated and the California AG. These settlements signal the end of chapter one in the story about deeply-discounted lab test pricing that is less than what labs bill Medi-Cal, the state's Medicaid program. But chapter two is likely to bring more surprises for labs in the Golden State.

ON AUGUST 30, THE CALIFORNIA ATTORNEY GENERAL announced a final settlement with **Laboratory Corporation of America** in a six-year-old Medi-Cal whistleblower case.

This agreement resolves LabCorp's role as one of seven defendant laboratory companies in the original *qui tam* action filed by **Hunter Laboratories, Inc.**, and Chris Riedel back in 2005. This outcome was expected because LabCorp had disclosed the basic terms of its tentative agreement with the state earlier this year.

It can be said that the settlement with LabCorp brings to a close one chapter in the ongoing story about deeply-discounted laboratory test pricing marketing practices in the California.

But at the same time, resolution of this whistleblower case opens a second, new chapter on this controversial topic. That's because the language of each "Settlement Agreement and Release" inked between the California Attorney General (AG) and the nation's two largest laboratory companies appears to create a future moment in time when the state will enforce the state law known as 51501(a) according to its interpretation of that statute.

Until that date, the language of the "Settlement Agreement and Release" appears to allow both LabCorp and **Quest Diagnostics Incorporated**—under the terms of their respective agreements with California—to continue offering discounted lab test prices to some providers that are less than the prices they bill Medi-Cal for the same lab tests. How this plays out in California's intensely competitive market for laboratory testing services

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remains to be seen.

There were no surprises in the LabCorp settlement. The nation's second largest lab testing company will pay $49.5 million. Of this amount, $35.1 million will go to the State of California. Whistleblowers Hunter Laboratories and Chris Riedel will get $14.4 million. LabCorp will also pay the legal fees of the whistleblowers.

Same Settlement Language

Notably, LabCorp has a "Settlement Agreement and Release" with the California Attorney General (AG) that, in all essential respects, is identical to the agreement that was executed earlier this year between **Quest Diagnostics Incorporated** and the California AG.

In LabCorp's settlement agreement, it states that "California and *Qui Tam* Plaintiffs allege that the LabCorp Defendants submitted or caused to be submitted false claims for payment to the California Medical Assistance Program, which is California's Medicaid Program (Medi-Cal)... in violation of California Code of Regulations, title 22, Section 51501(a)..."

The same document further states that "The LabCorp Defendants specifically deny any and all liability and wrongdoing. The LabCorp Defendants contend: (a) that their billing practices were at all times in material compliance with Section 51501(a), industry practice, and all other applicable laws and regulations..."

Thus, neither the State of California nor LabCorp has prevailed in their respective interpretations of how to comply with 51501(a). THE DARK REPORT was first to note this same fact was true of the "Settlement Agreement and Release" executed between the California AG and Quest Diagnostics earlier this year. *(See TDR, June 13, 2011.)*

As was the case in the settlement with Quest Diagnostics, LabCorp is to submit quarterly reports to the state that identify specific instances where it has extended a lab test price to a provider that is lower than the price for that test which it billed the Medi-Cal program. Like Quest, LabCorp can opt for a "transitional rate" when it files claims with Medi-Cal. The reporting requirement ends on February 1, 2014.

One way to read the language of the settlement agreements signed by LabCorp and Quest Diagnostics is that each company has negotiated a period of time that ends on February 1, 2014, during which they can offer substantially lower prices to providers in California while continuing to submit claims to Medi-Cal at a higher price. What happens after that date is left undefined. Lab lawyers must read between the lines to understand the true nature of the settlement agreement.

Further, does this aspect of these settlement agreements give the two national lab companies a competitive pricing advantage over other labs in California for the next 29 months? Will the California **Department of Health Care Services** (DHCS) now proceed to enforce its interpretation of 51501(a) against other California laboratories? Or, will DHCS allow labs now competing against the two blood brothers to match those low prices—at least until February 1, 2014?

Assume that the settlement of this whistleblower lawsuit closes chapter one in the story of the interpretation of 51501(a) and that chapter two is how California's lab testing marketplace operates between now and February 1, 2014.

Discounted Lab Test Prices

It could be that chapter three in this story is how similar lab test pricing *qui tam* lawsuits known to be active in the states of Florida, Georgia, Massachusetts, Nevada, and Virginia are resolved.

This is a story with significant consequences for the entire laboratory testing industry, since one outcome could be the end of deeply-discounted lab test prices that are not also offered to the Medicaid programs in certain states. TDR

Legal Update

National Group Names Riedel "Whistleblower of the Year"

WHISTLEBLOWING HAS ITS REWARDS. During 2011, one laboratory whistleblower not only harvested tens of millions of dollars in settlement awards, but he was recently honored by a national group for these same efforts.

Chris Riedel, President of **Hunter Laboratories, Inc.,** in Campbell, California, was recognized last month for his actions associated with the whistleblower lawsuit he filed in California that resulted in sizeable settlements with the defendant laboratory companies. Earlier this month, at a dinner in Washington, D.C., the **Taxpayers Against Fraud Education Fund** (TAF) gave Riedel its Whistleblower of the Year Award.

The case began in November 2005, when Reidel and Hunter Laboratories filed a *qui tam* action (or whistleblower suit) in San Mateo County Superior Court. The law suit alleged that seven California labs, including **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, had charged the state's Medi-Cal program more for laboratory tests than they charged other purchasers of comparable services in violation of state laws. Three years later, the state of California intervened in the case.

Discounted Lab Test Prices

In its lawsuit, Hunter Laboratories stated that it could not compete in a market in which major medical laboratories offered doctors, hospitals, and clinics far lower rates than they were charging Medi-Cal. It also alleged that such discounted prices for clinical lab tests given to certain providers, when not also extended to Medi-Cal, violated state law.

At the award ceremony, the fund's previous whistleblower of the year, Harry Markopolos, introduced Riedel. An accountant and financial fraud investigator in Boston, Markopolos worked for more than 10 years to bring the $60 billion Bernie Madoff fraud to the SEC's attention. Markopolos also co-authored the best seller, *No One Would Listen: A True Financial Thriller,* published by Wiley & Sons. It is the basis for a film, *Chasing Madoff.*

'Unique and Inspirational'

"Mr. Riedel's story is unique and inspirational, not just on a human level, but also from the perspective of all of us who want to see a new ethical center develop in corporate America," Markopolos said.

After starting Hunter Labs, "what Chris Riedel found, when he looked at the laboratory testing market in California, was nothing less than profiteering by the greedy at the expense of the needy," continued Markopolos. "When Chris Riedel and Hunter Labs tried to enter this market, they had two obvious choices: suit up and join the kickback and price-gouging operation that had already been in full swing for 15 years—or go home.

"What's unique about Chris Riedel and why he is TAF's Whistleblower of the Year for 2011, is that he did not do the obvious thing. Instead, he chose a third way. He chose integrity," Markopolos said.

THE DARK REPORT notes that the successful outcomes in the whistleblower lawsuit filed by Riedel and Hunter Laboratories are likely to encourage other lab industry whistleblowers to step forward. TDR

POC Testing Plays Role In Penna. Patient's Death

Clinicians ignored central lab tests showing patient's dangerously low blood glucose levels

CEO SUMMARY: In the report by the Pennsylvania Department of Health on the death of a patient at Lehigh Valley Hospital, it was noted that the clinical staff failed to notice discrepancies between results from point-of-care (POC) tests at the bedside and lab test results from blood serum run in the hospital's central laboratory. Experts point out that this case is an example of a failure to notice these discrepancies, a failure to report on the discrepancies, and a failure in communication.

FOLLOWING THE DEATH OF A PATIENT in a Pennsylvania hospital earlier this year, state investigators determined that errors in protocols were a contributing factor. The state report on this case indicated the clinical staff failed to notice discrepancies between test results from point-of-care (POC) tests at the bedside and results from blood serum tests run in the hospital's central laboratory.

For more than two decades, pathologists and clinical laboratory professionals have debated the accuracy and reliability of lab tests performed on point-of-care devices as compared to laboratory tests performed in central laboratories. This case provides a window on how and why differences in test results produced by the two methodologies have the potential to negatively affect patient care.

Using sources in the public record, the basic facts of this case appear to be that the patient was administered insulin to lower blood glucose levels, based on high blood glucose readings from tests performed with a point-of-care testing device. At the same time, in the patient's medical record, there were blood glucose results that showed a lower number from lab tests performed in the hospital's central laboratory.

In their report, state investigators determined that some members of the care team had noticed the discrepancies in the blood glucose results from the central lab and the POC tests, but that no effective steps to reconcile the differing blood glucose results were taken. *(See sidebar on page 9 for a summary of the report produced by the Pennsylvania Department of Health.)*

Patient Died In January

The patient was Sister Maria Angelita Soliman Quito, age 51, a native of the Philippines, who was a teacher at Immaculate Conception Catholic School in Pen Argyl, Pennsylvania. She was treated at **Lehigh Valley Hospital Cedar Crest**, in Allentown, Pennsylvania, and died on January 6, 2011.

Attorney Wayne Schaible of **McCann, Schaible & Wall, LLC**, in Philadelphia, represents Sister Angelita's estate. "One of the issues in the case is whether the POC test strips for blood glucose testing were defective, but there are more important issues in this case," Schaible said.

Pennsylvania State Department of Health

AN INVESTIGATIVE REPORT ISSUED BY THE PENNSYLVANIA DEPARTMENT OF HEALTH explains the steps clinicians took when caring for the patient who died in January as a result of a number of errors related to point-of-care testing at Lehigh Valley Hospital in Allentown, Pennsylvania.

"Review of point-of-care (POC) glucose monitoring testing and nursing documentation for MR1 [the patient's medical record] dated January 3, 2011, revealed that patient blood glucose was elevated between 253-480 mg/dl (milligrams per deciliter)," the report said. "Further review of nursing and laboratory documentation revealed that the patient's blood serum glucose was between 1-3 mg/dl at the same time. There was a discrepancy between the high results of the patient's POC blood glucose tests and the low laboratory serum glucose results.

"Review of Intensive Care Unit (ICU) nursing documentation and Advanced Intensive Care Unit (AICU-telemedicine) nursing documentation for MR1 dated January 3, 2011, at 4:00 a.m. revealed that the AICU nurse was aware of the discrepancies between the laboratory blood serum and point-of-care glucose tests results," the report said. "Review of MR1 revealed no documented evidence that the ICU or the AICU nurse communicated to the physician the discrepancies between the high POC testing versus the low laboratory blood glucose results.

"Review of the AICU telemedicine physician orders for MR1 dated January 3, 2011, at 6:06 a.m. revealed that an order was entered for Lantus (medication to lower blood glucose) 20 units, subcutaneous in the morning in addition to the insulin drip," the report said.

"Review of physician documentation for MR1 revealed no documented evidence on January 3, 2011, from 7:00 p.m. to 7:00 a.m. of the patient's progress notes from the AICU telemedicine physician who provided services to the patient… concerning the discrepancies between glucose testing results," the report said.

"Review of physician documentation for MR1 dated January 3, 2011, revealed no documented evidence that the patient's attending physician was notified of the patient's condition by the AICU telemedicine physician," the report said.

"Review of physician documentation in a neurology consultation for MR1 dated January 5, 2011, revealed that the patient was found in the morning of January 3, 2011, by the surgical team with fixed dilated pupils and was in an unresponsive coma," the report said. "The neurologist's impression for the patient in MR1 was documented as coma secondary to prolonged hypoglycemia that met brain death criteria."

"We have not yet been given access to the POC strips or to the meter, but from our perspective, whether the strips or the meter were defective is irrelevant because, before you start pumping insulin into someone who has no history of diabetes, you should do a lab test," he commented. "We were shocked to find that they did laboratory tests but they ignored the results of these tests.

"The patient had a kidney removed a number of days earlier but she was readmitted when she developed flu-like symptoms," he continued. "They decided to use a point-of-care test for a blood glucose level and when they saw it was high, they put her on intravenous insulin.

POC Vs. Core Lab Testing

"They should have looked at the central lab test results before they gave her insulin," he noted. "The POC strips could be wrong for a number of reasons. They could be outdated or subject to storage

issues. And the POC glucose meters could be wrong. They have to be calibrated regularly. But the larger point is that apparently they just ignored the central lab test."

Department of Health Report

A report from the **Pennsylvania Department of Health** showed the patient's blood sugar levels from blood serum tests done in the central laboratory were between 1 and 3 milligrams per deciliter (mg/dl).

THE DARK REPORT asked a recognized national expert in point-of-care testing to review the public information and comment on what lessons might be drawn from this case that would be useful to pathologists and clinical laboratory managers. Because of the ever-expanding use of POCT, the accuracy of POC test devices versus tests performed in central laboratories is a topic of high interest.

Further, because of pending litigation and because the public record about this case is not complete, THE DARK REPORT chose not to identify the expert. The views presented here represent the expert's assessment of how protocols involving laboratory testing may not have been fully followed by the patient's care team.

Articles published by the Allentown newspaper, *The Morning Call*, were one source of information about this case. After reviewing this information, the lab expert stated, "From the press coverage of this case, it appears that many issues were involved.

Low Glucose Levels

"The staff was relying on POC testing and it's clear from the newspaper that the patient had low glucose levels according to the tests coming from the central laboratory," commented the expert. "Keep in mind that central laboratories have critical-value call-back policies that are part of the required follow-through steps defined under recommendations of **The Joint Commission** (TJC).

"It appears that this patient had a critical value, meaning the main lab would have called a clinician on the patient's floor, either a nurse or a physician," explained the expert. "The central laboratory would have alerted the floor that there was a low level of blood glucose in this patient.

"The floor should have alerted the clinicians treating the patient," he continued. "So, it's not just that someone didn't remember to pick up the note that the glucose test performed in the central laboratory showed low values. They might have been notified about the low values and not acted on that information. Alternatively, that information was not passed to the staff at the bedside.

Communication Issues

"It appears there could have been a problem with the POC testing and with the lack of communication as well," he added. "It's impossible to know where the failure in communication occurred.

"There is one other important question about this case and that is whether there were lab values of 1 to 3 mg/dl," he commented. "It's almost physiologically impossible to get a lab value that low from a living patient.

"Such a critically low glucose value would have been called immediately to the floor by the staff in the central laboratory," observed the expert. "That's why this case shows that there was a breakdown in many areas and that the staff in all hospitals and care settings can, and should, do a better job of communicating.

"In addition, there is an aspect of this case that laboratory professionals need to recognize regarding POC technology," stated the expert. "POC glucose meters can do only what they are designed to do and that is provide estimates of the patient's glucose. They give only a ballpark estimate of whether the patient's glucose is high, low, or in the middle of the normal range.

It Is Important to Understand the Limits Of Point-of-Care Testing Technologies

"POINT-OF-CARE TESTING is not a means that anyone—physicians, laboratorians, or nursing staff—should use when looking for accuracy of precise glucose levels," stated one laboratory professional who is considered an expert in point-of-care (POC) tests and devices. "These devices are not high-precision laboratory instruments. They are just disposable technology to give a rough estimate of glucose or trends over time.

"Individual hospitals spend hundreds of thousands of dollars on precision lab instrumentation in the central laboratory to produce very precise traceable levels of glucose," stated the expert. "Those results cannot be compared to a disposable point-of-care test performed on the patient floor.

"Having said that, millions of these POC tests are used each year without incident because people understand their limitations," he continued. "Caregivers understand that they can use them as a guide. Then, if they see low values, they can rely on different technology, meaning the central lab blood serum test results, as a fall back.

"There are limitations to all lab testing methodologies, and it's our job as laboratorians to educate the people ordering the tests and interpreting the results so that they understand those limitations," concluded the POCT expert. "Sometimes the POCT results can be compromised by drugs, hemolysis of the sample, and

"The death of this patient is a very unfortunate situation, and it is a lesson for every organization that uses POC testing," noted the expert. "Whether test results come from a POCT device or the central laboratory, there is a need to be cautious. Laboratory professionals understand the limitations and capabilities of different test methodologies. If there's anything we can learn from this case, it's the need for better communication."

Hospital Issues Statement

Most pathologists and lab administrators are familiar with the challenges of performing point-of-care testing in hospitals and health systems. One issue is the capabilities of the technology incorporated in the POC assay. It is often not as robust as an assay that is performed on a calibrated analyzer in the central laboratory.

The second issue is the knowledge, training, and operation of hospital staff who may perform point-of-care tests. It is not uncommon for these operators to overlook important steps in performing a point-of-care test. Such omissions can affect the quality and reliability of the POC test results in such instances.

After this incident in January, the hospital issued a statement which stated that, because of expected legal action, it would be inappropriate to comment except to say the following: "We were extremely saddened by our patient's passing. All of our physicians, nurses, and staff are dedicated to carrying out our mission of healing, comforting, and caring for each patient. At the time it occurred, we reported the incident to the appropriate authorities and took immediate action to improve our processes and procedures." TDR

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Using Accurate Data To Grow Lab Outreach

Lab at Robert Wood Johnson Univ. Hospital uses real-time financial dashboard to lift revenue

CEO SUMMARY: In recent years, the laboratory outreach program at the Robert Wood Johnson University Hospital in New Brunswick, New Jersey, has achieved impressive rates of growth in specimen volume and net revenue. One reason for this success is that the lab outreach program monitors key data in real time and responds nimbly to the service requests of office-based physicians. It uses Lean to create operational efficiencies and closely monitors its cost of testing versus actual reimbursement.

HOW DOES A HOSPITAL MEASURE the success of an outreach program? Many hospitals evaluate success in terms of lab test volume. But for laboratory managers at the **Robert Wood Johnson University Hospital** (RWJUH) in New Brunswick, New Jersey, the key success factors for their laboratory outreach program include test accuracy, client satisfaction, and net revenue.

"Everyone recognizes how a successful laboratory outreach program can benefit its parent hospital," noted Charles V. Wilson, MHA, MT (ASCP), who is the Administrative Laboratory Director for the RWJUH. "But too often, managers of hospital laboratory outreach programs are guilty of failing to use the right mix of financial and productivity measures to guide their strategies and decisions."

Real Time Data Collection

That has not been the case at RWJUH. Since ramping up the laboratory outreach program in 2009, the RWJUH lab management team has been diligent in collecting accurate data in real time, then using that information to guide decision-making.

"In the first years of our outreach program, we moved at a deliberate pace so we could understand this business," explained Wilson. "We were determined to establish the right infrastructure to support profitable growth in specimen volume, client satisfaction, and net revenue."

Wilson made these comments during a session at the *Executive War College on Lab and Pathology Management* that took place last spring in New Orleans. It was 2008 when Wilson arrived at the 630-bed acute-care facility. During 2010, net revenue from the laboratory outreach program increased on a monthly basis.

Wilson credits this growth to the close monitoring of a wide array of data. "We use a financial dashboard program that provides information on the volume of tests at any given time, including clean claims, and other revenue data," he said. "An equally important factor in the success of the lab outreach program is our team of experienced and motivated staff.

"It is common to assess a lab's activity by talking about how many lab tests it performs," he commented. "But there is no value in performing lab tests if you are not

getting paid for the work. Your laboratory's value to your hospital is strongly associated with its ability to contribute to the bottom line. The laboratory must establish itself as a revenue producing center, as opposed to a cost center.

"It is much easier for a hospital laboratory outreach program to achieve a high revenue contribution when it pays attention to several key indicators," commented Wilson. "Along with high throughput, it is important to receive clean test orders, which, in turn, helps the lab submit a very high ratio of clean claims to payers.

"When I arrived at Robert Wood Johnson in November 2008, the laboratory was not involved in outreach," he said. "To get started and to achieve a high rate of growth, we identified three things that we would need.

Using Outside Vendors

"First, we needed a dedicated IT system that would allow us to provide advanced informatics solutions to our office-based physician clients," he stated. "Second, we wanted a dedicated billing system that was independent of the hospital's internal billing and collections department.

"The third essential need was a dedicated staff," added Wilson. "We wanted a top-notch lab outreach manager, a business development liaison, and a field service coordinator." Before joining RWJUH, the outreach manager and field service coordinator had worked with Wilson and so they could "hit the ground running," he said.

In addition, Wilson was careful to choose vendors he believed could support the rapid growth of the RWJUH laboratory outreach program. This included a company that provides connectivity to office-based physicians and another company that provides a sophisticated laboratory billing and accounts receivable system.

"This billing and A/R system features a detailed, real-time financial dashboard that continuously monitors our financial performance," he said. *(See sidebar on page 13.)*

Using Clean Claims to Bolster Success of Lab Outreach

CLEAN CLAIMS MAY BE THE SINGLE BEST WAY to insure the success of a hospital laboratory outreach program. That's the opinion of Charles V. Wilson, MHA, MT (ASCP), who is Administrative Laboratory Director for the Robert Wood Johnson University Hospital (RWJUH).

"Clean test orders are absolutely the key," declared Wilson. "And the secret to increasing the ratio of clean claims is to do a better job of getting lab test requests which are accurate and complete at the time the tests are ordered.

"The cleaner the test request forms, the faster they will go through your lab's revenue cycle," he continued. "Having accurate patient insurance and test information is critical to success."

Wilson believes that a solid business plan is essential for overall guidance and support of the outreach program. He recommends that the business plan be for five years and contain a detailed financial *pro forma.*

"This business plan should include a core planning team for patient registration, IT, finance, and other essential departments," he noted. "To gain full support and commitment, these departments must be sold on the fact that the lab outreach program is a hospital program. It is important for everyone to understand that all the outreach work coming into the laboratory helps contribute to the financial success of the hospital.

Making Lab More Efficient

"After getting off to a good start financially, our next strategy was to focus on laboratory operations," noted Wilson. "The lab operated well and we introduced Lean to create the efficiencies required to deliver exceptional value to patients and referring physicians.

"Office-based physicians are often difficult to please due to the high degree of customization required," Wilson added. "If your lab outreach program doesn't consistently deliver customized value-added service, it will be difficult to retain your clients.

Doing More Than Other Labs

"Service differentiation is the key to success with any lab outreach program," he continued. "We do what other competing labs can't or won't do to meet the needs of client physicians.

"The truth is, most labs could do it. But many labs are stuck doing what they've always done," noted Wilson. "The number one cause of failure of lab outreach programs is 'hospital-centric thinking.' The lab outreach program must be run as a nimble and savvy business entity.

"In order to be successful, your lab outreach program must consistently meet the expectations of your clients," Wilson added. "That means staff have to be willing to flex in order to do whatever is needed to support how these physicians practice medicine and serve their patients.

"In addition, you and your staff need a firm understanding of your lab costs," he added. "This is essential to success. If the cost of providing the testing services is more than your reimbursement, then the more work your lab does, the more money your laboratory will lose.

"You must assess your reimbursement against accurate costs and accurate charges," Wilson said. "Your entire lab staff needs to understand the relationship between costs, charges, and the actual amount reimbursed by payers.

"Inaccuracies with regard to costs and charges result in net losses even when lab test volume increases," he explained. "Therefore, all laboratorians must develop an understanding of the terms and metrics that drive reimbursement.

"There are practical benefits when the lab staff understands lab finances," he said. "They may be uncomfortable in this role at first, but you must find a way to get them on board.

"An effective financial dashboard is absolutely essential when managing costs and lab test volume," he continued. "We've built such a dashboard and it allows us to see our entire revenue cycle at a glance—everything including unbilled charges, accounts receivable, and collections. These are key performance indicators. We look at them frequently to see how we can improve our lab outreach revenue from one cycle to the next.

"Our goal is to quickly spot trends so we can immediately address problems or pursue opportunities," Wilson said. "An extremely valuable metric to monitor is the days sales outstanding or DSO.

"DSO is essentially a measure of your revenue cycle or how quickly you process your claims," he commented. "Our DSO is consistently less than 30 days. Most laboratories would be pleased to be under 40 days."

Based on the steady increase in specimen volume and net revenue, Wilson's laboratory has been given capital to support ongoing growth. "Reinvestment in the infrastructure of the laboratory is essential," he continued. "Our sizable laboratory capital budget for this year allowed us to add a new chemistry line, hematology analyzers, flow cytometers, and do complete renovations to several areas of the department.

"We are also doing a Lean analysis of our pre-analytic operations and looking to upgrade our client service center," he explained. "Our lab outreach program continues to gain momentum which brings more support from administration and other departments in the hospital.

"We see a bright future for our lab outreach program," concluded Wilson. "It also positions us to support efforts to more effectively integrate patient care." TDR

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Smaller Labs Should Do as National Labs Do: Jettison Unprofitable Physician Client Accounts

NATIONAL LABS are profitable because they have the size and volume to generate billions in revenue every year. But the nation's largest labs also manage their accounts according to certain protocols that are effective at maintaining profitability.

"With regard to billing and collections, national labs do two things very well," stated Larry Siedlick, CEO of the **ARx Group**, in Hauppauge, New York, which provides laboratory billing and revenue management services. ARx provides these services to the lab outreach program at Robert Wood Johnson University Hospital and other lab clients.

"First, they use accurate information to recognize that not all clients are 'good' clients," noted Siedlick. "This leads to the second thing they do well, which is to get rid of clients who don't pay their bills or don't pay quickly. These lab companies are very disciplined about that.

"For smaller labs, this means you should be wary about clients who have left the national lab firms," he added. "If your lab is taking this marginal business after the client was dropped by one of the national lab firms, it could cost your organization a small fortune.

"The national labs use good information to assess the profitability of individual client accounts and that's what your lab should also do," Siedlick noted. "The minimum information you need to assess each client is the volume, the gross charge, the cash collected for that client, the cash per accession or per requisition, and whether that client is profitable for your lab or not.

"It is also essential to know if the client pays its claims in a timely manner," he said. "This information is required to make good decisions quickly.

"Along with information about problem clients, you need to get the right information to bill and get paid," Siedlick continued. "That's another thing the national labs do well: They get the right patient and insurance information at the time of service. Your lab needs the correct policy numbers, the correct subscriber relationship, the correct date of birth, and other relevant details."

How a laboratory manages its claims and denials is another opportunity to boost collected revenue. "Better management of unbilled lab claims is a key part of laboratory billing and collection because the dollars associated with these claims can add up quickly," Siedlick said.

Working Denied Claims

"Similarly, better management of denied claims can generate substantial amounts of revenue," he commented. "Claims submissions is the main issue here and it is important to recognize that, no matter how much your lab's billing and collections team improves the claims it submits, most managed care organizations find a way to deny some percentage of claims.

"It's no surprise, then, that to manage denials well, it is necessary to have information on which claims were denied and why," continued Siedlick. "Your lab should follow up on each claim that is denied.

"This task is harder if the payer uses paper to send back the explanation of benefits (EOBs)," he added. "It means someone in your lab's billing department must manually go through each denial line by line. It is easy to miss essential information in this situation.

"This job is easier with payers that supply electronic remittance advices (ERAs)," he said. "Digital ERAs are easier to analyze and adjust. Plus, this digital format makes it possible to use software to review these lab claims and find the problem areas. The faster a lab can find the problem and fix that claim, the faster it will be paid by the managed care company."

Lab Briefs

THERMO FISHER BUYS INTRINSIC BIOPROBES, CONTINUES BUYING SPREE

IT'S ANOTHER ACQUISITION FOR **Thermo Fisher Scientific, Inc.**, of Waltham, Massachusetts. It purchased **Intrinsic Bioprobes, Inc.**, of Rochester, New York, earlier this month.

A manufacturer of immuno-enrichment and sample-preparation tools for quantitative mass spectrometry, Intrinsic Bioprobes' products will allow Thermo Fisher to offer improved quantitative protein biomarker detection, the companies said. The Intrinsic Bioprobes portfolio includes Mass Spectrometric Immunoassay (MSIA), a patented sample-prep technique for enrichment of low-abundance proteins in biological samples. Terms were not disclosed.

In July, Thermo Fisher acquired **TREK Diagnostic Systems**, a company in Basingstoke, England, that provides systems for microbiology, blood culture, microorganism identification, and antibiotic susceptibility testing. In May, Thermo Fisher acquired **Phadia**, in Uppsala, Sweden, for US $3.5 billion. Phadia specializes in allergy and autoimmune diagnostics.

KAISER AND UCSF COMPLETE GENETIC ANALYSIS OF 100,000 KAISER BENEFICIARIES

DNA FROM MORE THAN 100,000 KAISER MEMBERS has been analyzed by scientists from **Kaiser Permanente** and the **University of California, San Francisco** (UCSF). The members volunteered to participate in this large genomics project.

Called the Kaiser Permanente Research Program on Genes, Environment and Health (RPGEH), the project will produce data about drug metabolism and drug response to help researchers discover genetic factors that explain differences in the way patients respond to medications. The genotyping research is being conducted with funding from a two-year, $24.8 million grant that was issued in 2009 by the **National Institutes of Health** (NIH).

ASCLS AND CLMA ANNOUNCE NEXT STEPS IN PROPOSED MERGER

FINAL DUE DILIGENCE IS UNDERWAY as the **Clinical Laboratory Management Association** (CLMA) and the **American Society for Clinical Laboratory Science** (ASCLS) move forward on a plan to merge the two lab organizations.

There will be a detailed review of the financials of the organizations and a review of a legal opinion on the best way to merge. If both groups decide to merge after completing these final steps, the respective boards are expected to vote on combining the two organizations in about three or four months, according to a joint statement issued on August 17.

In March, both organizations notified their members that the boards of directors had formed a taskforce to study how to combine the two groups. Called the CLMA/ASCLS Strategic Alliance (CASA), the board had five representatives from each organization. CASA is studying how the combined organization could operate in terms of programs, services, governance, culture, and mission.

Founded in 1976, CLMA has a membership of 3,000 clinical laboratory professionals. CLMA provides leadership in the clinical laboratory industry supporting laboratory professionals at any stage of their career. Formed in 1933 as the American Society of Clinical Laboratory Technicians, the ASCLS is based in Washington, D.C., and works to support excellence in the practice of laboratory medicine. TDR

ELINCS Specifications Released in California

Labs will face big challenges when data and coding standards proliferate in 2012 and beyond

CEO SUMMARY: Clinical laboratories and pathology groups have a new tool to use for interfacing their LIS (laboratory information systems) with the electronic health record (EHR) systems of their office-based physician clients. It is ELINCS, an IT standard designed to support electronic lab test orders and lab test reporting. The California HealthCare Foundation sponsored the creation of ELINCS and it was accepted by HL7 in 2008. In California, there are already more than 200 provider sites using ELINCS.

LAST MONTH, THE COMPLETION of the ELINCS Orders specification was announced by the **California HealthCare Foundation** (CHCF). This is a key step to facilitate the transmission of lab orders and lab results between physicians and clinical labs.

Lab administrators and pathologists will want to learn more about ELINCS, which stands for (EHR-Lab Interoperability and Connectivity Specification). It is designed to standardize the formatting and coding of messages exchanged between laboratories and electronic health record (EHR) systems.

The ELINCS Orders specification is specifically designed to allow physicians to electronically send orders from EHRs to laboratories and for labs to electronically transmit electronic test results back to EHRs in a readable format.

The development of ELINCS was sponsored by the California HealthCare Foundation with the primary goal of improving the way laboratory test data move between laboratories and all classes of providers. CHCF sees this as a necessary step on the path to the tighter integration of clinical care, as well as the further integration of the healthcare informatics required to support integrated clinical care.

Development of ELINCS began in 2005. CHCF brought together EHR vendors, commercial lab companies, professional associations, nonprofit associations, and government agencies. By early 2011, more than 56 organizations in California had either implemented an ELINCS interface or were in the process of implementation. These organizations represent more than 200 healthcare provider locations.

Among the California labs now using ELINCS are **Foundation Laboratory**, **Laboratory Corporation of America**, **National Health Services, Inc.**, **Pathology Associates Medical Laboratory** (PAML), **Quest Diagnostics Incorporated**, and **Sierra View District Hospital**.

Release of the ELINCS specifications is a significant development for the laboratory testing industry. "This is an important specification because the federal **Office of the National Coordinator for Health Information Technology** (ONC) is preparing a fast-track implementation guide to facilitate the transfer of informa-

tion from labs to physicians' EHRs," stated Ken Willett. He is President, CEO, and Chief Technical Officer of **Ignis Systems, Inc.**, a company in Portland, Oregon, that links labs with physicians' electronic health record (EHR) systems.

"The ONC is responsible for the meaningful use criteria used by physicians when they adopt EHRs," he noted. "The ONC's Standards & Interoperability Framework references ELINCS as a starting point."

The ELINCS specification, which was accepted by HL7 in 2008, may be a challenge for lab IT departments. "That's because many laboratories do not currently comply with the standards needed to make ELINCS work seamlessly," observed Willett. "That is equally true of the physician EHR systems to which labs are interfacing, as many of these EHR systems are themselves not up to these standards.

Stepping Up To HL7 v.2.5

"Take the example of HL7 (for Health Level Seven), which is a standard for exchanging information among medical applications," said Willett. "Although the current version of HL7 is 2.5, only a small percentage of laboratory interfaces nationwide are based on HL7 2.5.

"For ELINCS to have maximum utility, labs and EHR systems will need to move up from the HL7 version 2.3 or 2.4 they currently use to HL7 version 2.5 and eventually to HL7 2.7," he added. "Another hurdle to ELINCS adoption is the need for providers to implement ICD-10 before the October 1, 2013, deadline set by the federal government.

"The ONC is unlikely to require compliance to the ELINCS or HL7 2.5 standards for labs and EHRs in the second phase of meaningful use requirements," noted Willett. "For the reasons listed above, if ONC tried to mandate ELINCS in the meaningful use standards, I would expect to see a lot of push-back from clinical laboratories." TDR

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ELINCS Uses LOINC For Specific Purposes

BEFORE THE ARRIVAL OF ELINCS, laboratories had the option of either developing a proprietary system or using LOINC—Logical Observation Identifiers Names and Codes — as a method for sending and receiving laboratory and clinical data from office-based physicians and other types of providers.

Some experts and the California HealthCare Foundation suggest labs use both ELINCS and LOINC, but doing so could be problematic. "LOINC is so fine-grained, that there are generally multiple codes for the same test," stated Ken Willett, President, CEO, and Chief Technical Officer of Ignis Systems. "Therefore getting consistent mappings from different labs is unlikely.

"In fact, the ELINCS specification references LOINC and provides a list of basic tests and the corresponding LOINC codes that labs should use for results for those tests," observed Willett. "This feature emphasizes LOINC codes for the 100 common laboratory tests that represent about 80% of the total volume of all laboratory tests that are ordered.

"But there is an important difference in the wording between the original ELINCS specification and the current HL7 2.5.1 Ambulatory Care Lab Result (ELINCS) spec," he said. "In the former, about 100 tests were identified and there were one or more LOINC codes specified for each. The implication is that to be ELINCS compliant, one of those LOINC codes must be used.

"The HL7 specification lists a somewhat larger set of about 150 tests, which represent 95% of all ordered tests," Willett explained. "But the list of tests does not contain the LOINC codes; it contains the parameters from which LOINC codes would be defined. Thus, there is the requirement to use LOINC with a guide to code selection but the specific codes for these common tests are missing.

"In my view, this approach by HL7 is more flexible," concluded Willett. "But it also makes conformance testing problematic."

TriCore Earns Multi-Site CAP 15189 Accreditation

TriCore's main lab and two hospital labs in Albuquerque successfully implement the QMS

CEO SUMMARY: To achieve the goals of continuous improvement and standardization across all facilities within its organization, TriCore Reference Laboratories opted to implement the CAP 15189 quality management system (QMS). Last month, the lab announced its accreditation to CAP 15189 and became the nation's first laboratory organization to earn a multi-site CAP 15189 accreditation. TriCore's administration says that its client physicians have noticed the improved testing services.

IN ALBUQUERQUE, NEW MEXICO, last month, **TriCore Reference Laboratories** became the latest laboratory to implement the quality management system (QMS) of CAP 15189 and earn accreditation to that standard. TriCore says it is the first multi-site laboratory organization in the United States to be accredited to this CAP 15189 standard.

The **College of American Pathologists** (CAP) now has 18 laboratory organizations which have achieved accreditation under its CAP 15189 program. The **American Association for Laboratory Accreditation** (A2LA) has one laboratory accredited to the standards of ISO 15189:2007.

TriCore made a major commitment to the 15189 QMS. In New Mexico, it employs 1,100 people who work in 54 sites. The lab contracts with 35 pathologists and scientific directors from two pathology groups. Among its 54 sites are 26 patient care centers. "All sites operate under the ISO 15189 quality management system," stated Jessie Salk, who is President and CEO of TriCore, "but only three of the sites are accredited to CAP 15189.

"Those three sites are the core laboratory and the two rapid response labs," continued Salk. "One of these labs is located at the **University of New Mexico Hospital** (UH) and the other is located at **Presbyterian Hospital**. All three of these lab facilities are in Albuquerque.

Quality Management

"We decided to implement the 15189 QMS at the core lab and the two rapid response labs first, because we can add other hospitals and sites later," Salk said. "Currently, the entire TriCore organization operates under the same QMS system because the cross-functional teams involved in this effort represented the various sites.

"One strategy at TriCore is to introduce continuous quality improvement across the entire organization," she noted. "In October 2009, we applied for CAP 15189 accreditation and had a gap assessment in April 2010. It took just over two years to fully implement the QMS, successfully complete our assessment, and earn accreditation for these three lab testing facilities.

"Implementation of the 15189 QMS has delivered significant benefits to us," stated Salk. "Like many laboratory organizations, we perform the same testing at multiple sites under the same management and technical requirements.

Separate But Equal

"Our hospital-based labs run very differently from the way we run the core lab," Salk explained. "That creates a dichotomy in how things work. So our ultimate goal was to standardize these three organizations.

"As a first step, in 2010 we standardized all the lab equipment in these different labs," she recalled. "The next step was to standardize the processes, the quality management system, and the focus on continuous improvement in each of our facilities. Now we can look at everything the same way across the system, regardless of the location.

"The laboratory staff at the UH lab and in the Presbyterian Hospital lab are our employees, but they are still part of those hospitals," Salk added. "We wanted to encourage more interaction and break down those silos. This would make it easier to share best practices, to standardize processes, to measure nonconformities, and to conduct root cause analyses.

"Once we got people from each facility into one room and had them talk about the process, the silos disappeared rather quickly," she said. "The teams identified the best processes for our clients and for our patients. Then we set standards for those processes and developed support systems to consistently meet those higher standards. Since we now measure processes across the system, we are faster and more accurate at spotting problems as they occur."

TriCore's Quality and Process Improvement Manager, Pat Strong, agreed. "Every member of the staff now has the training and the knowledge to recognize errors, then find the cause of these errors so they can be prevented and eliminated.

"With this training in place, we can now put more emphasis on the cost of poor quality," explained Strong. "Our staff understands that errors are costly. This is a very powerful tool to use."

"Now, if a specimen is misplaced, the entire staff recognizes that the processes or systems we had in place may have been the cause of that lost specimen," observed Salk. "The QMS helps us do more than simply find or replace that lost specimen. Our lab staff has the knowledge and the tools to identify and eliminate the constraints or systemic problems that caused us to lose the specimen in the first place.

"Our accreditation to CAP 15189 means we all have to dig deeper to find the root cause of problems," she added. "Then, once we identify that root cause, we can fix or eliminate it."

Even more powerful is the fact that TriCore's lab team has implemented processes to prevent errors before they occur. "Much of our continuous improvement activity centers around corrective and preventive action," noted Salk. "Corrective action helps us to prevent problems from recurring, while preventive action prevents problems from occurring not just in the core laboratory, but in all locations across our organization.

Increased Client Satisfaction

"Another benefit of TriCore's CAP 15189 accreditation is the improved ability to move staff from one location to another if needed, since they know the systems at all locations," Salk said. "Improving client satisfaction is our next big objective in the coming months.

"As our lab improves processes and performance measures, it's definitely improving service to clients," she added. "That makes us more competitive in our service market. Each time we improve our work processes and service levels, our customers recognize and comment on those improvements. This is not the end or our efforts," she added. "We have just begun this journey." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's a laboratory with what may be one of the world's biggest accounts receivable problems. In South Africa, the **National Health Laboratory Services** (NHLS) says it is owed $1.8 billion Rand (about US $214 million) from its client accounts. As reported by a regional television station (*eyewitnessnews.co.za*) in the country, SouthAfrica's various provincial health departments have not been paying their lab testing bills. NHLS is the exclusive contractor for clinical laboratory testing that originates in all government hospitals and clinics in South Africa.

ADD TO: *Big Accounts Receivable*

In a briefing to the South African parliament's health portfolio committee, NHLS' Chief Executive Officer, Saggie Pillay, stated that the two provinces of Gauteng and KwaZulu-Natal owe his lab a total of 2 billion Rand. Pillay said that, because of this huge unpaid accounts receivable balance, his laboratory has been unable to update aging equipment and infrastructure at the 260 laboratories his organization operates across all of South Africa.

ABBOTT WINS BIG LAB CONTRACT IN GLASGOW

It is billed as the "largest laboratory contract in the world" by the **National Health Services Greater Glasgow and Clyde Trust**. As construction proceeds on a consolidated pathology "super lab" in Glasgow, **Abbott Laboratories, Inc.**, has been awarded a seven-year contract worth £100 million (US $154.6 million). Abbott will be responsible to provide what is described as "round-the-clock lab services across the west of Scotland giving rapid testing and results." This is the second similar contract Abbott has won in Glasgow.

TRANSITIONS

- Kathy Teitzel has been appointed the new General Manager for **PacLab Network Laboratories**, based in Renton, Washington. She came to PacLab from **Quest Diagnostics Incorporated** and served in management prior to that with several clinical laboratory companies in the Seattle region.

- **Health Network Laboratories** of Allentown, Pennsylvania, recently selected Sherri Dobis to be Vice President, Business Development. Dobis was formerly an executive with **Novation**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 17, 2011.