Volume XVII, Number 13 Monday, September 13, 2010

Specialized Information Publishers Foundation
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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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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Labs Can Turn the Tables on the Payers

PRE-AUTHORIZATION OF GENETIC AND MOLECULAR TESTS is now on the radar screen of the nation's larger health insurance companies. In most circumstances, payer pre-authorization requirements serve to exclude many smaller providers from access to patients. But local labs have a chance to guarantee their place as a preferred, in-network provider of expensive genetic tests.

As you will read on pages 10-16 of this issue, the health insurance industry has three distinct needs that can be best met by local clinical laboratories and pathology groups. First, payers want to cut through the code-stacked claims for many genetic and molecular tests to understand: 1) what specific diagnostic test was ordered by the physician; and, 2) what specific disease or medical condition triggered the test request.

Second, payers want to establish appropriate ordering guidelines and treatment protocols associated with specific molecular assays. They also want physicians to be educated about these guidelines and protocols. Again, this plays to the clinical strengths of pathologists and laboratory scientists.

Third, health insurers need an efficient and accurate system to manage pre-authorization of genetic and molecular tests, along with a way to confirm that claims meet coverage guidelines. Because labs receive lab test orders directly from physicians, they are well-positioned to assist payers in a positive way.

Pathologists and lab administrators should view this as a rare opportunity to score a trifecta (the bet based on correctly picking the first-, second-, and third-place finishers in a horse race) with payers. Local laboratories can develop the capability to help payers fulfill these three objectives.

This will directly benefit the lab because it can be rewarded by the payer in several ways. One, the lab will have preferred network access to patients. Two, it can negotiate reimbursement based on the value of the service it delivers (and not on the cheapest price bid for the molecular test). Three, because it is part of the pre-authorization process with the payer and the physician, the lab knows it is accepting a specimen for which its claim will be paid in full.

I strongly recommend that lab administrators and pathologists bring this opportunity to their executive teams and craft an appropriate business strategy. This may be a "once in a lab career" opportunity to turn the tables on payers. In return for delivering recognizable value on the use of expensive genetic tests, your lab can negotiate reimbursement based on that value. TDR

Two New Lab Companies Will Open in L.A. & Denver

Different laboratory joint ventures pair PAML with a major health system in each community

CEO SUMMARY: It is unprecedented for two multi-billion-dollar health systems to announce laboratory testing outreach joint ventures just days apart. In Los Angeles, Providence Health & Services will partner with PAML to start a commercial lab company in the San Fernando Valley. In Denver, Centura Health and PAML formed a similar clinical laboratory testing joint venture to compete for the laboratory test referrals of office-based physicians across greater Denver and Colorado.

MAJOR HOSPITAL LABORATORY TESTING OUTREACH joint ventures (JVs) are preparing to open in Los Angeles and Denver. Both new commercial laboratory partnerships were announced in the past two weeks.

In each case, a multi-billion-dollar integrated health system announced an agreement to establish a commercial laboratory partnership with **Pathology Associates Medical Laboratories, LLC,** (PAML), of Spokane, Washington. Each joint venture will represent PAML's first presence in both Los Angeles and Denver.

It was August 31 when **Providence Health & Services** of California and PAML released the news that they would form a new clinical laboratory company, to be called **California Laboratory Associates, LLC** (CLA). The new lab company will be based in Burbank. It will utilize the recently-remodeled laboratory at 431-bed **Providence Saint Joseph Medical Center**.

According to the two partners, California Laboratory Associates will launch business operations early in 2011. CLA will initially serve physicians and other clients in the San Fernando Valley. It intends to eventually offer lab testing services throughout Southern California.

Just eight days later, on September 7, **Centura Health** of Denver, Colorado, and PAML issued a press release announcing the creation of **Colorado Laboratory Services, LLC** (CLS). This commercial clinical laboratory joint venture will commence operations in the coming months.

CLS will utilize the laboratory at Centura's 593-bed **St. Anthony Central**

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.)**

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

Hospital, which is located in Denver. Centura Health is the largest healthcare system in Colorado.

These two new laboratory joint ventures demonstrate that PAML's lab testing business model continues to find favor among administrators of major hospitals and health systems. PAML operates similar joint ventures with hospitals and health systems in Washington, Idaho, and Utah. *(See TDR, November 19, 2007).*

Further, it was in the fall of 2009 that **Catholic Health Initiatives** (CHI) became an investor and partner in PAML. CHI operates 78 hospitals in 38 states and has annual revenue of $8.6 billion.

➤Formation Of Centura Health

In fact, Centura Health has a joint operating agreement (JOA) with CHI. Centura Health was formed in 1996 when sponsoring organizations Catholic Health Initiatives and **Adventist Health System** brought their hospitals in the Denver region together to form the integrated delivery network. Thus, the formation of Colorado Laboratory Services might be considered "first fruits" from the new business relationship between CHI and PAML that was established in the fall of 2009. *(See TDR, November 12, 2009.)*

PAML's business model for these joint ventures is simple and designed to tap the complementary core strengths of the participating partners. The hospital or health system provides the laboratory which is based in the community. It will provide most of the laboratory testing for the outreach lab venture. It usually has a local service infrastructure of patient service centers, couriers, and established, long-standing relationships with physicians in the community who refer patients to the hospital.

For its part, PAML provides a sophisticated package of all the essential services required for the lab testing joint venture to compete at a high level. PAML manages the joint venture, provides its well-developed suite of integrated lab informatics, and handles marketing, sales, managed care contracting, client services, and billing and collections, among other things. It also provides reference and esoteric testing for specimens not tested by its hospital partner.

➤Tough Competitor

With the right hospital or health system partner in a region, PAML's joint venture business model starts with advantages that position it to be a very tough competitor. For example, in and around Denver, Centura Health operates 12 hospitals. Thus, not only will Colorado Laboratory Services immediately become a local lab competitor, with its main lab located at St. Anthony Central Hospital near downtown, but it also starts with 11 other strategically-located testing and service centers located in and around each of Centura's other 11 hospitals.

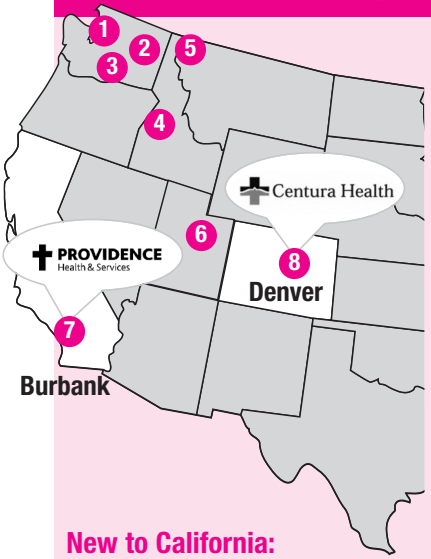
It will be the same story with California Laboratory Associates. CLA's primary laboratory will operate from Providence Saint Joseph Medical Center in Burbank. The other five Southern California Providence hospitals in Mission Hills, San Pedro, Santa Clara, Tarzana, and Torrance will provide CLA with service hubs that make it a local laboratory provider in each of those communities.

➤Interest In Laboratory JVs

The announcement of the creation of two major new laboratory testing companies coming only eight days apart signals that PAML's joint venture business model continues to appeal to hospital/health system administrators. Moreover, reduced Medicare reimbursement in coming years may make the concept of a laboratory outreach joint venture even more attractive to hospitals and health systems.

If this is true, PAML may be positioned to have its pick of opportunities to develop laboratory joint ventures with some of the nation's most respected hospitals and health systems. TDR

With Two New Hospital Partners, PAML Ready to Compete in Los Angeles, Denver



New to California:
7 California Laboratory Associates

New to Colorado:
8 Colorado Laboratory Services

In 1996, PACLAB Network Laboratories in Seattle was PAML's first joint venture. The newly-announced laboratory companies in Burbank, California (with Providence Health & Services–California Region) and in Denver (With Centura Health) will be the seventh and eighth laboratory joint ventures developed and managed by PAML.

Joint venture lab companies managed by PAML will soon total eight in five states. Below are the six existing lab JV locations, plus PAML in Spokane, WA

1. PACLAB NETWORK LABS, LLC, Seattle
2. PATHOLOGY ASSOCIATES MEDICAL LAB, LLC, Spokane
3. TRI-CITIES LABORATORY, LLC, Kennewick
4. TREASURE VALLEY LABORATORY, Boise
5. ALPHA MEDICAL LABORATORY, LLC, Coeur d' Alene
6. MOUNTAINSTAR CLINICAL LABS, LLC, Salt Lake City

Colorado Laboratory Services, LLC

Partnership with:
Centura Health, Denver, CO, and PAML, LLC, Spokane, WA

Local Laboratory:
Will use lab at St. Anthony Central Hospital, Denver, CO

Centura Health

Centura Health Stats:

2010 Revenue.....$1.8 billion
Patient Days 356,750
Outpatient Visits.....938,505

Facilities:
12 hospitals, 7 senior living communities. Centura Health is Colorado's fourth largest employer with more than 13,000 associates

California Laboratory Associates, LLC

Partnership with:
Providence Health & Services, California Region, and PAML, LLC, Spokane, WA

Local Laboratory:
Will use lab at Providence St. Joseph Medical Center in Burbank, CA

PROVIDENCE Health & Services

Providence California Region Stats:

Acute Beds.....1,357
Long Term Care Beds:.....611

Facilities:
27 hospitals in system, 6 hospitals in California Region

More Hospitals Consider PAML's Lab JV Model

➤Decision of two major health systems to ally with a partner demonstrates renewed interest

➤➤CEO SUMMARY: One joint venture at a time, PAML is convincing hospital and health system CEOs about the benefits of building a thriving laboratory outreach business. For their part, facing budget cutbacks and a decline in Medicare reimbursement, more hospital administrators are beginning to recognize how and why laboratory outreach testing programs can bring substantial clinical and financial benefits to their organization. These are auspicious developments for hospital labs across the nation.

INDEPENDENT DECISIONS by two multi-billion-dollar health systems to expand their laboratory outreach programs via partnerships with **Pathology Associates Medical Laboratories, LLC** (PAML), may represent a significant lab industry market milestone.

For PAML, both new laboratory joint venture agreements—one with **Providence Health & Services** of California, and the other with **Centura Health** of Denver—are important validation of its unique business model. Having these health systems as partners will add to PAML's credibility and make it easier for the Spokane, Washington-based lab company to enter similar deals with other major multi-hospital health systems.

For Providence Health-California and Centura Health, their respective partnerships with PAML will allow them to accelerate the expansion of their laboratory outreach efforts. The direct benefit will be an increase in lab specimens and revenue from the outreach market. But an equally important benefit will be how the lab outreach program supports each health system's strategy of fostering tighter clinical integration with office-based physicians in their service areas.

For the nation's laboratory testing industry, these two lab joint venture companies might well signal the earliest days of a new competitive factor. The emergence of two well-financed and well-positioned new laboratory companies in the metropolitan areas of Los Angeles and Denver demonstrates how quickly local hospitals and health systems can change the competitive balance in their local lab testing marketplace.

➤Lab JV In Seattle Succeeds

That has certainly proven true in Seattle. Since its formation in 1996, **PACLAB Network Laboratories** (with PAML as partner and general manager), has captured market share at a steady rate. It has grown to encompass 11 participating hospital members. Its annual revenue is close to nine figures.

PACLAB is now one of Seattle's three largest lab testing enterprises. It holds a market share in the Seattle region that is at least equal to **Laboratory Corporation of America** and **Quest Diagnostics**

Incorporated. This is a notable accomplishment, since both national lab companies operate a major lab facility in Seattle and are considered "local labs" to office-based physicians in the region.

Of course, the organizers of the new laboratory companies in Los Angeles and Denver hope to match or exceed the financial success of PACLAB in Seattle. Were that to happen, it would be powerful validation of PAML's laboratory joint venture business model—and an encouragement for other hospitals and health systems to intensify their own laboratory outreach programs.

Lab administrators and pathologists will want to track the market share progress of both **California Laboratory Associates, LLC** (CLA–the JV involving Providence and PAML), in Los Angeles and **Colorado Laboratory Services, LLC** (CLS–the JV between Centura and PAML), in Denver. Neither of the two national labs wants to see a replay of the Seattle market share re-alignment happen in Los Angeles and Denver. For that reason, there is likely to be intense competition for physician office clients in both cities.

News Offers Two Stories

There's a double story within the news that PAML has new laboratory joint ventures in Los Angeles and in Denver. The first story is that two of the nation's larger and respected health systems are willing to expand their laboratory outreach programs—and went outside their organizations to find the expertise they wanted to optimize success.

The second story is that, at the stroke of a pen, new laboratory ventures—involving a multi-hospital player in a major metropolitan region and PAML—can instantly emerge to become a credible competitor to existing labs in the area. Should new lab JVs like these two develop in other cities, backed by major health systems in that region, this would not be an auspicious trend for the two blood brothers. TDR

Other Lab Firms Pursued Hospital Lab Joint Ventures

OVER THE PAST 30 YEARS, a number of commercial laboratory companies pursued the strategy of developing laboratory outreach joint ventures with hospitals. Only Pathology Associates Medical Laboratories (PAML) seems to have enjoyed long-term success with this business strategy.

In the 1970s and 1980s, **International Clinical Laboratories, Inc.** (ICL), gained a reputation for establishing successful and long-lasting lab JVs with hospitals. Although it was acquired by **SmithKline Beecham Clinical Laboratories** in 1988, several of the ICL-created lab JVs continue to operate.

During the 1980s and 1990s, two Canadian lab companies entered the United States with a primary strategy of creating lab outreach JVs. **MDS Diagnostics Services** and **Dynacare, Inc.**, each devoted years to wooing hospitals with the goal of recruiting them into a laboratory joint venture.

MDS did have operational lab JVs in Poughkeepsie, Memphis, Atlanta, and Miami, which it developed with different hospital partners over a 12-year period. It exited the United States in the mid-2000 period and sold its interests in these laboratory operations.

Dynacare similarly tried to develop hospital laboratory joint ventures, but found it faster and easier to acquire labs that came up for sale. It had a true hospital lab joint venture in only a few locations. Dynacare was acquired by Laboratory Corporation of America in 2002.

Another interesting attempt to have a commercial laboratory company support hospital laboratory outreach programs was a partnership between **Premier, Inc.**, the group purchasing organization (GPO), and Quest Diagnostics. It was organized in 1998 for the purpose of consulting with hospital and health system labs and creating lab JVs. Despite a concerted marketing effort by both partners, there was inadequate interest by hospitals and the partnership was quietly disbanded.

Lab Briefs

BOSTON INVESTORS PURCHASE INTEREST IN DR LAL PATHLABS

PATHOLOGY AND CLINICAL LABORATORY COMPANIES IN INDIA continue to attract investor interest. Last month, **TA Associates**, a private equity firm in Boston, Massachusetts, announced that it had purchased a minority interest in **Dr Lal PathLabs** of New Delhi, India.

TA Associates bought one-half of the shares held by **Sequoia Capital**. News reports say that Sequoia had invested $6 million in Dr Lal PathLabs in 2005 and then put in another $4 million in 2007.

One news outlet reported that TA's stake in Dr Lal PathLabs was 16%. It also said that TA Associates paid $35 million for those shares. Assuming these numbers are accurate, it would indicate that Sequoia Capital's five-year investment in Dr Lal PathLabs has generated substantial profits.

U.S. SPENDS $55.6 BILLION BECAUSE OF MEDICAL MALPRACTICE

YOU MAY HAVE ALWAYS WONDERED how much medical malpractice costs the American healthcare system each year. Now the **Harvard School of Public Health** has released a report that says malpractice cost totals $55.6 billion annually.

The research team stated that most of this expense comes from "defensive" medical practices, which include such items as extra diagnostic tests and scans. It estimated that these costs were as much as $45.6 billion of the total.

The findings were published in the journal *Health Affairs*. Also included in the total of $55.6 billion were administrative costs, payments to plaintiffs, and fees paid to lawyers. The study excluded malpractice premiums because this represents the insurer's actuarial estimates of malpractice indemnity costs and defense costs. Including premium costs would be double-counting.

The team, lead by Michelle Mello, Professor of Law and Public Health at Harvard's Department of Health Policy and Management, estimated that malpractice indemnity payments were $5.72 billion annually, in 2008 dollars. This was made up of $5 billion in actual damages and only about $2 billion in punitive damages.

"Physician and insurer groups like to collapse all conversations about cost growth in healthcare to malpractice reform, while their opponents trivialize the role of defensive medicine," stated Amitabh Chandra, who is a Professor of Public Policy at Harvard's Kennedy School of Government and worked on the research team. "Our study demonstrates that both these simplifications are wrong—the amount of defensive medicine is not trivial, but it's unlikely to be a source of significant savings."

MED LAB WORKERS STRIKING IN NEW ZEALAND

STARTING EARLY THIS SUMMER, a variety of strike actions by medical laboratory workers has taken place in laboratories across New Zealand. The **Medical Laboratory Workers Union** says that the pay of its members, who have four-year degrees, is not in line with comparable professions.

During the weekend of September 11, medical laboratory workers initiated a 24-hour strike against the three district health boards in Auckland. Over the summer, other strike actions have included "sick outs"—where a number of lab workers do not report for work on selected days. Hospital labs in several cities have been affected by the various forms of strike actions. Health authorities have responded in some cases by suspending striking lab workers. TDR

LIS Update

Epic Launches LIS Software To Fill Out Ancillary Offerings

New LIS is called "Beaker" and three versions target clinical labs, public health labs, and AP

MANY PATHOLOGISTS and laboratory administrators may be unaware that a company called **Epic Systems Corporation** is considered by some experts in healthcare informatics to be a disrupter of the status quo.

Based in Verona, Wisconsin, Epic is best known for its acute and ambulatory EMRs (EpicCare), which took the top two spots on the "2009 Best in KLAS Vendors for Software" report. The company has carefully nurtured a reputation for a relatively clean implementation, effective integration with other informatics systems, and ease of use by physicians.

In recent months, Epic has introduced a laboratory information system (LIS) product. It is called "Beaker." It comes in three versions, which are designed to be specifically functional for three different applications: clinical laboratories, anatomic pathology laboratories and public health laboratories.

Clin Lab and Public Health

"Beaker Clinical Labs" and "Beaker for Public Health Labs" integrate with Epic's Outreach application. As conjoined programs, they provide a Web-based interface through which external healthcare providers can enter orders and receive results online. Web-based specimen inquiry is another feature.

"Beaker for Anatomic Pathology" is intended for surgical pathology and cytology laboratories. It features barcode-enabled workflows, and when integrated with Beaker Clinical LIS, patient histories can be accessed.

Beaker is a new LIS offering and little is known about it. Some experts believe that Epic, to sustain the effectiveness of its EHR product, is sequentially developing all of the ancillary IT systems required by a hospital.

Ancillary Software Offerings

Some of the ancillary software systems currently offered by Epic include patient management (Resolute), practice management (Resolute/Prelude/Cadence), pharmacy (Willow), and radiology (Radiant). All of these were listed in the 2009 Best in KLAS report.

Laboratory administrators and pathologists will want to learn more about Epic Systems Corporation. Its EHR system is used by a number of leading healthcare organizations, of which **Kaiser Permanente** is the largest. Epic says that, upon completion of current sites, its EHR will by used by 170,000 physicians in the United States. This represents almost 25% of the nation's physicians.

It is unclear at this point if Epic wants to become a major player in the LIS marketplace. Should it have that goal, it will need to offer a robust, multi-function LIS solution. To accomplish that, it would probably beef up the capabilities of Beaker in each future release. TDR

CEO Summary: Pre-authorization of expensive genetic and molecular tests is fast-becoming a priority for most of the nation's health insurers. For clinical labs and pathology groups that don't respond, this trend is a threat. On the other hand, because payers need all the skills and knowledge that labs possess to intelligently manage utilization of molecular testing, there is an opportunity for the lab industry to deliver a new value stream to payers that triggers value-based reimbursement for these new laboratory services.

Opportunity for labs to be paid on value and not as a commodity!

Payers Move to Pre-Authorize Expensive Genetic Tests

Part One of Three Parts

PRE-AUTHORIZATION of expensive genetic and molecular tests is the big trend among the nation's largest payers. For clinical labs and pathology groups, it is a trend which should not be ignored.

"Health insurers are reacting to the rising cost of genetic and molecular testing," stated Matthew B. Zubiller, Vice President, Advanced Diagnostics Management, for **McKesson Corporation**, in San Francisco, California. "When faced with any new healthcare technology or prescription drug which quickly becomes a major cost, payers have a time-tested response—to help control appropriate use, they either deny coverage requests for these new procedures or require pre-authorization."

As a trend, payer requirements for pre-authorization of genetic and molecular tests have the potential to stratify the nation's clinical laboratories and pathology practices into one of two groups. One group will be those labs approved as in-network providers of genetic tests. The other group will be out-of-network labs which, lacking a contract, will not be among a health insurer's preferred service providers.

"Before developing an appropriate strategy for their laboratory organization to respond to this new trend, pathologists and laboratory administrators will need to understand three aspects of the genetic test pre-authorization trend," observed Zubiller. "First, health insurers will follow the same game plan they have used in past years to manage other expensive new technologies. So we know what to expect.

"Second, laboratories have an opportunity to step up and help health insurers manage utilization of expensive genetic and molecular tests, specifically to ensure that the doctor orders the right test at the right time," he noted. "Such services have high value and contribute to improved patient outcomes.

"This opens the door for laboratories to be paid for value delivered," said Zubiller. "This can move lab test reimbursement away from today's commodity-priced fee-for-service mindset to a true relationship based on value.

"Third, labs will use sophisticated decision support and informatics solutions to provide these value-added services to payers and to physicians," added Zubiller. "Smart use of informatics will allow the laboratory to offer precise, real-time solutions."

Zubiller made these comments while presenting as part of THE DARK REPORT'S recent audio conference, "Why Health Insurers Want to Pre-authorize Expensive Genetic and Clinical Pathology Lab Tests." He next explained how health insurers have handled pre-authorization in response to other new healthcare technologies.

"For decades, health plans have implemented pre-authorization whenever utilization—and thus costs—have increased," Zubiller said. "Upon the introduction of new pharmaceuticals, radiological imaging, or surgical methods, the reaction from health plans is typical—they deny the coverage request or require pre-authorization.

"Labs increasingly face this same situation when they request payer approval for genetic and molecular testing," he added. "Currently, it's rare for a payer to simply approve any type of expensive diagnostic testing without at least collecting more information justifying its use.

"The current process of collecting that additional information generally requires some manual steps," noted Zubiller. "That means it is both time-consuming and expensive for laboratories, their ordering providers, and the health plans reviewing the requests."

Yet, this unmet need for accurate and timely information about a genetic test request is what provides laboratories with an opportunity to step up and fulfill the unmet need of the health insurers. "Going forward, the laboratory that is capable of

providing this type of information will be delivering a value-added service to both payers and providers," predicted Zubiller.

"Labs can add value in several important ways," he noted. "A starting point is to work more closely with health plans to educate physicians about: 1) Which genetic tests are appropriate; 2) Which genetic tests are covered; 3) Which tests are not covered; and, 4) Which unique labs may perform these genetic tests.

Shift To Value-Based Fees

"As clinical labs and pathology groups work more closely with health plans on this issue, they will help to shift the model for reimbursement from one in which payment is fee-for-service or capitation—often based on a commodity mindset of cheapest price—to a model based on performance, on value, and on appropriate utilization," commented Zubiller.

"If a clinical laboratory can move from the position of 'I just do the test,' to the position of, 'I work with my health plan to provide a valued set of decision-support services to manage the appropriate utilization of these diagnostic tests,' then that lab has shifted from just a provider of tests to a custom-care partner," he said.

"However, under the existing fee-for-service system, laboratories are not reimbursed for spending the time necessary to offer advice about these new diagnostic tests," observed Zubiller. "That's a flaw that needs to be fixed.

Fair Lab Reimbursement

"Because of this existing situation, many laboratories do not provide clear clinical and financial decision-support information to help physicians select the right genetic or molecular test," he said. "At the same time, most laboratories are also not assured of fair reimbursement."

"The good news is that this can change in ways that are favorable to laboratories," noted Zubiller. "With the rapid uptake of expensive genetic tests by many physicians, health insurers are now taking the first steps toward developing the tools needed to gather the information necessary to approve requests for molecular and genetic testing.

"However, until these tools and pre-authorization systems are in place, most health plans 'fly blind' in the face of orders and coverage decisions for expensive genetic tests," he continued. "The reason is simple.

"Health plans lack appropriate data at the time a genetic test is ordered. This makes it difficult for them to respond appropriately and rapidly," Zubiller noted. "Laboratories thus have the opportunity to fill that data gap for health plans. They can also educate physicians about which tests are most appropriate for each patient and where these genetic tests can be performed or sent out. But at the moment, most laboratories are ill prepared to take on that role."

Lab As Custom-Care Partner

Pathologists and laboratory administrators are likely to recognize the typical models payers commonly use for managing utilization of radiology or specialty drugs. "We see health insurers use these same models today to manage utilization of advanced molecular diagnostics and genetic testing," stated Zubiller. "It's a fact that, in today's healthcare marketplace, clinical laboratories and pathology groups are neither prepared nor equipped to work with health insurers and physicians in this way.

"In fact, it's common for laboratories to try to avoid these types of requirements by negotiating them out of their managed care contracts," remarked Zubiller. "This contracting strategy may be useful to a clinical laboratory or pathology group in the short term, but it's not a sustainable strategy and may lead to further price compression."

According to Zubiller, whenever health plans want to measure utilization, they have traditionally turned to claims

Why Current Utilization Management Methods Are Inefficient and a Better Solution is Needed

Efforts by health insurers to implement pre-authorization requirements for expensive genetic and molecular tests are often inefficient. The reasons for this situation include manual procedures, the difficulty in accessing essential data in a timely fashion, and the lack of an integrated systems solution to pre-authorization, utilization management, and claims processing.

Existing Situation Shows Challenges for Efficient Pre-Authorization

High Growth Diagnostics

- Molecular diagnostics rapid growth is increasing overall lab spend and utilization
- CPT coding is insufficient to manage utilization
- Compliance with medical policies is low
- Data necessary to coordinate care is unavailable

Inefficient Management of Benefits

- Existing processes are necessary to control medical spending, but costly themselves
- Poor collaboration among payers and providers
- Slow adoption and limited impact of payer-provider portals (poor utilization of single-payer portals)

data. However, when it comes to genetic testing, he says, claims data does not tell payers what they need to know. That causes payers to question whether a physician's order for a molecular or genetic test is warranted for the patient.

"This situation exists because of the limited codes available to describe molecular and genetic tests," observed Zubiller. "There are roughly two dozen codes to describe 2,000 tests. This problem continues to intensify because more genetic and molecular tests are introduced every week!

"This is one reason why laboratories 'code stack' their claims for many types of genetic and molecular tests," he stated. "But the downside to code-stacking is that health plans then find it difficult to recognize precisely which specific lab tests were performed.

"Code-stacking also works against the laboratory performing the test because it means the health insurer is unable to distinguish a specific genetic or molecular test based on its clinical value," he commented. "In this regard, code-stacking actually leads to further commoditization of laboratory test reimbursement.

"Further, code-stacked claims data have limited ability to describe the clinical context of the test," stated Zubiller. "That makes it difficult for a health insurer to determine the clinical reasons why these lab tests were ordered for that patient."

Three Challenges For Payers

The nation's health insurers face a triple challenge in coping with the tidal wave of genetic and molecular testing that is swamping their claims and utilization departments. The three issues are: 1) The need to control the growing annual cost per beneficiary of molecular testing; 2) The need to manage an already huge number of molecular and genetic assays—to which new assays are being added weekly; and 3) The desire to significantly reduce the cost required to pre-authorize genetic and molecular tests, as well as the cost to process the resulting claims.

Zubiller believes clinical labs and pathology groups have the opportunity to make themselves valued contributors with payers by helping with all three challenges. "Let's take each challenge in order," he said. "First is the spiraling cost of this testing. Estimates are that the U.S. healthcare system currently spends more than $6 billion on molecular and genetic tests each year.

"Health plans now struggle to manage a marketplace where hundreds of clinical laboratories regularly submit claims for 2,000 different molecular assays."

"For many health plans, this rate of utilization already represents spending of about $10 to $30 per member per year," Zubliller added. "They recognize that the per-member spend on molecular testing will increase steadily. Payers are very interested to work with any clinical laboratory and pathology group which can help them more efficiently manage how genetic and molecular tests are utilized by clinicians.

"The second payer challenge is to manage the daunting number of genetic and molecular assays," commented Zubiller. "A bell curve that shows the utilization of these 2,000 tests will have a 'long-tail' distribution. This means that the bulk of the volume is at the beginning of the curve to the right and then it elongates as it moves to the left."

Managing The Long Tail

Pareto's Law defines the long tail of a distribution as the 80% of the items that represent only 20% of the transaction volume. "This makes network management of that long tail very difficult," explained Zubiller. "For example, years back, when a handful of labs first started doing a limited menu of genetic and molecular tests, health plans could manage the first dozen laboratories that performed these tests.

"In each year since then, new tests have been introduced and a greater number of labs have begun performing these genetic and molecular tests," Zubiller said. "Health plans now struggle to manage a marketplace where hundreds of clinical laboratories regularly submit claims for those 2,000 different molecular assays.

Labs That Step Up

"Payers want to understand what each lab does, which tests each lab offers, and how the genetic and molecular tests are used for particular disease states," he observed. "Today, most health plans neither have this information nor the staff to manage it. A laboratory that can step up and help the payer with this challenge will be providing real value—and should be paid appropriately for that value.

"Managing pre-authorization and reimbursement is the third major challenge for health insurers," said Zubiller. "I think 'flying blind' aptly describes how health insurers respond when a coverage request or a claim arrives for a genetic or molecular test," Zubiller said. "Payers have three options.

Costly For Payers

"First, they can just approve the request, which they are unlikely to do without understanding the test. Second, they can just deny it, and they don't want to do that either. Third, they can look at the code range for genetic tests and then require prior authorization. But pre-authorization is costly for health insurers—as it is also costly for laboratories and providers," he explained.

"For example, one pre-authorization of a genetic or molecular test can cost the health insurer, the laboratory, and the provider each between $50 and $100,"

McKesson Uses a Systems Approach To Evaluate Genetic and Molecular Test Claims

SEEKING A WAY TO MANAGE REQUESTS for reimbursement for molecular and genetic tests, McKesson asked experts in its InterQual division to develop criteria that health plans could use to understand the evidence and make decisions about the appropriate use of these tests.

"InterQual is our clinical decision-support division," said Matthew B. Zubiller, McKesson's Vice President of Advanced Diagnostics Management. "Working with them, we created a set of evidence-based criteria and assessments for the 430 tests that represent the bulk of today's costs for the molecular and genetic tests.

"This study went beyond pharmacogenomic testing," he explained. "Our study team looked at all the advanced genetic and molecular testing used across the entire clinical spectrum.

"The criteria and assessments developed for each molecular and genetic test gives some guidance to both health plans and providers about what they should do for their covered populations and patients," stated Zubiller. "For those laboratories receiving specimens and responsible for sending out such tests, this same information lets them know if the test being ordered meets the payer's criteria and where that specimen should be sent.

"The path to value-based reimbursement starts with clear and transparent coverage criteria, matched by measurable utilization," continued Zubiller. "Once these criteria are established, health plans must continue to maintain a staff delegated to make effective decisions.

"This is where McKession's vision of a systems-based approach can be an effective solution," he commented. "Using an integrated informatics system to connect payers, providers, and labs reduces or eliminates manual procedures. It becomes simpler to collect the correct information at the point of care and it accelerates the coverage and reimbursement process.

"The beauty of this system is that it works with all participants in health care," Zubiller noted. "That is true whether the payer is a health plan, such as **UnitedHealth**, or a genetic test manufacturer, such as **Genzyme**.

"Most tools currently used to manage genetic testing are payer-based solutions and not a systems-based solution," observed Zubiller. "Payer-based systems vary significantly. Many plans have different processes that keep providers guessing about what meets the requirements for medical necessity.

Uneven Playing Field

"Similarly, take the example of when a payer offers capitation to a specific lab," he noted. "That creates an uneven playing field because capitated reimbursement can often obscure the actual utilization that occurs. We prefer a market-driven model that encourages a payer to select a laboratory partner based on the cost and quality of the evidentiary results the lab provides.

"This vision requires a system that offers a consistent work flow for labs and providers—regardless of the payer," continued Zubiller. "At the same time, this system must efficiently accommodate each payer's different medical, network, and payment policies"

"Such an integrated systems solution creates an objective pre-authorization and reimbursement process," summarized Zubiller. "That levels the playing field so labs can compete—not on the basis of price alone—but on a combination of price, quality, and levels of services. Not only does this benefit providers and patients, but it contributes to a more efficient healthcare system."

noted Zubiller. "That covers clinical data collection, the telephone calls, and the faxing of documents back and forth. These activities are time consuming for everyone—payers, physicians, and labs.

"Currently, health plans have no systems approach to solve this problem," he said. "As a result, payers are interested to see how labs can help them manage utilization. The starting point is to enable a health insurer to measure the rate at which genetic and molecular tests are utilized.

Tools to Manage Utilization

"If clinical labs and pathology groups gathered and provided this information, it would enable health insurers to apply utilization management tools more effectively, rather than shooting first and aiming later," Zubiller explained.

Part Two of this Three-Part Series will provide detailed information about how several companies, including McKesson, are entering the marketplace with solutions designed to help health insurers, clinical laboratories, and physicians deal with payer requirements for pre-authorization, utilization management, and claims processing for genetic and molecular tests.

In Part Three, THE DARK REPORT will provide a case study of how **MuirLab**, in Walnut Creek, California, is responding to payer requirements for pre-authorization of expensive genetic and molecular testing.

Payers' Problems

This first installment has provided lab administrators and pathologists with an insider's understanding of the problems payers face in their efforts to bring the spiraling number of genetic and molecular tests under control. Laboratory leaders can use this understanding to craft an effective strategy for their lab organization.

THE DARK REPORT has been first in the lab industry to identify the trend of payer pre-authorization for genetic and molecular testing.

Order the Right Test At the Right Time

HEALTH PLANS AND LABORATORIES have an opportunity to align their efforts to support physicians ordering "the right test on the right patient at the right time."

"This can position clinical laboratories and pathology groups to make a major contribution," observed Matthew B. Zubiller, McKesson's Vice President of Advanced Diagnostics Management. "Labs can help support the rapid adoption and proper utilization of those genetic and molecular tests that have a significant impact on controlling medical costs.

"Diagnostic testing typically impacts 70% of healthcare decisions—including prescription of drugs, hospital inpatient admissions, and surgeries," he continued. "If labs can demonstrate appropriate utilization and decision support associated with how physicians order and use these lab tests, then labs can, in fact, partner with health plans to reduce the total cost of care."

Among the 2,000+ molecular tests now available, Zubiller estimates that most health plans can manage coverage requests and reimbursement for only a handful of them. Moreover, the genetic and molecular industry is growing at a rate of 15% to 20% annually. "To say that these tests are a growing problem for health plans is an understatement," declared Zubiller.

This important development presents clinical laboratories and anatomic pathology groups with an opportunity to collaborate with payers to deliver value—and be paid appropriately for that value. For that reason alone, this is an opportunity which every lab should want to pursue. TDR

Contact Matthew B. Zubiller at Matthew.Zubiller@McKesson.com or at 415-983-8505.

California Pathologist Wins Medi-Cal Pay Case

Judge's ruling overturns Medi-Cal finding that a lab medical director is liable for overpayments

CEO SUMMARY: It was a case that stretched back several years. Medi-Cal officials, wanting to pursue collection of what it deemed overpayments, claimed that the pathologist who was on the license of two defunct lab companies as medical director, was personally liable for the $6.37 million. An administrative judge had found in favor of Medi-Cal in this case. However, this ruling was overturned on appeal by another judge, who ruled that a medical director is not a "provider" as defined by law.

LAST YEAR, A CALIFORNIA JUDGE RULED against Medi-Cal, the state's Medicaid program, and in favor of a pathologist. The judge's decision ended what might be described as a case of regulatory over-reach.

Pathologist Kazuo Yamazaki, M.D., had filed a petition for administrative mandamus. This action came in response to a California Medi-Cal decision that found Yamazaki—as the medical director on the license of two laboratory companies—personally liable for repayment of more than $6.37 million that had been paid to those two now-defunct clinical laboratories. *(See TDR, November 10, 2008.)*

Had Medi-Cal regulators prevailed in this case, it would have established a precedent that any pathologist who was on a laboratory's license as the medical director could be held personally liable for any overpayments paid by the Medi-Cal program to that laboratory.

In Yamazaki's case, the money in question had been received by **Clinical Technical Laboratory** (CTL) and **Goodwill Diagnostic Laboratory** (GDL) as reimbursement for claims filed with Medi-Cal between 1999 and 2002. Medi-Cal later determined that there had been overpayments.

Medi-Cal auditors began precedings against the Los Angeles-based clinical laboratories in 2002, after Department sanctions had led to revocation of the labs' CLIA compliance certificates. Eventually, both laboratories ceased testing and closed their doors.

Lab Records Not Found

Months later, auditors were unable to locate any records that would substantiate the lab companies' original claims that were the source of the alleged overpayments. Auditors thus determined that all of the monies paid to the two laboratories should be repaid.

Medi-Cal officials then came up with an odd interpretation of the Business and Professions Code Section 1265. Rather than hunt down the owners of the defunct laboratory corporations, Medi-Cal officials decided to hold the labs' medical director personally liable to repay the money, which totaled $6.37 million.

In addition, Medi-Cal determined that, under their codes, Yamazaki could be considered a "provider" and therefore liable for the overpayments, even though none of the funds had been personally requested or received by the pathologist.

The case was significant because it set an important precedent that affects how Medi-Cal can pursue the recovery of overpayments to California clinical laboratories in the future. The judge ruled that Medi-Cal's decision to find Yamazaki personally liable for the funds simply because he had been the Laboratory Director during this period "lacked merit."

Never Got The Medi-Cal Money

In his decision, the judge stated that "Even if Yamazaki is a 'provider' within the literal meaning of Welfare and Institution Code section14043.1(o), ... Yamazaki cannot be held personally liable for overpayments that he never received."

The judge further stated that by "focusing on the definition of 'provider,' the Department neglects the underlying purpose of the statutes authorizing the Department to recover overpayments.

"An overpayment is a payment in excess of what is due," he wrote in his decision. "Or, in the context of Medi-Cal, the excess of the amount paid to a provider over the amount due that provider. The act of collecting or recovering an overpayment from a provider therefore connotes that the provider has been 'overpaid.' It follows that the Department cannot recover an overpayment from a provider unless the provider has *received* an overpayment.

"Since it is undisputed in this case that Yamazaki was not an enrolled provider and never received any Medi-Cal payments, much less overpayments, the Department abused its discretion in concluding that he is liable to repay the overpayments received by the laboratories."

With this ruling, the judge gave pathologists and other employees of California laboratories an important protection. If these individuals have not signed and submitted a provider agreement, and have not been assigned a provider number, then these individuals are not "providers" under California state statutes. The court ruling effectively prevents Medi-Cal from pursuing future overpayment cases in a similar manner.

It is worth noting that the original administrative judge who heard this case in 2006 did rule that Yamakazi was liable for the overpayment. That judge ordered Yamazaki to pay Medi-Cal the $6.37 million. Had this judgement declaring the pathologist—as medical director—personally liable for Medi-Cal overpayments, it would have made it more difficult in California for labs to recruit pathologists to be medical directors. TDR

California Medi-Cal Program Revisiting "Discounted" Fees

IN RECENT MONTHS, the California attorney general has settled with several of the seven laboratories named in a *qui tam* lawsuit laboratory companies that involves charges that the laboratories overbilled Medi-Cal, the state's Medicaid program.

One of the laboratories named in the lawsuit was **Westcliff Medical Laboratories** of Santa, Ana, California. As part of its Chapter 11 bankruptcy action last May, it entered into an agreement with the state attorney general to resolve the claims in the lawsuit. That agreement cleared the way for Westcliff to be acquired by **Laboratory Corporation of America**. *(See TDR, June 1, 2010.)*

Now there are rumors in California that a number of laboratories have gotten demand letters from Medi-Cal officials asking for repayment of certain amounts. This demand is based on Medi-Cal's determination that the lab had extended a cheaper price to certain physicians. Medi-Cal wants the benefit of that cheaper price. It is demanding that the subject lab charge Medi-Cal that same lower price.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Researchers at **North Carolina State University** are developing a method that might make it possible to diagnose and treat cancer through the use of special microneedles they developed. NCSU researchers use the microneedles to deliver nanoscale dyes based on quantum dots to locations under the skin. "Our findings are significant, in part, because this technology will potentially enable researchers to deliver quantum dots, suspended in solution, to deeper layers of skin. That could be useful for the diagnosis and treatment of skin cancers, among other conditions," stated Roger Narayan, M.D., Ph.D., Professor at NCSU's Biomedical Engineering Department.

ADD TO: *Microneedles*

The microneedles delivered a water-based solution containing fluorescent quantum dots into pig skin. Multiphoton microscopy was used to confirm how and where the microneedles delivered the quantum dots. This technology could contribute to more rapid diagnosis of cancers or other medical problems.

PHILIPPINE LABS MUST ACCREDIT TO ISO 15189

For those watching the global progress of ISO 15189 as the basis for laboratory accreditation and/or licensing requirements in different countries, the Philippines can now be added to the list. The Philippine Department of Trade and Industry (DTI) is requiring all medical laboratories in the nation to be accredited by The Philippine Accreditation Office (PAO) as meeting the requirements of ISO 15189:2007 Medical Laboratories.

TRANSITIONS

- **PrimeraDx** appointed Matthew McManus, M.D., Ph.D., to the position of President and CEO. Based in Mansfield, Massachusetts, **PrimeraDx** develops multiplexed, quantitative assays for molecular diagnostics. McManus was most recently the head of **Cleveland Clinic Laboratories** and COO of the Clinic's Pathology and Laboratory Medicine Institute.
- Eric Olson was appointed to be President of the **IVD Industry Connectivity Consortium** (IICC), a global non-profit organization that is dedicated to improving how *in vitro* diagnostic (IVD) analyzers connect with healthcare information technology (IT) systems. Olson will continue in his current position as Vice President of Informatics and eBusiness at **Siemens Healthcare Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 4, 2010.