Volume XII, Number 4 Monday, March 7, 2005

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 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

"Lowest-Priced" Chickens Came Home to Roost

IN READING THE INTELLIGENCE BRIEFINGS on reference/esoteric laboratories in this issue, I found it interesting that **American Medical Laboratories** (AML) is no longer an independent lab company serving this market segment and that, of the four remaining independent lab companies focused exclusively on reference and esoteric testing, the only firm not operating in the black is **Specialty Laboratories, Inc.**

These two outcomes fulfill a prediction made almost six years ago by THE DARK REPORT. In the August 30, 1999 issue of THE DARK REPORT, our headline was "Reference Labs Intensify Battle for Send-out Tests." We predicted that hospital laboratories would benefit as competing reference labs offered both lower pricing and enhanced IT services to woo new clients. In particular, we noted that AML, as a vigorous new entrant into the national reference/esoteric testing marketplace, would aggressively use low prices to capture new reference testing clients. AML would be the same type of low-price competitor as **Specialty Laboratories, Inc.** had been in earlier years, once it had, like AML, declared that it wanted to be a full-fledged national provider of reference and esoteric testing.

Another prediction made at that time was that a laboratory company relying on aggressively-discounted test prices to attract new clients would be challenged to generate enough revenues to earn profits and run a top-quality operation. Such laboratories are spending significant amounts of money to maintain an extensive sales and marketing program. Then add the cost of enhanced IT services. Because new clients would enjoy discounted pricing, it would make it tough for such laboratories to both recover the sales/marketing cost to acquire a new client and generate enough operating margin to sustain normal business activities.

Granting the truth of the above statement, is there any surprise that American Medical Labs, facing the need to raise capital, sold itself to **Quest Diagnostics Incorporated** in 2002? Or that, of the four national reference/esoteric labs covered on pages 12-14, the only one losing money at this time is Specialty Labs? This is a useful validation of THE DARK REPORT'S prediction almost six years ago. It's also a reminder to hospital lab outreach programs that pricing does matter. It takes adequate pricing to support the financial margins required to operate a high-quality laboratory. TDR

FL Medicaid Gives Up On Statewide Lab Contract

For the moment, laboratories in Florida have stopped a "bad" contracting proposal

CEO SUMMARY: With the withdrawal of the December 13, 2004 "Invitation to Negotiate" (ITN), Florida's Medicaid bureaucrats seem to have thrown in the towel—at least for the moment—on the effort to give a single laboratory company an exclusive three-year contract to provide laboratory testing services throughout the state. Labs in Florida are relieved, but remain wary that this contract proposal may resurface.

IT WAS A VICTORY. But it remains to be seen whether it was a victory of common sense over a bad idea—or just another pause before Florida's Medicaid bureaucrats make another attempt to award a single lab company with a three-year statewide laboratory testing contract.

The news was made official on February 18, 2005. Florida's **Agency for Health Care Administration** (AHCA) posted a "Notice of Withdrawal" stating that it had withdrawn AHCA ITN (Invitation to Negotiate) 0508, issued on December 13, 2004, for Medicaid Independent Laboratory Services.

"This is a welcome development," said Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA), based in Washington, DC. "ACLA had filed a challenge on several issues improperly addressed in the ITN. We had confidence that we would prevail if a hearing before an administrative judge was to take place."

Neither Mertz nor any lab manager in Florida has been told by AHCA officials why the ITN was pulled and what might come next. "ACLA has had no direct contact with AHCA and so we have no knowledge about how and why this decision was made," said Mertz.

There is still bad news for clinical laboratories in Florida. The appropriations bill passed by the Florida legislature which authorized that a statewide laboratory testing contract be awarded by Medicaid has another clause. Effective April 1, 2005, if AHCA has

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.65 per week elsewhere (billed semi-annually).

not awarded the laboratory testing contract, it is to institute a 10%, across-the-board, reduction in reimbursement paid for outreach laboratory tests.

Twist In The Story

However, there is a twist in this story. The enabling legislation which authorizes this fee reduction expires on July 1, 2005. That is the end of Florida's current fiscal year. One laboratory executive told THE DARK REPORT that he believed it would be difficult for AHCA to implement this lab test fee reduction during the 120 days remaining before the statutory authorization expires.

Another complication could result if the Florida legislature, set to convene its next session on Tuesday, March 8, 2005, were to pass a law that extended the fee cut mandate—or even deepened it. In fact, it is believed at least one Florida legislator has spoken out in favor of instituting an arbitrary 20% reduction in current Florida Medicaid lab test reimbursement schedules.

Such comments reinforce the belief by many Florida laboratory executives that AHCA's withdrawal of the ITN for the statewide lab test contract is not a significant event. Labs will need to fight an ongoing battle to protect both access to Medicaid patients by "any willing laboratory provider" and reasonable reimbursement for outreach lab services.

Ridiculous Battle

THE DARK REPORT would like to point out what a ridiculous battle AHCA, and the Florida State Legislature have decided to fight over the cost of Medicaid outreach laboratory testing services. Florida Medicaid officials acknowledge that the program currently spends approximately $37 million per year on outreach laboratory testing (excluding testing performed by hospital laboratories). It was their hope that the proposed, three-year, statewide lab testing contract, after its award to one lab company, would cut these costs by at least 10%, or $3.7 million per year.

What is never discussed is that Florida's Medicaid spending is currently $14 billion per year. In percentage terms, the Florida legislature and AHCA have targeted outreach laboratory testing as a way to achieve a potential total savings of 0.03%!

At the same time, elected government officials and state bureaucrats overlook the simple fact that laboratory testing costs average 5¢ of every $1 spent on healthcare. Yet laboratory tests play a key role in 70% of the decisions to treat a patient.

Can't Cover Lab Test Costs

A Florida pathologist observed to THE DARK REPORT that Florida Medicare currently pays around $14.50 for a liquid prep Pap test. After the 10% fee reduction, that would leave a reimbursement of $13.05, from which the laboratory would need to pay for the liquid prep kit (at about $9.00), cytotechnologist and pathologist review, amortization of instruments, logistics, IT, and billing/collection costs. And that doesn't include overhead expenses.

Intelligent managers know that, to maximize their effectiveness, they must put their limited resources to work paring down the largest cost items. Certainly any management consultant worth his/her salt, reviewing the actions of Florida's legislature and AHCA, would make the obvious observation that laboratory testing services should be enhanced in ways that help physicians with early detection and proactive patient monitoring.

That would easily generate savings to exceed $3.7 million per year in this $14 billion program, while improving outcomes for Medicaid patients in Florida. And isn't improving healthcare a major goal of Medicaid? **TDR**

Contact Alan Mertz at 202.637-9702

Spectrum Owns Medex, Comments on Trends

North Carolina's lab outreach giant gains access to managed care contracts

CEO SUMMARY: Spectrum Laboratory Network recently completed its acquisition of MEDex Laboratories, Inc. of Kingsport, Tennessee. It is becoming a regional laboratory powerhouse, challenging Laboratory Corporation of America in North Carolina and establishing a sales base in Atlanta, long-dominated by Quest Diagnostics Incorporated. It is also adding managed care contracts.

HAVING COMPLETED ITS ACQUISITION of **MEDex Laboratories, Inc.** on December 12, 2004, **Spectrum Laboratory Network** has a claim to be the largest hospital laboratory outreach program in the United States.

Net collected revenues from Spectrum's outreach clients are projected to be as much as $90 million during 2005. THE DARK REPORT is not aware of any hospital laboratory outreach program in the United States which equals or exceeds that total.

Largest Lab Firms In USA

Further, Spectrum Laboratory Network is probably the second largest, non-public laboratory company in the United States that primarily serves office-based physicians with routine and other testing services. **Clinical Pathology Laboratories, Inc**. (CPL) of Austin, Texas remains the largest private laboratory company, with estimated annual revenues in the range of $140 million.

Spectrum, based in Greensboro, North Carolina, paid $10.8 million to acquire MEDex, which had filed for Chapter 11 bankruptcy action in 2003 after it was discovered that its then-CEO, Michael Ladd, had conned both the lab company directors and its bankers to the tune of about $8.5 million. Ladd was convicted of criminal charges and currently is serving a 41-month sentence in a federal prison. *(See TDR, May 27, 2003.)*

"Based on financial documentation provided by the bankruptcy court during the time of the sale, MEDex had between $10 million to $12 million in laboratory business," stated Nate Headley, CEO of Spectrum. "Since acquiring MEDex in December, however, we believe MEDex clients will generate between $16 million to $17 million in net revenues for us this year.

"That's because of two factors. First, our billing and collections department is more sophisticated than the one at MEDex," explained Headley. "It allows us to more accurately bill and collect a higher percentage of gross billings than was true of MEDex.

"Second, our laboratory offers a fuller menu of laboratory testing services to MEDex's clients. So we are seeing higher volumes of specimen referrals from selected MEDex clients," he commented.

Spectrum Laboratory Network is owned by **Moses Cone Health System** and **High Point Regional Health System**. In recent years, it has posted dramatic growth in its laboratory outreach program. Several operational strategies underpin this sustained growth in outreach revenues.

As the new owner of MEDex Laboratories, Spectrum Laboratory Network now serves fives states. They are: North Carolina, South Carolina, Virginia, Tennessee, and Georgia. "As we've grown, Spectrum has developed name recognition and credibility in our service markets," stated Headley. "This now helps our sales program. Physicians know us and it helps shorten the sales process needed to bring on new client accounts."

Access to MC Contracts

Spectrum's size and reputation is helping it acquire something else which often eludes hospital lab testing outreach programs: managed care contracts. Headley observes that there is a new trend appearing in the marketplace.

"As a regional laboratory, we are now getting attention from national health insurance companies," he explained. "We recently signed a contract with **Cigna Healthcare** that covers all their health plans across our five-state service area.

"I believe our success in obtaining this contract reflects a new interest in regional laboratories by the national health insurers," he continued. "Cigna has also inked a regional contract with Clinical Pathology Laboratories."

Headley's observation is consistent with developments covered by THE DARK REPORT. Last year, **UnitedHealth Group** added **Esoterix, Inc.** to its national contract as a reference and esoteric test provider to its specialist physicians. *(See TDR, June 28, 2004.)*

Laboratory Provider Panel

In the case of the UnitedHealth contract with Esoterix, the insurer was motivated for three reasons. One, UnitedHealth wanted leverage when negotiating with its existing two contract lab providers, the two blood brothers. Two, with physicians objecting about service issues involving contract lab providers, UnitedHealth wanted to expand the lab provider panel to grant physicians more choices.

Third, leakage from its national lab contracts continued to be a problem. Adding Esoterix to the national contract was seen by UnitedHealth as a way to increase the overall volume of lab testing reimbursed at national contract pricing.

"In Spectrum's negotiations with large health insurers, we see these same motives," commented Headley. "It is strong evidence that health insurers, having worked almost exclusively with national laboratories for nearly ten years, now have a growing interest in adding regional laboratories to their provider panel. But that is only true if the regional laboratory has a good network of patient service centers, rapid response laboratories, logistics, and a robust laboratory information capability."

Payers' Interest Is Shifting

"The interest of major health insurers in expanding their lab provider panel to include select regional laboratories is a significant change over past years," added Headley. "It shows how the competitive landscape for the two national lab companies is changing.

"At the same time, it is our view that both national lab companies are

We Missed One!

It Was Really Six Lab Acquisitions in Ten Weeks

THERE WERE AT LEAST SIX CLINICAL LABS acquired during December 2004 and the first six weeks of 2005. In our last issue of THE DARK REPORT, we listed only five transactions.

That list overlooked the acquisition of MEDex Laboratories, Inc. of Kingsport, Tennessee by Spectrum Laboratory Network. The amended listing below shows laboratory acquisitions closed between the second half of December, 2004 and the first week of February, 2005. The balance of 2004's lab acquisitions was listed in the February 14, 2005 issue of THE DARK REPORT.

This flurry of laboratory acquisitions reveals the shift in deal-making. Other than the $175 million paid by Laboratory Corporation of America for US LABS, Inc., the sellers are relatively smaller laboratory companies.

Here's the Amended Lab Acquisition Scorecard:

(showing acquisitions completed at end 2004 and early 2005)

Date	Buyer	Seller	Purchase Price*	Revenue of Target*	Purchase Price to Revenue
Dec-04	LabCorp	Clinical Laboratories of Black Hills	ND	ND	NA
Dec-04	Spectrum Lab Network	MEDex Laboratories	$10.8	$10.8	1.00
Dec 04	National Lab Partners, LLC	Universal Diagnostic Laboratories	ND	ND	NA
Jan-05	Adventist Health Corp	Cytology Services of Maryland	ND	ND	NA
Feb-05	Quest Diagnostics	Omega Medical Labs	ND	ND	NA
Feb-05	LabCorp	US LABS	$175.0	$75.0	2.33

** In millions • ND is "not disclosed • NA is "not available"*
Source: Haverford Healthcare Advisors, public records

maintaining a consistant discipline in pricing," he said. "Maybe that is a sign of lessons learned from the 1990s, when deeply-discounted capitated contract pricing hurt the entire laboratory industry."

Competition in Spectrum's market area remains intense, particularly with **Laboratory Corporation of America**. "For example, LabCorp is making significant efforts to introduce browser-based lab ordering and resulting systems to their client-physicians," stated Headley. "We encounter these arrangements a significant amount of time.

"To counter this, we have made regular investments to our information technology capabilities over the past three years," said Headley. "Currently, 75% of our daily lab test orders are received via the Internet. These requisitions come from clients using our Web browser-based system to fill out test requisitions and transmit that information to us."

Browser-Based Lab Orders

Spectrum uses **Atlas Development Corp.'s** "LabWorks" as its Web browser-based lab test ordering/resulting system. It maintains a staff of customer service reps and "Atlas installers" in the field. The objective is to help new clients quickly install and train on Spectrum's browser-based lab ordering/resulting system.

"We support the cost of this field staff because it saves us money throughout our work processes," said Headley. "For example, Spectrum's days sales outstanding (DSO) is currently at 47. Because a high number of our requisitions are received electronically over the Internet, they are legible and contain more comprehensive information. This helps us prepare and submit more accurate claims and bills on the first pass.

"As another example, our daily flow of requisitions exceeds 10,000," he noted. "Yet we operate with only eight people entering orders."

"As another example, our daily flow of requisitions exceeds 10,000," he noted. "Yet we operate with only eight people entering orders. This reflects the progress we've made developing a system where a high percentage of our orders are received electronically and contain greater amounts of accurate and complete information.

Daily Shift In Paradigms

"In fact, our laboratory is seeing a daily shift in many of the paradigms which traditionally dominated laboratory operations," offered Headley. "Internet-based information services is only one example. It is a radically different way for a physician's office to order laboratory tests and receive the results. But at the same time, this Web-based electronic ordering/resulting capability creates new opportunities for our laboratory.

"It gives us an opportunity to offer new features to physicians and their staffs. We can also provide useful services to patients in a cost-effective manner. And, even as we are doing this for our customers, our laboratory has the opportunity to cut costs and improve its performance throughout our operation," declared Headley.

Whether or not Spectrum Laboratory Network is the nation's largest hospital lab outreach program, its swift growth must be recognized as a major management accomplishment. It was just 1997 when three health systems in North Carolina invested $6 million to build the off-site laboratory facility and launch its laboratory outreach sales program.

Financial Struggles

Most laboratory administrators and pathologists know that, in its early years, Spectrum struggled to reach financial break-even. The turnaround started with the arrival of a veteran commercial laboratory industry executive. Working in tandem with his management team, most with hospital laboratory experience, the combination of skills has created a successful laboratory organization.

Many aspects of the Spectrum story should encourage leaders of hospital laboratory outreach programs throughout the United States. Further, Headley's comments about changes in the lab testing marketplace confirm several trends identified by THE DARK REPORT.

Several Evolving Trends

First, physician acceptance of Web browser-based lab test ordering and resulting systems is increasing. One reason is that the national laboratories are devoting resources to convert their client base to this mode of ordering. In so doing, the competitive bar is raised for hospital laboratory outreach programs.

Second, it is noteworthy that Headley believes managed care companies have a genuine interest in using regional labs to expand their provider panels. This would be a most positive development for hospital lab outreach programs that have strong market share and the infrastructure necessary to meet the needs of payers.

Contact Nate Headley at 336-664-6100.

Profit Squeeze Pressures Specialty Laboratories

Growth in revenue & specimen volumes still not enough to generate net profits

CEO SUMMARY: Despite much success and milestones at Specialty Laboratories during the past 36 months, it has yet to achieve the most important goal of all: net profits. One reason is familiar to all laboratory administrators and pathologists: with its existing fixed overhead and cost structure, Specialty Labs' key goal is to increase speciment volume and revenues past its break-even level.

DESPITE STRONG GROWTH in revenues and specimen volumes during the past two years, Specialty Laboratories, Inc. finds itself struggling to generate net profits.

It is a "good news/bad news" story. The good news is that the company successfully moved past its regulatory crisis of 2002. It has also built a state-of-the-art laboratory facility in Valencia, California and completed a problem-free relocation there in December 2004.

The bad news is that Specialty Laboratories accepted the resignation of both its Chairman and its CEO in recent weeks. On February 10, Specialty's Chairman Richard E. Belluzo resigned "to focus on other professional obligations."

Belluzo's resignation was followed four days later by the resignation of Douglas S. Harrington, M.D., Specialty Lab's CEO. He will work through March 29, 2005 and will assist in a search for his replacement. Specialty's new Chairman is Richard K. Whitney, a director who was recently the CFO of **DaVita, Inc.**, a dialysis company. Specialty's Executive Vice President and CFO, Kevin R. Sayer, will serve as acting CEO after Harrington departs.

Several factors contributed to this major change in senior leadership—the second in the 36 months since federal and state lab regulators pulled the lab's license for a variety of violations. *(See TDRs, April 1 and May 13, 2002.)*

Revenues Up, As Are Losses

For the year ending December 31, 2004, Specialty Laboratories reported revenues of $134. 8 million. This is an increase of 12.7% from revenues of $119.6 million in 2003. However, profitability continues to elude the company. Its net loss for 2004 was $13.0 million, compared to a net loss of $6.4 million in 2003.

Specimen volume in 2004 increased by 20.8%, rising to 3.0 million specimens from the 2.5 million it reported in 2003. This substantial growth in specimen volume illustrates the paradox facing Specialty Laboratories' executive team.

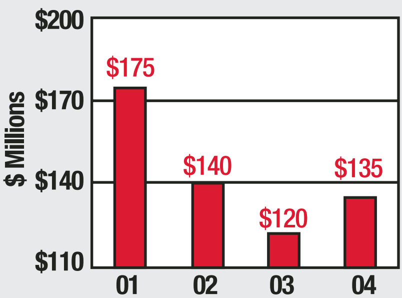
Specialty's Paradox: Revenues Up, No Profits

TO UNDERSTAND THE BUSINESS PARADOX facing Specialty Laboratories, it is necessary to study the two graphs below. One shows yearly revenues and the other shows net earnings/losses.

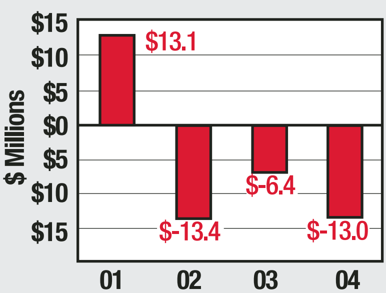
The first year in each chart is 2001, when Specialty Laboratories posted its strongest financial performance in its history. It was 2002 when Specialty Laboratory was sanctioned by federal and state laboratory regulators. Both annual revenues and net earnings dropped significantly that year.

Since 2002, Specialty Laboratories has shown steady growth in yearly revenues. However, for a variety of reasons, the company failed to generate net profits in either 2003 or 2004. There is optimism within the company that it can become profitable in 2005.

Annual Revenues



Annual Profit/Loss



In the marketplace, its sales and marketing efforts are generating new client accounts. That is a strong sign that Specialty Labs has credibility in the marketplace. But to acquire and service these accounts, Specialty is outspending revenues. Among other factors, it increased its costs with the construction of its new laboratory.

Growth Strategy

Specialty Labs' strategy to resolve this negative cash flow is to grow the business. That will allow it to realize economies of scale while accessing a higher level of revenues. On the business development side, Specialty Laboratories is hiring new sales representatives. On the operational side, it has a brand-new laboratory facility. It plans to increase automation and the new laboratory has plenty of capacity to handle increased volume of specimens.

As the two financial charts at left illustrate, Specialty Laboratories is showing sustained growth in revenues. At the same time, because of a variety of factors, some dating back to 2002 and some related to the construction of the new lab facility in 2004, Specialty Labs has yet to report net profits.

Because Specialty Laboratories has a strong balance sheet (cash and assets of about $40 million as of December 31, 2004), it has the financial strength to sustain it while it executes its growth strategy in the marketplace. In fact, the company is telling Wall Street that it expects to post revenue growth of between 10% and 14% during 2005. At the same time, it also predicts that it will not report net profits for the first two quarters of 2005.

Seen in that context, the departure of Specialty Laboratories' Chairman and CEO within days of each other last month can be interpreted as a sign that there is significant pressure on the executive team to perform. Another sign of this pressure is the fact that, within a week of Harrington's resignation, at least seven senior executives at Specialty Labs were offered "retention bonuses."

These retention packages have one thing in common: each promises the executive a bonus of between $20,000 to $100,000 if that individual is still employed by Specialty Laboratories as of February 20, 2006. A resignation or termination for cause prior to that date means the employee forfeits the bonus.

Still A Tough Competitor

Assessing all of these factors, it seems reasonable to expect that Specialty Laboratories will continue to be a tough competitor in the marketplace. It has some $40 million of capital in its war chest and is expanding its sales force to pursue more new business. Also, as of October 2004, Specialty Labs has a contract with **Premier, Inc.,** the nation's largest GPO (group purchasing organization). This gives it better access to hospital laboratories which are members of Premier.

Because Specialty Laboratories has demonstrated strong growth in revenues and specimen volumes, the most appropriate question to ask is "when will Specialty Labs again be profitable?" This is a company which has ample assets, is considered credible in the lab testing marketplace, and has demonstrated that it can bring in new business.

It will not be an easy road. The management changes documented in this intelligence briefing provide evidence of that. One financial analyst tells THE DARK REPORT that until Specialty Laboratories can raise its annual volume to around $155 million, it is unlikely to show profits. To achieve that, Specialty's management team will need to increase its annual revenues by 14.9% in 2005. TDR

Major Shareholder May Have Played a Role

THERE MAY BE ADDITIONAL INFLUENCES behind the abrupt decisions of Specialty Laboratories' Chairman and CEO to both resign just four days apart.

It might be described as the "Jim Peter, M.D. Factor." James B. Peter, M.D., Ph.D., is the founder of Specialty Laboratories and the company's longtime leader. He currently serves as a Director and holds a significant amount of Specialty's outstanding stock.

Under the scenario painted by those familiar with some of the dynamics affecting Specialties' Board, there has been a fundamental difference of opinion on which strategies should be used to again make Specialty Laboratories a profitable company. When it became clear that a board consensus was not to happen, the Chairman and CEO opted to pursue other interests.

Peter, known to have fixed convictions and an energetic defense of these convictions, was said to favor different business strategies than the prior Chairman and CEO. Their departure was recognition of this difference.

Following the unexpected and rather swift departure of these two individuals—both liked and respected by employees of Specialty—there was a need to stabilize the remaining executive team. This was particularly important, since Specialty Labs is at a delicate point in its turnaround. The decision was made to offer "retention bonuses" of between $20,000 and $100,000 per person to seven key executives, payable if they are still employed as of February 20, 2006.

"Irreconcilable differences" within Specialties' Board of Directors are requiring an expensive resolution. During the next 12 months, the company will spend "$1.1 million associated with the recently-announced departure" of its CEO, along with $390,000 in retention bonuses.

Managed Care Update

Medicaid's Exploding Costs Threaten Tight State Budgets

Tennessee's Medicaid woes illustrate the intractable nature of the problem

MEDICAID FINANCING in Tennessee has reached a crisis point. But Tennessee is not alone. Soaring Medicaid costs are stressing state budgets across the country.

According to figures issued by the **National Association of State Budget Offices**, total state and federal spending on Medicaid services will top $300 million for 2004. More remarkably, that is 50% more than what was spent just 48 months earlier! In 2000, total state and federal Medicaid spending was about $200 billion.

Since 2000, states have collectively spent about 10% more each year to fund their share of Medicaid programs. It will be the same in 2005, with double-digit increases expected during the year.

Understanding The Problem

For lab administrators and pathologists, understanding the fundamental economics of the Medicaid program is necessary to understand how and why Medicaid officials in different states are tinkering with Medicaid laboratory testing reimbursement and contracting practices. Below-cost reimbursement schedules and irrational laboratory testing contract requirements are a response to inadequate finances in the program.

In the absence of a free market, bureaucrats are left to devise strategies to help their state's Medicaid program make available funding stretch enough to cover costs.

Medicaid is suffering from its design flaws. When it was originally conceived some 40 years ago, it covered about 4 million low-income people. Today, Medicaid covers 53 million people. That's one in six Americans. It spends more than the federal Medicare program. There are states where Medicaid now eats up more than one-third of the state budget.

Tenncare's Temporary Fix

As an update to our coverage of radical reforms to Tenncare, Tennessee's experiment in managed Medicaid, the latest proposal from the governor is to abandon its current model and adopt a managed care form of Medicaid. *(See TDR, December 13, 2004.)* Of the 1.3 million individuals covered under the existing Medicaid program, 323,000 people will be dropped from coverage. These are individuals who do not meet Medicaid requirements and who have chronic conditions that put private insurance beyond their reach.

Estimates are that Tennessee will save $575 million during the next budget cycle. This Medicaid plan preserves full benefits for 612,000 children and maintains "reasonable" benefits for 396,000 adults. However, there has been no discussion of how this state will fund increased Medicaid costs in coming years. **TDR**

National Reference Labs Undergoing Changes

Each of four reference/esoteric lab firms is developing new business strategies

CEO SUMMARY: Maybe it's a coincidence. More likely it is a response to changes in the reference/esoteric marketplace. Specialty, Esoterix, ARUP, and Mayo have each recently reassessed their core strategies and are shifting their business emphasis. Because three of these four companies are profitable, it is not an industry segment under duress. Rather, this shift in direction is to better pursue opportunities in the market.

FOUR OF THE NATION'S LARGEST reference/esoteric laboratory companies are each undergoing a corporate reassessment expected to change, in some specific way, their corporate structure and particular business strategies.

The companies are **Specialty Laboratories, Inc.** (Valencia, California), **Esoterix, Inc.** (Austin, Texas), **ARUP Laboratories, Inc.** (Salt Lake City, Utah), and **Mayo Medical Laboratories** (Rochester, Minnesota). These are the largest of the nation's major laboratory companies that operate with a primary focus on providing reference and esoteric testing to hospital laboratories and other specialist physicians.

It may be a coincidence that each company is actively evaluating new business strategies. Alternatively, this may be a sign of intensified competitive pressures in the reference/esoteric testing marketplace. To respond effectively, the four lab companies are having to change some aspect of their business and/or market focus.

The most visible changes are happening at **Specialty Laboratories, Inc.** The story on pages 8-10 provides details on how and why Specialty Laboratories is putting added emphasis into its growth strategy.

Esoterix Looks For a Buyer

Esoterix is next on the list of four reference lab companies developing new business strategies. On February 18, 2005, a Wall Street news source disclosed that Esoterix was for sale and that **J.P. Morgan Chase & Co.** had been engaged to assist in locating buyers for Esoterix. On February 22, this same source reported that **Quest Diagnostics Incorporated** had looked at the Esoterix package and was not interested.

The sales price for Esoterix was reported to be around $240 million. According to **TheDeal.com**, this price was calculated using a factor of eight times Esoterix' EBITDA (earnings before interest, taxes, depreciation and amortization).

Motive for the sale of Esoterix is simple. In 1994, at the time Esoterix was founded, it was **Behrman Capital LP** which provided the investment capital from its first venture fund. Five or six years later, Behrman Capital provided additional funding from another of its venture funds.

Need To Close The Fund

Venture funds are closed after a set period of time, often ten years. It is likely that Behrman Capital needs to cash out its investment from the first venture fund (dating back to 1994) so it can return original capital and profits to the investors. To accomplish this, Behrman Capital must convert its equity ownership in Esoterix into cash.

Esoterix is a financially-strong laboratory company. During the past four years, it has posted impressive and consistent growth rates for both revenues and net profits. Its primary business lines are: 1) reference and esoteric testing it provides to hospital laboratories and specialist physicians; and, 2) a thriving division in clinical trials testing.

Given Esoterix's financial strength, if no buyer is found, it is likely to seek capital through other sources, such as an IPO (Initial Public Offering). If so, it would be the first laboratory company to go this route since Specialty Laboratories went public in 2000. In fact, in recent years, Esoterix has hired two different Chief Financial Officers specifically because they had IPO experience and could guide the company through this process.

Three Possible Outcomes

Esoterix faces three possible outcomes. One, if purchased by an existing laboratory company, then its operations would be integrated into that laboratory's infrastructure, even if Esoterix was allowed to conduct business under its own name.

Two, if it was purchased by a non-lab company or a new group of investors, it would probably operate with little or no change to its existing operation. Three, were Esoterix to complete an IPO, it is likely to continue operating as it is today.

Across the country, in Salt Lake City, ARUP Laboratories has been finalizing refinements to its business arrangements with the **University of Utah**, with which it has multiple connections. The information which follows comes from a variety of sources. There may be some inaccuracies, but overall it is believed to be a fair representation of recent events.

Most lab directors and pathologists know that ARUP Laboratories is one of the lab industry's most impressive success stories. Since its founding in the early 1980s, it has consistently posted double-digit growth in revenues and specimens year after year.

A Large Employer In Utah

As well, ARUP is becoming one of Utah's largest employers. It has almost 1,800 employees and occupies four sizeable buildings. It seems this large size caught the attention of the University of Utah's former president in recent years. This launched discussions between that president's office and the executive officers of ARUP Laboratories.

The president's office was interested to determine if ARUP Labs' growth made it timely to revisit the business agrements that exist between the laboratory company and the university. One of the issues believed to be part of this conversation was how ARUP pathologists split duties between teaching and clinical practice in the medical school and medical center, and their duties for ARUP Laboratories.

Multiple sources tell THE DARK REPORT that, in general, the tenor of these talks was amicable, and, at least in the initial stages of this process, the president's office was exploring ways to recast the business relationship between ARUP Laboratories and the University of Utah. The goal was to appropriately recognize ARUP Lab's current size and impact on the working routines of the ARUP pathology group and the University itself.

During the past year, a new president arrived at the University of Utah. At that time, these discussions took a turn considered to be more favorable to maintaining the business relationship closer to the status quo. In recent months, the two parties have come to basic agreement.

For laboratory clients of ARUP Labs, this process has been nearly invisible. Going forward, it is expected that ARUP Laboratories and the University of Utah will continue to collaborate in mutually beneficial ways. The clients of ARUP Laboratories should only see positive changes.

Developments At Mayo

At Mayo Medical Laboratories (MML), the fourth reference/esoteric laboratory to adopt new business strategies, the pressure to change was a consequence of 9/11. With foreign visitors encountering new restrictions on entry into the United States, the flow of overseas patients coming for treatment at **Mayo Clinic** declined by a significant number.

One consequence of this unexpected development was a decline in revenue. In the years since 9/11, Mayo Clinic's senior administration began reassessing all aspects of the organization. During the years 2003 and 2004, attention was focused on Mayo Medical Laboratories. Its strategic role within the Mayo organization was studied and assessed.

During this period, multiple sources offered information about what was occurring. However, when queried by THE DARK REPORT, senior leaders at Mayo Medical Laboratories declined to comment on any aspect of this process. So the outline of developments which follows is believed to be close, although specific details may not be fully accurate.

During the assessment period involving Mayo Medical Labs, several strategic questions were asked. Was a commercial reference laboratory business appropriate to the mission of Mayo Clinic? Was MML using capital and resources to best advantage of Mayo Clinic? What was the best strategic plan going forward?

This assessment process is believed to have included investment bankers. Their role was to provide a market value for MML and evaluate a variety of business options that could maximize that market value for Mayo Clinic.

In 2005, it is obvious that Mayo Medical Laboratories continues as it always has—but with one noteworthy difference. Over the past year, MML is seen to be more aggressive in offering discounted pricing than it ever was in prior years. It is clearly willing to compete more assertively for new client accounts.

THE DARK REPORT considers this to be a visible sign that MML has changed some of its business strategies. It is an outcome of the strategic assessment of MML's core business and how it can best serve the mission of Mayo Clinic.

Positive Changes

It is noteworthy that Esoterix, ARUP Labs, and Mayo Medical Labs—each a profitable company—are simultaneously developing new business strategies. It is evidence of how competitive pressures are forcing change, even on successful companies. The beneficiaries of this change will be hospital labs and private labs. They should see improved services and competitive pricing for their send-out business. TDR

Baylor Univ. Lab Serves ED Needs With STAT Lab

Rapid response laboratory is solution to meet emergency department needs

CEO SUMMARY: Throughout the United States, hospital laboratories are working to meet ever-increasing lab testing demands by emergency department physicians. In response, many labs debate the benefits of a point-of-care testing (POCT) solution versus operating a rapid response lab in or next to the emergency department. Baylor chose the latter, and reports that it was a win-win for all stakeholders.

By Pamela Scherer McLeod

EMERGENCY DEPARTMENTS are demanding more from the laboratories that serve them. Among these needs are an expanded menu of tests and faster turnaround times for laboratory results.

Across the country, hospital laboratories are responding with three primary strategies. One is to provide an expanded menu of POC (point-of-care) tests in the emergency department (ED). Two is to establish a rapid response laboratory in or near the ED. Three is to use pneumatic tube systems and other methods to get ED specimens into the core laboratory to support faster turnaround times.

One laboratory which was an early-adopter of the rapid response lab approach is **Baylor University Medical Center**, located in Dallas, Texas. In 1999, it was one of the first hospitals in the nation to build a rapid response laboratory in the emergency department. THE DARK REPORT recently conducted a site visit to Baylor for a first-hand look at this solution and its impact.

"There was a need to address overcrowding in the emergency department," stated Michael Nicar, Ph.D., Director of Baylor's core laboratory. "With 1,000 beds and 80,000 ED patients per year, the core lab was struggling to fully meet the needs of the ED physicians. As it turns out, the catalyst for implementing the rapid response lab located in the ED here at Baylor was one of the ED physicians.

Unexpected Benefits

"On the whole, our rapid response lab solution has worked well for the ED, for the laboratory division, and for the hospital itself," noted Nicar. "What surprised us, however, were a number of positive outcomes which had not been anticipated."

"Before the STAT laboratory, our ED was dependent upon a pneumatic tube system," recalled Pamela Bollinger, M.T., Manager of both the ED rapid response lab and the hematology laboratory. "Baylor is a huge facility. Any failure of the pneumatic tube system was a huge problem. The system became especially strained when pharmacy also wanted to hook into it. One solution, at the time, was to establish a tube system 'user group.'

"This was a workaround for the shortcomings of the pneumatic tube system," she added. "It turned out the the effective response to the problem was locating a rapid response lab within the emergency department. That alleviated the problem."

As the laboratory and ED crafted a solution, funding was not an issue. "Administration judged the STAT lab for the ED as a new cost center. It was incorporated into the pathology department's budget," Bollinger said.

Next was staffing. "Prior to the rapid response lab, we had two phlebotomists serving the ED," explained Bollinger. "To service the ED, we replaced the phlebotomists with a total of six MTs. We established our space requirements and re-engineered the work flow process. As an example, ED specimens going to the core lab were identified by colored labels.

Increased Interaction

"Obviously, operation of the rapid response laboratory required a new level of cooperation and interaction across several departments," she said. "Interaction increased between lab personnel and the ER physicians and nurses, as well as with the admissions department. This is not typically the case for core lab personnel."

The big win for the rapid response laboratory is the reduction in test turnaround times. "We've realized reductions of 50% or more in the turnaround times of the most-used tests," Nicar commented. "Currently, we average about 22 minutes on CBCs and 30-35 minutes on chemistry and troponin tests.

"With faster test results, our ED physicians are able to treat patients with greater accuracy and speed," he continued. "Since launch of the STAT

POCT or STAT Lab? How Baylor Chose One

BACK IN 1999, Baylor University Medical Center's decision to opt for a rapid response laboratory within the emergency department (ED) followed an already-established precedent within Baylor.

"At that time, we already had a satellite laboratory alongside the surgery suites," stated Pamela Bollinger, M.T., Manager of Baylor's ED rapid response lab. "For both the laboratory and physician staff, this meant the concept of a rapid response laboratory next to a clinical service was not breaking new ground. That concept was already accepted and working successfully elsewhere in our hospital.

"That made it easier to plan our rapid response laboratory to be located within the emergency department," she continued. "Also, we believed that a rapid response laboratory solution would make it easier to select instruments and test methodologies that would correlate with test results produced in the core laboratory. That was particularly true six years ago, because point-of-care technologies were not as advanced as they are today.

An upcoming issue of THE DARK REPORT will cover how Baylor developed the test menu and selected instruments and test methodologies to use in their ED STAT laboratory. This analysis will also cover the issues and solutions adopted by the Baylor laboratory to get rapid response lab test results into the LIS.

Four Positive Outcomes From Baylor's ED Rapid Response Lab

1 → **50% reduction in TAT**

2 → **Improved interdepartmental cooperation and physician satisfaction**

3 → **Greater efficiencies in core lab**

4 → **Overall cost savings**

lab, physician satisfaction with lab testing services has definitely gone up.

"Another cost-saving strategy we initiated was to start sending a.m.-admit patient testing to the STAT lab via pneumatic tube," noted Nicar. "This strategy allowed us to shut down what we called the "a.m. admit lab" during this time. Because it is a slower time in the ED, we now tube specimens to the rapid response lab because it has the capacity to handle these additional tests."

"Our STAT lab has contributed to improved ED cardiac and stroke care," said Nicar. "We do troponins in the ED STAT Lab. We also now do BNP in-house, in the core lab. In the last month, Baylor initiated new stroke protocols in the ED. To support this, we provide troponin, CBC, chemistry, and coagulation tests. Coag specimens are directed straight to the coag STAT lab and bypass the serum room."

Baylor's laboratory team points to a number of unexpected and useful outcomes resulting from the operation of its rapid response laboratory in the emergency department. "The rapid response lab increases 'face time' between lab personnel and ED physicians and nurses," stated Patricia Williams, M.T., Education Co-ordinator for the pathology department. "Ordinarily, these clinicians don't interact with MTs working in the core lab. So our entire laboratory division benefits from this higher level of professional interaction."

Reduction In Labeling Errors

"In fact, one striking example is how interpersonal relationships helped us reduce errors in labeling and fostered greater cooperation between lab and ED personnel," explained Williams. "There were instances when ED nurses did not get the labels just right. Our lab personnel helped the ED nurses—who are involved in the diagnostic and treatment process—understand how specimen labeling errors extend lab test turnaround times. It was an 'aha' moment when they realized how a labeling error would delay the time required for the lab to produce and deliver the information they need to assess the patient.

"Another bonus outcome from our ED rapid response lab was a major gain in the core laboratory," added Bollinger. "Because core lab personnel are no longer interrupted by STAT testing requests, we've seen a significant gain in productivity in our core lab. That is the type of positive impact which is often overlooked in these types of arrangements."

Lab Test Correlation

Correlating the tests between the core laboratory and the rapid response lab took effort at Baylor. "We use the same instrumentation and methodologies in both labs," said Nicar. "This is essential to cut down on time-consuming correlation problems. Physicians appreciate the consistency in the lab results. Consistent instrumentation also makes it easier for core lab personnel to cover the STAT lab when necessary.

"Overall, we judge our ED rapid response lab to be a successful solution," Nicar declared. "One key lesson to share is that staffing it with the right people is essential. Their close interaction with ED physicians and nurses makes that essential"

Would Baylor do anything differently, based on its experience? "We would allocate more space for the STAT lab," answered Nicar. "In fact, Baylor is adding a new ED building which incorporates a rapid response laboratory. This new lab will have bio-terrorism testing capabilities because it is part of the front-line services of our emergency department." **TDR**

Contact Michael Nicar, Ph.D., Pamela Bollinger, M.T., and Patricia Williams, M.T. at 214-422-9567.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It was good news for the nine-year old boy with the rare brain tumor he named "Frankstein." On midnight, Monday, February 14, 2005, the family received a telephone call from the surgeon who performed the biopsy on February 2, 2005. He confirmed that the biopsy was negative for cancer. What is interesting about the lengthy delay in reporting this to the family is that the pathology department of **Cedars-Sinai Medical Center** decalcified the specimen and completed the diagnosis in just 48 hours. It had e-mailed the pathology results to the referring physician on February 4, 2005. This story had become national news because, following chemotherapy, the family lacked funds to pay for a conclusive, specialized biopsy. To raise the money, the boy's parents were selling a bumper sticker on E-Bay that read "Frank Must Die." *(See TDR, Feb. 14, 2005.)*

RAPID HIV-1/HIV-2 TEST

Bio-Rad Laboratories, Inc. has received FDA clearance to market a rapid test that can detect both HIV-1 and HIV-2 viruses. This is the first rapid test for both HIV types to receive clearance in the U.S.

GENETIC-VARIATION MAP AIMS TO RECORD SNPS

"HapMap" is an international effort involving research scientists in many organizations with a common goal: to create a haplotype map of human genetic variation. Haplotype describes a pattern of associated SNPs (single nucleotide polymorphisms). SNPs are expected to account for many differences between individuals. SNPs are genetic variations between individuals that may involve just one base pair in a sequence of DNA. As happened in the mapping of the human genome, new technologies are making it faster and cheaper to scan genomes and identify SNPs and haplotypes. The leading firm in this effort is **Perlegen Sciences, Inc.**, based in Mountain Park, California. Over five years, it has produced a proprietary data base of 1.6 million SNPs.

ADD TO: HapMap

Now, in a move evocative of **Celera Inc.** during the race to map the human genome, Perlegen has offered to integrate its own SNP into the HapMap project. Further, by years-end it expects to contribute a total of four million SNPs to HapMap. The company is scanning 270 genomes used as a reference by HapMap researchers. These scans reveal the frequency with which various SNPs appear across populations. This data is needed to then conduct disease studies. This data is expected to open up the field of personalized medicine, including pharmacogenomics and theranostics. It will lead to a new generation of diagnostic tests.

GOVERNMENT FUNDING OF HEALTHCARE AT 49%

It's a startling prediction. Health analysts at the **Centers for Medicare and Medicaid Services** (CMS) recently published a study that projects that, by 2014, the government will be paying 49% of all healthcare costs in the United States. Published in *Health Affairs*, actuaries at CMS attribute a significant part of increased costs to Medicare's new program to cover prescription drugs. Currently, government pays 46%. The share government paid was 43% in 1980 and 38% in 1970.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 28, 2005.

PREVIEW #4

EXECUTIVE WAR COLLEGE

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

IBM's Vision of Health Info Technology

It's a *War College* Exclusive! Hear IBM's Worldwide Genetics Leader lay out his company's grand vision for giving the clinician an informatics middleware solution that provides real-time, on-demand answers. Laboratory test data plays a key role in a product that will connect clinical repositories, the patient EMR (electronic medical record), and clinical treatment pathways to guide the clinician to both the right diagnostic conclusion and the appropriate therapy.

Full program details available now!

visit darkreport.com

UPCOMING...

- ***Battle Heats Up Between Pathologists and Insurers Over Clinical Path Professional Fees.***
- ***Point-of-Care Testing: Breakthroughs and Setbacks Among Early-Adopter Labs.***
- ***Negotiating Send-Out Testing Contracts: New Strategies for a Win-Win Deal.***

For more information, visit:

www.darkreport.com