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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

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R. Lewis Dark

Founder & Publisher

Government Health Contracting Has a Seamy Side

WHAT MIGHT HAPPEN TO YOUR LABORATORY if either or both Medicare and your state's Medicaid program initiated some type of competitive bidding for laboratory testing services?

I'll bet there would be a level of financial pain, not to mention the consequences to physicians and patients as long-standing laboratory relationships were changed in favor of the laboratory which won such a competitive bidding project. Certainly the concept of competitive bidding runs contrary to the stated goals of Medicare and Medicaid. How often have we heard government healthcare regulators and elected officials tell us that government-funded care must provide equal access to all patients and all providers?

If Medicare and state Medicaid programs continue moving toward some type of bidding format involving laboratory services, it will favor certain types of laboratories over others. Clearly smaller labs and specialty testing labs will find themselves at a disadvantage. That is why I think the events in Florida deserve much more attention by the laboratory industry.

If Florida Medicaid perseveres and awards a single laboratory with an exclusive, three-year contract to provide all non-hospital lab testing, it is a financial hammer to 97 other independent laboratory companies in Florida currently serving Medicare beneficiaries. Shouldn't this cause concern among lab firms in other parts the United States? And—by the way—hospital laboratory outreach programs are to be exempted from this state-wide, sole-source contract! That's a double standard which creates two classes of citizens and treats them differently.

Are you interested in learning more about this threat? If so, I recommend you carefully read our expose of the unprofessional, if not outright incompetent, efforts by the Florida Medicaid agency to draft a contract awards process for its statewide laboratory services contract. *(Pages 13-17 in this issue.)*

As usual, it's information you'll find nowhere else but in THE DARK REPORT. Our sources are many and deep and we reveal how flawed this contracting process has been from the start. Equally disturbing is the trail of evidence that hints at how one politically-connected laboratory company in Florida is influencing contract specifications to favor it. As you read this story, think about the consequences if your state's Medicaid agency decided to follow that of Florida's and initiate restrictive lab contracting policies. TDR

OIG Releases Opinion On AP Lab Condominiums

Specific on key points, OIG's guidance alters compliance risk for AP lab condo owners

CEO SUMMARY: In responding to a request for an advisory opinion, the Office of the Inspector General (OIG) issued an advisory opinion which declares that anatomic pathology (AP) lab condominiums "could potentially generate prohibited remuneration under the anti-kickback statute." It also voices concerns about how the operation of such AP laboratory condos could violate the Stark Law.

JUST TWO WEEKS AGO, the **Office of the Inspector General** (OIG) released a new advisory opinion which reshapes compliance policies that affect the operations of clinical laboratories and anatomic pathology (AP) group practices.

The OIG advisory opinion was posted on Friday, December 17, 2004. It deals with the essential elements of the "anatomic pathology laboratory condominium" business model. In this arrangement, a promoter puts a number of fully-equipped pathology laboratories in separate rooms in a single building. A pathologist and histotechnologist go from room to room during the day to perform the work on behalf of each lab's owners. *(See TDRs, July 19 and August 9, 2004.)*

In the advisory opinion, numbered 04-17, the OIG stated that the AP laboratory condominium scheme "could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [name redacted] under sections of the Act."

The advisory opinion also called attention to how the AP laboratory condominium arrangement "raises potential issues under the Stark Law." The OIG noted, in a footnote, that such arrangements would be "impossible to monitor" for compliance and "therefore would be prone to substantial abuse, including, without limitation, the risk of inappropriate utilization and improper claims."

Despite the quiet Christmas season, it didn't take long for news that

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

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the OIG had posted this opinion letter to catch the full attention of law firms across the country which advise laboratories, pathology groups, and specialist physicians who own AP laboratory condominiums. These are the lawyers who have been asked to provide opinions as to whether anatomic pathology laboratory condominium schemes meet federal and state compliance regulations and statutes.

Lab Company's Request

OIG Advisory Opinion 04-17 is a redacted version of the letter sent to **In-Practice Pathology Group, Inc.**, a wholly-owned subsidiary of **CBLPath Holdings Corporation** (also the parent company of the AP specialty lab, **CBLPath, Inc.**) In January 2004, CBLPath, based in Ocala, Florida, requested an advisory opinion from the OIG on its proposed plan to offer anatomic pathology laboratory condominiums and services to specialist physician groups.

"We requested the OIG advisory opinion in response to developments in the marketplace," stated William W. Curtis, Chairman and CEO of CBLPath. "Particularly within the medical specialties of urology, gastroenterology, and dermatology, there was rising interest in these types of pathology lab arrangements.

Assessing Compliance Risk

"That caused us to look at the form and shape of AP laboratory condominium business models already in operation," he continued. "It was our assessment that the circumstances of these business arrangements between the lab condo promoter and participating specialist medical groups was more aggressive than was intended by the Stark Law exception.

"Frankly, it was a level of compliance risk and legal uncertainty CBLPath was not ready to take," declared Curtis. "That is why we requested an advisory opinion by the OIG. CBLPath developed what we considered to be a conservative version of the AP laboratory condo business model.

"We wanted to minimize or eliminate the 'Catch 22' that so often surrounds laboratory compliance issues," he said. "It was our view that, if the OIG blessed our AP lab condo model, we would then offer it to a narrow band of the largest specialist groups—those which have the scale of specimen referrals to truly and fully meet the intent of the Stark Law.

"Alternatively, if the OIG did not approve the business model of the AP laboratory condo, then its advisory opinion would put us in a position to offer specific guidance to physicians interested in these types of arrangements. In either case, the OIG's advisory opinion would level the competitive playing field and further define the compliance risk triggered by these types of laboratory business models," observed Curtis.

Looking For More Detail

"We were also hopeful that the OIG's advisory opinion might offer specific details about 'do's and don'ts'," Curtis said. "As an example, in their advisory opinion, the OIG considered it problematic that CBLPath was also in a position to directly compete for the AP services."

Did CBLPath get the OIG advisory opinion it hoped would create a level playing field? "The OIG certainly weighed in with a clear 'no' on the anti-kickback component of an AP laboratory condominium arrangement," noted Curtis. "Another major red flag is the footnote referencing its concerns about violations of the Stark Law.

"This opinion obviously has direct implications to our proposed business model for AP laboratory condo arrangements," Curtis observed. "But I think the OIG's advisory opinion triggers

CBLPath's Attorney Discusses Key Issues in OIG's Advisory Opinion

IN THE VIEW OF THOMAS BARTRUM, the release of Advisory Opinion 04-17 by the Office of Inspector General is consistent with earlier compliance guidance on contractual joint ventures between physician groups and other providers.

Bartrum is an attorney for **Waller Lansden**, based in Nashville, Tennessee. While he was at **Baker Donelson**, he was part of the CBLPath, Inc. legal team which drafted the request for an advisory opinion on CBLPath's anatomic pathology (AP) laboratory condominium business model. He participated in conversations with the OIG as the government agency developed its response, which it published on December 17, 2004 as OIG Advisory Opinion 04-17.

"It was clear, from the start, that the OIG was uneasy with the concept of AP laboratory condominiums," noted Bartrum. "We pointed out that, since a physician group could build its own in-house pathology laboratory, hire its own pathologist and directly bill for these services, the AP laboratory condo was simply a variant of an established practice. However, that didn't seem to catch the attention of the OIG.

Senator Grassley's Impact

"The agency seemed to have a strong sense of purpose," continued Bartrum. "The letter sent to the OIG by Senator Charles Grassley asking them to investigate these AP lab condo schemes had an impact. It allowed us to have high-level talks with OIG officials. They wanted to understand the market context that caused us to ask for an opinion. It also seemed to be a high priority to deliver an answer to the questions raised in our request.

"If there is any single 'walk-away message' I got from Advisory Opinion 04-17, it's that the OIG has a definite problem anytime an existing provider allows a referring physician to capture revenue that historically went somewhere else," stated Bartrum. "This recent opinion ties back to the OIG's Special Advisory Bulletin on "Contractual Joint Ventures," dated April 30, 2003. This point pertains to the AP lab condo concept, which effectively allows the referring physician to capture revenue that formerly went to a pathology group or laboratory."

Bartrum believes the OIG will have more to say on this issue. "The OIG work plan tends to be a road map for issues which the government considers to be a priority," he said. "I think it is noteworthy that the OIG added a pathology services study to its 2005 work plan." *(See TDR, November 1, 2004.)*

Stark Law Exposure

"I also think it is noteworthy that the OIG took pains to state, in Advisory Opinion 04-17, that the **Centers for Medicare and Medicaid Services** (CMS) is responsible for guidance on the Stark Law and how it relates to these AP lab condos," added Bartrum. "Because of our discomfort with the content of this Advisory Opinion, we have initiated discussions with CMS as to how broadly we can be comfortable with the in-office exception. This may take a while, because CMS has always been measured and deliberate in its public pronouncements involving the Stark Law."

Bartrum also had a fascinating side observation about the downstream impact of the OIG's advisory opinion. "Typically, the more the government focuses on a compliance topic, the more likely it is to give employees discomfort that they may be breaking the law," he said. "Thus, OIG and CMS opinions and comments about AP lab condos tends to put this topic in the compliance spotlight that attracts the notice of potential whistleblowers. It may be two or three years before some whistleblower lawsuits appear, but it does represent one more risk to implementing this business model."

broader implications in situations where non-pathologist physicians want to share in the revenues from pathology services generated by their patient referrals," explained Curtis.

"There is plenty of evidence that the OIG is looking at the entire range of ancillary services—not just pathology—and is finding that the Stark Law exception encourages the very abuses that the Stark Law was designed to prevent," said Curtis. "We certainly got this message during our interaction with the OIG."

Evolving Legal Concepts

"Moreover, we think the OIG may be signaling an interest in reconsidering the topic of client billing between a laboratory and the referring physician," continued Curtis. "We see an evolution in legal concepts that effect the situation where a physician marks up a clinical service—like a laboratory test—without adding value. The mark-up is directly connected to his/her ability to refer the patient to the lab which performs the test.

"If you read the OIG's advisory opinion, where it discusses these elements of our proposed AP laboratory condo arrangement and you take out the word 'lab' and substitute 'ancillary service,' the OIG's language could apply to the larger topic of client billing. This advisory opinion may be a signal that the OIG is becoming increasingly uncomfortable with any type of ancillary service arrangement."

Compliance concepts do evolve over time. The lab industry saw this happen with the definition of "inducement" during the 1990s, which eventually affected how things as simple as how lab test requisition forms were arranged and printed. The direct statements in Advisory Opinion 04-17 represent further steps in the OIG's thinking about AP laboratory condos and self-referral concerns. TDR

Contact William Curtis at 352-732-9990; Thomas Bartrum at 615-726-5720; Brad Smith at 336-584-5171.

LabCorp's Brad Smith Assesses OIG Opinion

FOR ONE LAWYER with long and detailed experience in Medicare compliance at the highest levels, there was little ambiguity in the Office of the Inspector General's (OIG) Advisory Opinion 04-17, dealing with anatomic pathology (AP) condominium laboratory arrangements.

"Often these opinion letters are nuanced and take some effort to interpret," said Brad Smith, Executive Vice President and Chief Legal Officer at **Laboratory Corporation of America**. "However, this advisory opinion is strongly-worded on the key issues and there is no lack of clarity on the essential points.

"That is true of the anti-kickback exposure of these arrangements," he continued. "The reference to the potential of these schemes to violate the Stark Law was also very direct. No matter how you might want to sugar-coat this opinion, it is definitive on a variety of core issues.

"I think most individuals managing clinical laboratories would recognize the same type of scheme—operating an off-site, even out-of-state clinical lab 'owned' by a physician group referring the specimens—to be in violation of a number of compliance requirements. That's because, on the clinical side, there is a clear sense of compliance do's and don'ts," observed Smith.

"The anatomic pathology laboratory condominium scheme is in such deep conflict with those compliance norms that it is difficult to understand the mindset that allows physician groups, promoters, and pathologists to consider that this type of contractual joint venture meets both the form and the intent of the law," offered Smith. "The OIG's direct statements on the key issues in its advisory must be read in context with the inclination of some individuals to adopt a loose interpretation of compliance regulations. These individuals are willing to push compliance boundaries and hope that enforcement action is never taken."

Analysis of OIG's Opinion Shows Compliance Shift

Violations of anti-kickback and Stark laws may be triggered by anatomic path lab condos

CEO SUMMARY: Attorney Richard Cooper believes the latest Advisory Opinion by the Office of the Inspector General (OIG) is consistent with its earlier anti-kickback law pronouncements about situations where a physician is in a position to profit from the patients he/she refers. Cooper also comments on the vulnerability of the anatomic pathology laboratory condominium to violations of the Stark Law.

THERE'S A LITTLE OF THE OLD and a little of the new in the latest advisory opinion issued by the **Office of the Inspector General** (OIG) last month. That's the opinion of one veteran lab industry attorney.

"Advisory Opinion No. 04-17 should be studied with care," observed Richard S. Cooper, Attorney and Partner at **McDonald Hopkins**, a law firm headquartered in Cleveland, Ohio. "Although it is focused directly on the business model of the anatomic pathology (AP) laboratory condominium, the advisory opinion provides insight into how the OIG views several broader issues of laboratory compliance."

Both clinical laboratories and anatomic pathology group practices will want to understand the implications of OIG Advisory Opinion No. 04-17. Among other subjects, it addresses the anti-kickback statute and Stark Law in ways that extend longstanding efforts by government regulators to identify and control inducements that occur between laboratories and referring physicians.

"It is important to view this advisory opinion as a logical extension of the OIG Special Advisory Bulletin on 'Contractual Joint Ventures,' dated April 30, 2003," said Cooper. "The OIG's comments in this newest advisory opinion are consistent with earlier statements it has published on this subject. In that context, this advisory extends existing OIG guidance.

OIG Concerns

"The April 30, 2003 bulletin and the December 17 opinion should be read and studied together," added Cooper. "The first document addresses general issues in contractual joint ventures involving physicians. The second document is specifically directed to joint ventures involving referring physicians and anatomic pathology services.

"In both documents, the OIG addresses situations where a physician generates patient referrals and wants to offer a clinical service for which his/her patients will be referred. The OIG is concerned about this type of situation: a physician goes to an existing provider

already offering this service. The physician partners with that provider to serve the patients he/she refers. The referring physician receives money from these services. The OIG notes that such arrangements have the potential to trigger violations of federal statutes," he said.

"The OIG's advisory opinion stated the proposed arrangement could potentially violate anti-kickback statutes and subject the provider to sanctions," explained Cooper. "This was based on its evaluation of a rather simple business model.

AP Laboratory Condo Model

"As described in the Advisory Opinion, the Requester would, at an off-site location, build up to five separate pathology laboratories in a single building. Each laboratory would be owned by a different physician group practice. The Requester would 'furnish all necessary management and administrative services, equipment leasing, premises subleasing, technical, professional, and supervisory pathology services, and, if requested, billing services for each Physician Group to operate its own Path Lab'," noted Cooper.

"Requester would execute four contracts with each AP laboratory condominium owner to cover the details of the management arrangements," he added. "Pathologists and technical staff would rotate among the individual pathology labs and would only provide services on behalf of that laboratory owner while in that particular lab owner's space.

Two Major Issues

"This was the business model evaluated by the OIG," said Cooper. "There are two main points in this advisory opinion which should be understood by all clinical lab directors and pathologists. One involves anti-kickback issues. The other involves potential violations of the Stark Law.

"Let's take the anti-kickback topic first," stated Cooper. "The statute makes both parties liable when a kickback situation occurs. Remuneration is defined by the statute to include a transfer of anything that has value.

"The OIG's 2003 bulletin addresses this point. It says that when a physician group does a joint venture (JV) with another group or provider to capture referral revenues—and the JV partner is already in that line of business and does virtually everything to service the referrals—this situation has the appearance of a sham arrangement organized expressly to capture revenues for the referring physicians.

"The OIG does recognize legitimate joint ventures," observed Cooper. "But the OIG is concerned with JVs where a physician group shares in the revenues from its referrals without sharing risk and without having substantial involvement. The OIG is alert to JVs where the physician group originating the referrals is effectively a partner on paper and is neither a partner at risk nor a partner involved in operations.

Contractual Joint Ventures

"This was the gist of the OIG's 2003 Bulletin on contractual joint ventures," he noted. "In Advisory Opinion 04-17, the OIG examines the anatomic pathology laboratory condominium from this same perspective.

"In fact, the OIG makes precisely this point in three places in the advisory opinion. The first relevant comment is: 'On the whole, the Physician Group would commit almost nothing in the way of financial, capital, or human resources to the Path Lab, and, accordingly, would assume no or very little real business risk'," quoted Cooper.

"The second comment is: 'The Physician Group's actual financial and business risk would be nonexistent or

minimal, because it would have complete control over the amount of business it would send to the Path Lab and could make substantial referrals to the Path Lab. In fact, ...by basing the Monthly Fee for each Physician Group on historical utilization data generated by the Physician Group, the parties can easily insure that the business generated by the Physician Group would be sufficient to meet or exceed the Monthly Fee.'

Profits From Lab Referrals

"The third comment is: 'Accordingly, based on the facts presented here, we are unable to exclude the possibility that the parties' contractual relationship is designed to permit the Requester to do indirectly what it cannot do directly; that is, pay the Physician Groups a share of the profits from their laboratory referrals. In other words, the Requester may be offering the Physician Groups impermissible remuneration by giving them the opportunity to obtain the difference between the reimbursement recieved by the Physicians Groups from the Federal healthcare programs and the fees paid by the Physician Groups to the Requester (i.e., the profit from pathology services ordered by the Physician Groups).'

Federal Enforcement

"These legal concepts are familiar to most laboratory managers and pathologists," added Cooper. "They underlay aggressive federal enforcement of laboratory industry business practices for more than 20 years.

"The OIG provided these comments to explain why it determined that AP laboratory condominiums "could potentially generate prohibited remuneration under the anti-kickback statute'," said Cooper. "Taken in context with earlier statements by the OIG, this opinion is consistent. It is a

Missing Legal Opinion Raises Many Questions

IN RESEARCHING THE BACKGROUND and development of the anatomic pathology (AP) laboratory condominium business model earlier this year, THE DARK REPORT found a circumstance both noteworthy and troubling .

Nowhere in the marketplace could there be found a legal opinion which assessed the legal and compliance issues involved in operating an AP laboratory condominium. In fact, during a call to the law firm of one AP laboratory condo company, THE DARK REPORT was told, point-blank, that a legal opinion existed, but had not been shared with anyone *not* employed by the company—including physician groups which had purchased an AP lab condo.

As clients of THE DARK REPORT know, some of the smartest legal minds in the lab and pathology profession consider the business scheme of the AP laboratory condo to fall outside acceptable compliance parameters. Thus, the fact that no legal opinion produced by an AP lab condo company circulates in the marketplace is evidence that even these companies recognize the questionable compliance grounds upon which this business model is built.

"McDonald Hopkins takes the same view and has the same experience," said Richard Cooper, attorney at this Cleveland, Ohio-based law firm. "None of us, nor any of our physician group clients, have ever seen a legal opinion prepared by any of these AP laboratory condo promoters.

"In fact, when specialist groups contact us to discuss their interest in buying an AP lab condo, we ask them to get a copy of the legal opinion prepared by the promoter," he continued. "Never has a group succeeded in obtaining such an opinion. Moreover, most of these physician groups never contact us again. I believe at least a few proceeded to buy their AP laboratory condo, even though the lack of a legal opinion can be considered a sign of the high compliance risks triggered by this type of contractual joint venture."

clear warning of how the OIG might proceed to build a case against AP laboratory condominiums."

Potential Violations

The second main point in the advisory opinion is a reference to the potential of the AP laboratory condominium to trigger a violation of the Stark exception. "This reference is a footnote," Cooper commented. "The OIG states that it is the role of the **Centers for Medicare & Medicaid Services** (CMS) to issue opinions about the application of the Stark Law.

"Having made that statement, the OIG then goes on to make a specific comment, which reads 'We observe, however, that the actual operation of an arrangement is crucial to compliance with the law, and that the proposal to segregate space and equipment and rotate pathologists and technicians and account for their time spent in each Path Lab would be virtually impossible to monitor (particularly in an off-site facility) and therefore would be prone to substantial abuse, including, without limitation, the risk of inappropriate utilization and improper claims'," quoted Cooper.

Stark Law Violations

"The OIG intentionally flagged an obvious way the operation of an AP laboratory condominium complex can cross the line into Stark Law violations," said Cooper. "Both pathologists and the specialist physicians in these types of joint ventures need to understand that, even if the operating agreement fully meets the law, the business model on which it depends will only be as good as how it is operated by humans."

"Our law firm has always considered AP lab condominiums as likely to be problematic—and the referring physicians at risk—because the pathology laboratory is not located within their clinic, and in some cases, is located in another state," said Cooper. "And, as the OIG so cogently points out in this Advisory Opinion, the very structure of these AP lab condos is 'prone to substantial abuse'."

Stepping back, Cooper says it is important to recognize that each of the two main elements in the opinion carries a different kind of risk. "There are 'safe harbors' defined within the anti-kickback law," he explained. "If a business arrangement falls outside the safe harbor, it still may be compliant. That means a failure to qualify for a safe harbor does not automatically mean a violation of the law has occurred.

"And, as the OIG so cogently points out in this Advisory Opinion, the very structure of these AP lab condos is 'prone to substantial abuse'."

"In contrast, the Stark Law defines an exception to self-referral," he continued. "Anytime a business arrangement fails to meet the requirements of an exception related to Stark services, then a violation of the Stark Law has occurred. This is one big reason why the OIG's effort to comment on the susceptibility of the AP laboratory condominium to fall outside the Stark Law exception is noteworthy. It believes this is a major source of compliance risk."

These are clear signs that federal regulators look unfavorably upon this business model. Going forward, the interesting question will be whether OIG Advisory Opinion 04-17 causes some AP lab condo owners to reconsider their compliance risk and decide to shut them down. **TDR**

Contact Richard Cooper at 216-348-5438.

More Lab Consolidation: LabCorp Buys US LABS

LabCorp strengthens its cancer testing resources & gains a West Coast laboratory

CEO SUMMARY: Following three years of rapid growth in specimen volume and revenues, US LABS has accepted a purchase offer from Laboratory Corporation of America. Both US LABS' fast growth and its sale to a national lab demonstrate that there is still opportunity in laboratory testing—and that one of the two blood brothers is ever ready to open its purse and offer a tidy sum to acquire such a lab.

COMPARED TO THE LAST BIG ROUND of laboratory acquisitions in 2002, the purchase of **US LABS** for $155 million by **Laboratory Corporation of America** shows how the laboratory marketplace has shifted in recent years.

First, US LABS is focused on a particular slice of the diagnostics testing market: reference and esoteric cancer testing. It is not the standard laboratory business model of offering routine chemistry and hematology testing services to office-based physicians.

Earlier Lab Acquisitions

Second, at an estimated $75 million in annual revenues, US LABS is not "big" in the traditional sense. During 2002, the four biggest laboratory companies acquired that year had anywhere from three to six times that revenue.

Three, US LABS is a fast-growth success story. In 2001, the first full year it pursued the oncology testing market, annual revenues were $16 million. For 2004, analysts estimate US Labs will close the books with approximately $75 million in annual revenues.

So, having demonstrated the ability to sustain strong growth in specimen volume and revenues over several years, why is US Labs selling now?

"US LABS had just begun working with investment advisors to prepare for an IPO (Initial Public Offering) in the second half of 2005," explained Judd Jessup, CEO of US LABS. "During the early phases of this process, LabCorp stepped up with a price that the Board considered reasonable, particularly when it considered the uncertainties and risks involved in waiting to try an IPO in future months.

"Because US Labs was launched and funded with venture capital, it was always intended that the probable exit strategy for the venture capitalists was either an IPO or a direct sale," explained Jessup. "LabCorp's combination of timing and price was viewed favorably by the Board and shareholders."

The two companies believe the sale will close sometime in the first quarter of 2005. The management team of US LABS is expected to remain. Few details about LabCorp's plans have been

made public. However, it is believed that LabCorp intends to operate US LABS as a wholly-owned subsidiary, using its own name at its present location in Irvine, California.

"...we offered pathologists a way to practice more sophisticated pathology without competing against them. It proved to be a win-win business relationship."

Jessup attributes the company's growth to its strategic business plan. "US LABS is a national anatomic pathology company offering sophisticated reference and esoteric cancer testing primarily to community hospital-based pathologists," he said. "Our unique twist was to partner with these pathologists. We offered them the option of having us provide the technical services and allowing them to perform the professional services.

"Along with fast turnaround times and an advanced menu of testing services, we offered pathologists a way to practice more sophisticated pathology without competing against them. It proved to be a win-win business relationship," he noted.

Technical & Professional

US LABS was first to develop the use of the **ChromaVision** Automated Cellular Imaging System (ACIS®) as a way to provide technical services on a cancer case, then digitally transmit the pathology images to the referring pathologist so he/she could diagnose the case and sign it out. That part of US LABS' business became attractive enough that ChromaVision restructured itself, built its own laboratory and became a competitor. *(See TDR, August 30, 2004.)*

Another facet of the US LABS story is that it represents a significant business turnaround. In the early years, US LABS struggled to attain profit margins desired by its professional investors. In fact, Jessup was made CEO of the company back in 2001 specifically to help the company regain its financial balance, following a breakneck year of growth where costs outpaced revenue.

Jessup does acknowledge that current market uncertainties involving the IPO and Medicare reimbursement policies played a role in US LABS' decision to sell at this time. "Reimbursement is always an issue," he observed. "For example, this year Medicare made significant changes to reimbursement for flow cytometry procedures."

Cancer Testing

Looking forward, Jessup believes there won't be much change at US LABS under its new ownership. "LabCorp has a major commitment to sophisticated reference and esoteric testing," he noted. "It is investing to expand its presence in the cancer testing marketplace, which is exactly where US LABS is already positioned. Both companies expect this to be a good marriage."

Jessup will give credibility to those words because he, as well as most of the US LABS executive team, intend to stay after the company's sale to LabCorp. But Jessup has an added motive. US LABS is his first management assignment in the laboratory industry. Through 1996, he was active in managing some of the nation's largest managed care companies.

This gives him some unique insight that he wanted to share with readers of THE DARK REPORT. "Having sat at both sides of the managed care table, I can tell you that it is much more pleasant to be on this side. It is invigorating to work in a laboratory that clearly does good for both physicians and their patients." TDR

Contact Judd Jessup at 949 450-0145.

Molecular Update

Roche/Affymetrix Microarray Cleared for Clinical Use by FDA

MOLECULAR DIAGNOSTICS took a big step forward in December. During the month, the **Food and Drug Administration** (FDA) cleared the first microarray instrument system and microarray-based laboratory test for clinical use.

The FDA announced on December 23, 2004 that it had cleared the GeneChip® System (GCS) 3000Dx for clinical use. **Affymetrix, Inc.** of Santa Clara, California manufactures this instrument system.

Also on the same day, the FDA announced clearance of the AmpliChip™ Cytochrome P450 Genotyping Test for clinical use. This test kit is manufactured by **Roche Molecular Systems, Inc.**, based in Pleasanton, California.

Cleared In Europe and USA

Both products received regulatory clearance in Europe this September. With regulatory clearance on both continents, the Roche/Affymetrix system becomes the first microarray system and diagnostic test to reach the clinical marketplace.

Because the Affymetrix AmpliChip test instrument has cleared this regulatory step, it becomes a favored technology platform upon which other proprietary microarray tests can be run. Lab managers and pathologists can expect a variety of biotech and IVD companies to develop diagnostic tests specifically designed to run on the AmpliChip instrument. That makes FDA clearance for the test kits easier, faster, and cheaper.

As an example, within days of the news that the FDA had cleared the GeneChip instrument for clinical use, Affymetrix announced a licensing deal with **Veridex, LLC**, a business unit of **Johnson & Johnson Company**. Veridex plans to develop cancer markers to run on the GeneChip instrument system.

For Roche, the FDA's decision allows it to move other microarray tests through the development pipeline and into the clinical marketplace. This first test, the P450 Genotyping Test, extracts DNA from a patient's blood. It searches for 31 different polymorphisms in the cytochrome P450 gene. These polymorphisms identify genetic variations which affect whether a patient's liver can metabolize certain drugs fast, slow, or not at all.

The market for this test appears to be substantial. The polymorphisms it detects affect metabolization of about 25% of all prescription drugs. This test represents its own milestone, because it is the first down payment on the promise of pharmocogenomics—the ability to determine a patient's genetic predisposition to benefit (or not) from a specific drug and anticipate whether or not it may cause clinically significant side effects.

The importance of this development should not be underestimated. As clinicians begin to use this test, and the other tests expected to follow, it will be necessary for laboratories to acquire microarray technology and offer molecular tests to their physicians. That will require significant investments of capital and the need to have lab staff with the technical skills required to perform these tests. TDR

Florida Medicaid Contract Is On-Again, Off-Again

Bidding process was restarted last month, then stopped following a written protest

CEO SUMMARY: Start with a flawed idea: Medicaid lab testing costs in Florida can be cut by awarding an exclusive statewide contract to one laboratory company. Compound that bad idea by designing a contract awards process that guarantees the state will pay twice for a number of tests while at the same time reducing patient access—thereby increasing patient and physician costs while lowering the quality of service.

By Robert L. Michel

IT'S NOT ONLY A BAD IDEA IN CONCEPT, but it's proving to be an even worse idea in execution. Florida's effort to conduct a bidding contest to award a three-year statewide Medicaid laboratory testing contract to one laboratory gives much evidence that a disaster is in the making.

The concept of the "bad idea that gets worse with time" was reinforced by events in Florida during the past three weeks. Florida's **Agency for Health Care Administration** (AHCA) issued a second, revised set of contract award documents on December 13, 2004.

Not only have major problems in the first draft of the contract awards process not been corrected, but the revised contract design makes it likely that AHCA's downstream costs associated with non-hospital laboratory testing will go up, not down. In the face of three speedily-submitted formal protests, AHCA has already suspended this second attempt to move toward a contract award.

This "bad idea" started as a response to a law passed by the Florida legislature calling for AHCA to slash Medicaid costs. That was why, earlier this year, ACHA announced that it would conduct a bidding process and award a single laboratory the three-year exclusive right to perform all non-hospital laboratory testing in the state. *(See TDRs, April 26, and November 22, 2004.)*

ACHA estimates value of this contract is $100 million. It declares this figure to be a savings of about 10% over Medicaid's projected cost of lab testing during the coming three years.

Potential Service Declines

Never mind that every laboratory which has expressed an interest in bidding admits that it lacks the network of patient service centers, rapid response laboratories, and courier logistics to provide adequate services. Or that this contract award, by definition, reduces patient access to services and places physicians at a disadvantage when laboratory tests are needed for Medicaid patients. (And isn't the core mission of both the Medicaid and Medicare programs to guarantee easy access and high-quality medical services?)

When ACHA issued the first bidding documents last March, it was, at a minimum, guilty of poor communication. At a maximum, the design of both the bidding process and the timeline to award the contract gave critics plenty of ammunition to claim that AHCA already had in mind which laboratory company it preferred to be the winner.

Any lab manager or pathologist with experience at negotiating contracts with managed care companies and government health agencies recognizes when contract specifications are written to favor specific laboratories. ACHA's March 7, 2004 document contained ample evidence to support this argument.

In the face of heated criticisms and valid objections, the agency quickly withdrew the RFP (Request for Proposal) in April. Not much happened through the balance of the year. That changed on December 13, 2004, when AHCA released a second set of contract documents.

"Invitation To Negotiate"

Now the bad idea has morphed into an "ITN" (Invitation to Negotiate). ACHA's new bid process calls for laboratories to submit 198 individual capitated price calculations, comprised of 11 regions, six age categories, and three classes of eligibility. Under the revised timeline (now suspended), AHCA would receive proposals by February 7, 2005 and open them publicly on this date.

Next would come a period when ACHA would evaluate the proposals and enter into negotiations. Using the data from all labs' bids, it would negotiate a single contract with a single laboratory. That decision would be made public on March 18, 2005 and the statewide lab testing contract would become effective on April 4, 2005.

Of course, this timetable is likely to be revised. ACHA suspended this process in response to multiple formal protests on both bid issues and rules issues. Protests were sent by the **American Clinical Laboratory Association** (ACLA), **Laboratory Corporation of America**, and **Quest Diagnostics Incorporated**. Strangely, although the employment of pathologists at up to 97 laboratory companies in the state is at risk, no pathology professional association has weighed in on behalf of its membership.

Now let's get to the meat of this "bad idea that gets worse in the execution." ACHA's stated goal is to reduce the cost of non-inpatient lab testing to Medicaid. In its ITN documents, ACHA provides utilization data and pencils in capitated rates that are set at a minimum/maximum bid range at 50% to 90% equivalent of existing Florida Medicaid fee-for-service rates.

Why plug in a minimum cap rate that's 50% of existing utilization and fee-for-service rates? That's because ACHA says it expects the winning lab-

Only Five Labs Attend ACHA's Vendor Meeting

WHEN FLORIDA'S MEDICAID AGENCY convened its Vendor's Conference on December 21, 2004, just five laboratory companies were present to learn about the contract awards process and ask questions.

In attendance were **Laboratory Corporation of America**, **Quest Diagnostics Incorporated**, **Nationwide Laboratory Services** (formerly **ESRD Laboratories**, a division of **Royco**) in Fort Lauderdale, Florida, **Doctors Laboratory** of Valdosta, Georgia, **Cognoscenti Health Institute** of Orlando, Florida, and **DaVita Laboratories** of Deland, Florida.

Nationwide and DaVita are primarily ESRD (end-stage renal disease) laboratories. That fact has significance as explained in the sidebar on page 16.

oratory will enjoy significant economies of scale. Based on pricing this additional testing at marginal costs, the winning laboratory can "afford" to provide Medicaid testing services at this price.

What ACHA cannot answer is how the winning laboratory will fund the necessary expansion in service infrastructure (additional blood draw sites, rapid response labs, more courier cars, more couriers, and the like) on a cap rate that may be half of existing Medicaid fee-for-service reimbursement. Which, by the way, is already set at 65% to 70% of Medicare for comparable CPT codes.

Furthermore, every lab still considering a bid tells ACHA that it will incur substantial capital costs to establish the minimum service infrastructure needed to fulfill the contract. That explodes the theory that labs can price this bid based on marginal costs. Oh, and we haven't yet discussed information technology costs. That comes in a moment.

Let's get to the topic of capitated rates as a way to lower ACHA's non-inpatient lab testing costs. We've just covered the objection that ACHA's assumption about using prices based on marginal test costs is fallacious. But it gets worse! (In keeping with the concept of "every bad idea gets worse in execution.") ACHA's incompetence in designing the ITN is revealed in the next major criticism of its plan.

Hospital Outreach Excluded

ACHA is excluding hospital laboratory testing outreach programs from this three-year exclusive statewide contract. Hospital lab outreach programs will continue to be paid on a fee-for-service basis anytime they provide lab testing services to non-inpatient Medicaid beneficiaries.

However, that arrangement means ACHA will pay twice for lab testing services provided to patients served by hospital lab outreach programs. That's because ACHA will pay a global cap rate to the sole-source lab contract winner. Whenever a patient, already covered by the cap rate, is served by a hospital laboratory outreach program, ACHA will reimburse that hospital lab on a fee-for-service basis.

It's the same type of "leakage" problem that plagues private payers. ACHA was clueless to this huge flaw until December 21, 2004. At its Vendor Conference in Tallahassee, laboratory representatives asked the agency if it knew about this flaw in its contract documents. It is reported that the analyst responsible for the documents took a while to grasp the consequences of this situation—but ACHA's agency head recognized it immediately.

More Downstream Problems

Let's refocus on the subject of information technology expenses. This is another legitimate criticism of why the ACHA ITN is poorly-designed and is likely to trigger downstream problems if it is implemented as it stands.

The ITN requires the laboratory to create electronic interfaces with at least three major data users, as well as referring physicians. One system is a prescription-ordering and dispensing system. Another is the Medicaid fiscal agent (for future patient electronic medical records and disease management programs). The third interface is a Medicaid Encounter Data System (MEDS). All three of these are either under development or "to be identified in the future."

Lab managers and pathologists know that interfaces between a laboratory information system (LIS) and other computer systems are probably the single most complex management challenge in lab operations. Interface projects, like upgrades, are expensive, consume huge amounts of staff and management time, and never work to the expectations of all parties.

Yet, in ACHA's ITN process, no allowance has been made for the winning laboratory's cost to comply with this requirement. Moreover, ACHA is asking labs to demonstrate capabilities of interfacing to systems which ACHA has yet to define for its own purposes.

Some other criticisms of the ITN include: 1) obvious inaccuracies in the utilization data, which shows "Pregnant Women" in the age groups of 1-5 years and 55+ years; 2) addition of a COLA accreditation option to the requirement that laboratories be accredited by CAP/JCAHO (this benefits only one of the five labs at the Vendors' Conference); 3) it will be an impossible task for both the winning lab and AHCA to track and pay the correct capitation rates for 198 categories of regions, age-groups, and edibility classes each month; and, 4) lack of specific language in the ITN which defines service and quality measures.

Poorly-Crafted ITN

These examples indicate the individuals who crafted this ITN, as well as the original RPF released last March, lack effective knowledge about the organization of laboratory services. The documents fail to incorporate the types of requirements that insure that Medicaid's primary goals of quality, universal access, and accountability are realized upon execution of the proposed contract.

In fact, this last failing was pointed out during AHCA's Vendor Conference. Lab representatives in attendance pointed out significant discrepancies in the utilization of lab testing between the 11 Medicaid regions in Florida. It was then noted that the ITN fails to address inappropriate utilization as a way to control costs, with the additional benefit of improving patient outcomes. The cost-saving emphasis of the ITN was instead devoted to forcing down reimbursement paid to the contract-winning laboratory.

ESRD Carve-Outs: A Sign of Contract Bias?

FROM THE MOMENT LABORATORIES IN FLORIDA first read the RFP documents issued last March by the Agency for Health Care Administration (AHCA), there were questions about specifications that were interpreted to give certain labs an advantage in the bidding for the exclusive, statewide three-year Medicaid lab testing contract.

Evidence that such bias exists was reinforced with the release of ACHA's revised bidding documents on December 13, 2004. The ITN (Invitation To Negotiate) contained an interesting clause, titled "End State Renal Disease (ESRD) Speciality Laboratories May Request An Exemption from This ITN)."

It allows labs which only provide ESRD testing to be carved-out of the exclusive statewide Medicare testing contract, upon their request and a review by AHCA. ACHA's bid schedule includes a date, April 7, 2005, when ACHA is to issue its decision on requests for ESRD exemptions.

WIthin Florida, competing laboratories note that one particular laboratory company stands to benefit from this provision. The newly-renamed Nationwide Laboratory Services occupies a brand-new, but underutilized 100,000 square foot lab facility. Nationwide is a division of Royco, which owns dialysis centers in the state. Royco also owns ESRD Laboratories, a business division that operates within Nationwide's laboratory building.

The ESRD exemption allows Royco to have it both ways. Its Nationwide Lab unit is a declared bidder for the statewide Medicaid contract. But if it loses, Royco's ESRD Lab division can apply for an exemption and retain access to lab tests done for Medicaid dialysis patients. It is believed the link in this relationship is Scott Hopes, PHD. He is currently a vice president at Nationwide. In recent years, Hopes served on one of AHCA's advisory boards. This link, along with Royco's ample political donations in recent years, is believed to be why ACHA's bid documents include "odd" terms favorable only to Royco's business interests.

As a further point, better utilization of lab testing would not be encouraged by the mechanism which pays a monthly capitation rate to the contract lab while simultaneously reimbursing non-inpatient Medicaid testing done by hospital lab outreach programs with fee-for-service payments.

Asking For A $1 Co-Pay!

As a final insult to common sense, the ITN proposes that Medicaid patients pay a $1.00 co-pay each time laboratory tests are ordered. It deducts this amount from existing laboratory reimbursement when calculating savings to be realized from this contracting initiative.

One Florida laboratory executive observed to THE DARK REPORT that this is a splendid example of flawed bureaucratic thinking. This requirement overlooks the fact that, by definition, Medicaid patients don't have much money. It also ignores the fact that, because of Medicare and Medicaid compliance requirements, laboratories must spend significant amounts of money in attempts to bill and collect from *all* patients, regardless of how small the co-pay or deductible might be.

Not The End Of The Story

Are these enough examples? Currently 98 independent laboratory companies serve Florida's Medicaid beneficiaries. This number does not include hospital laboratory outreach programs.

Yet, on the basis of a contract awards program that is poorly-conceived and badly-designed, 97 of these laboratories may lose access to Florida Medicaid patients for at least three years. At the same time, there is considerable risk to Florida's Medicaid program that implementation of a sole-source lab services contract may prove highly disruptive to both patients and clinicians. Who is measuring *those* costs to Medicaid as they occur?

The purpose of this intelligence briefing is to reveal details that usually remain unknown to laboratory leaders outside Florida. If competitive bidding is a concept that will spread within Medicare and the state Medicaid programs, then it is incumbent on government health officials and the laboratory industry to get it right the first time.

Florida Medicaid's 'bad idea" is to shoehorn the entire state's Medicaid testing needs onto a single laboratory. That "bad idea" gets worse because of the design of this contract program magnifies the flaws in the original concept.

Serving The People?

If government is to serve the people, how can ACHA ignore a unified message by the state's most respected laboratory companies? Whether from $5 billion Quest Diagnostics or $5 million Cognoscenti, the message to ACHA is consistent: no single lab can handle this work effectively. Nor can a single lab company build the sub-contract network required, at the price and terms specified in the ITN.

Is this a political issue? Sure. Medicaid is an entitlement program with exploding costs. Florida's legislature passed a law that mandated action by ACHA as a way to demonstrate that it was responding to the funding crisis.

So the buck was passed to ACHA. In its defense, this is not something it asked to do. But it must respond to the politics of the situation. That is how one state's bad idea grows worse in implementation.

Two lessons are to be learned from this situation. First, lab managers and pathologists need to be alert to similar "bad ideas" in their state's Medicaid program and head them off before they take root. Second, whenever bureaucrats design something, it seems like everybody loses—even the very people they earnestly want to help! TDR

Contact Robert Michel at labletter@aol.com.

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

More evidence of the move to an all-computer economy has surfaced. During 2003, consumer use of credit cards, debit cards, and other electronic payment methods eclipsed paper checks for the first time. The study was done by the **Federal Reserve Bank of Atlanta.** It reports that 36.7 billion checks were paid in 2003, for a total of $39.3 trillion. By comparison, there were 44.5 billion electronic payments with a value of $27.4 trillion. These statistics reflect the same trends seen by laboratories, where patient payment options are expanding to include credit card and debit card options.

TRESTLE ACQUIRES INTERSCOPE

Keep an eye on **Trestle Corporation** of Irvine, California. It is quietly building a line of telepathology products for clinical applications and pharmaceutical development. It recently acquired **Interscope Technologies Inc.,** based in Wexford, Pennsylvania. This telepathology firm included UPMC pathologist Michael J. Becich, M.D., Ph.D. as a founding investor.

CALIFORNIA IPA OFFERS WEB LINK TO LAB TEST DATA

This news item involves an IPA with 700 physicians, **Allscripts Healthcare Solutions,** and **Laboratory Corporation of America.** In the San Francisco Bay Area, **Brown & Toland Medical Group** now offers its physicians free access via Web browser to laboratory test results from LabCorp. This is Brown & Toland's first step to provide a subscription-based, complete electronic medical record (EMR) service to its member physicians. "To get lab results, all they have to do is configure their browsers to run it and come to training," explained Peter Alperin, M.D., Medical Director at Brown & Toland. "We have many labs in our network, but the largest non-hospital lab is LabCorp. Almost every doctor is using it." Brown & Toland's strategy is to offer this free service as a way to encourage physicians to contract for other EMR modules that it offers.

ADD TO: *IPA EMR*

The information technology is provided by Allscripts, which has a national business relationship with LabCorp for a product that enables Web browser-based lab test orders and results reporting. Brown & Toland wants to provide full EMR services for about $350 to $450 per month. It believes this is a way for smaller medical groups, with just a few physicians, to migrate to a full EMR at reasonable expense. This example shows the growing interconnections between laboratories, IT companies, and what can be called "middlemen" in helping physicians move to a fully-electronic medical record. It also shows how a national laboratory wants to leverage its IT capabilities by helping office-based physicians make the transition from paper records to EMRs.

TRANSITIONS

• Martin J. Stefanelli recently resigned his position as Executive Vice President and Chief Operating Officer of **AmeriPath, Inc.,** headquartered in Riviera Beach, Florida. Stefanelli was previously at **DIANON Systems, Inc.,** where he served in several executive roles.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, January 24, 2005.

PREVIEW #1

EXECUTIVE WAR COLLEGE

May 3-4, 2005 • Astor Crowne Plaza Hotel • New Orleans

Case Study—NorDX Laboratories, Health System Lab Outreach Captures Market Share

NorDX Laboratories, based in Scarborough, Maine, built a new laboratory facility and entered the outreach market in the tough managed care environment of the late 1990s. Today it is the dominant laboratory in the Greater Portland Area. It provides an expanded menu and services to its hospital owner and operates an automated central lab. NorDx is actively developing its molecular diagnostics program and is a prime example of how hospital lab outreach programs can be profitable.

Full program details available soon!
visit www.darkreport.com

UPCOMING...

- ***Why Molecular Diagnostics Caused the Chinese Wall between Anatomic Path and the Clinical Lab to Crumble at This Hospital.***
- ***Is Anti-kickback Compliance Law Changing How Labs and Pathologists Should Offer Client-bill Discounts?***
- ***Five Potent Secrets for Increasing Outreach Specimen Volumes and Profits.***

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