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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

Lab Landscape Changing as ACOs Get Started

FOR THOSE OF YOU INTERESTED IN HOW the development of accountable care organizations (ACOs) in a community causes a realignment among providers and the clinical laboratories serving them, I offer you the example of **Genesis Health System** in Davenport, Iowa.

As you will read on pages 3-4, this five-hospital health system has just acquired the clinical laboratory assets that were owned by **Metropolitan Medical Laboratory, Inc.**, and were operated inside two of the Genesis hospitals. The owner of Metro Lab was a local pathology group that, not surprisingly, has service contracts and client relationships with many different providers in the Davenport metro.

What motivated the administrators at Genesis Health to change its long-standing contract relationship with Metro Lab was its need to more comprehensively integrate its clinical services and its operations. This is necessary to meet the needs of the multiple ACOs for which Genesis Health is a participant.

Among the reasons for the lab acquisition discussed by the laboratory administrator in our exclusive interview was the need for Genesis to achieve a more effective integration between its hospital information system (HIS) and the laboratory information system (LIS). Support for CPOE was one such requirement for the HIS/LIS integration at Genesis Health.

Another element motivating this acquisition was the fact that Metro Lab, like any good community laboratory company, was serving a wide range of providers within the community. However, this was sometimes putting it at cross-purposes with the interests of Genesis Health System.

Collectively, these are two reasons why Genesis wanted to own and operate the clinical laboratories in its two biggest hospitals. In my view, this lab acquisition represents an early marketplace example of how health systems will be paying closer attention to the role of laboratory testing in the operation of ACOs and how the ACOs deliver clinical services.

There are several hundred ACOs now launching clinical services. Administrators of these ACOs will be looking at lab testing services with the goal of improving patient outcomes and reducing the cost of care. Hospitals and the pathologists serving them are sure to be relating to each other differently because of the need for these ACOs to integrate clinical services. TDR

Hospital System Acquires Labs In ACO Strategy

Genesis Health acquires laboratory assets from Metro Lab to better integrate lab services

CEO SUMMARY: Moving to deliver services as an accountable care organization (ACO), Genesis Health System of Davenport, Iowa, has acquired the laboratory assets in two hospitals previously operated by Metropolitan Medical Laboratory, PLC, a lab company owned by local pathologists. Genesis aims to improve data integration to support CPOE. It also plans to pursue cost savings and economies of scale in the five hospital laboratories within its health system serving the Quad Cities area.

CONTINUING TO POSITION ITSELF to deliver more efficient healthcare, the **Genesis Health System** in Davenport, Iowa, is integrating the service elements needed to operate as an accountable care organization (ACO).

On July 1, Genesis, which operates the Genesis ACO, acquired the assets of clinical laboratories operated in two of its five hospitals in the Quad Cities area. The seller was **Metropolitan Medical Laboratory, PLC**. Genesis Health is a five-hospital system that also owns a 170-physician practice, along with other health care providers. It serves a 12-county region in Eastern Iowa and Western Illinois.

Genesis is hiring all 90 lab employees employed by Metro Labs in the two facilities. Metro Labs will continue to operate labs throughout Davenport, continuing a tradition that goes back to 1914 when the clinical lab services company was formed.

The 14 pathologists who currently work at all five Genesis sites will continue to serve as contractors providing laboratory directorship and pathology services through **Pathsource Diagnostics** and **Quad Cities Pathologists**.

"This lab acquisition positions Genesis Health to become part of accountable care organizations that are already operating," commented Keith Wachter, MT(ASCP), the Director of Laboratory Services for Genesis Health. "There are four important reasons to acquire the assets of these two labs.

"First, it will allow us to have better integration of patient data," he noted. "As part of our long-term strategy, we anticipate sharing data. That requires information to be interchangeable, as it should be in an ACO.

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"Although Metro Labs has its own freestanding laboratory information system (LIS) that is interfaced to our hospital information system (HIS), that interface is not ideal," noted Wachter. "As currently configured, the HIS has a limited ability to take full advantage of all of the capabilities of the LIS.

"Ideally, the HIS should be able to use the data from the LIS for decision support and it can't do that," he explained. "However, now that Genesis owns both the HIS and the LIS, we can format the lab data in a way that allows the two systems to interact in the best, most efficient way.

"The second reason we did this acquisition was to pursue further cost savings," stated Wachter. "After analysis internally and from two consulting firms, we believed there is the potential to run these two labs with modest savings. Ownership of these labs allows us to further standardize across the system and pursue more economies of scale in lab services across all five hospitals.

Retaining The Lab Business

"That leads to the third reason we did this deal," he continued. "We believe that by acquiring the assets of these two labs, we can retain the business within the Genesis system instead of contracting that business out to others.

"This strategy is part of a system-wide initiative—whether it's physical therapy, home care services, hospice care, or laboratory testing," continued Wachter. "We believe that keeping our service offerings inside the health system will serve us over the long term.

"Our fourth reason is to achieve better integration of clinical services," he said. "Now we will have a lab team dedicated to serving the Genesis Health System. Not that there was anything wrong with the previous arrangement, but by owning the assets of these two labs, everyone can work together to control test utilization and costs.

"Having said all that, an important part of this deal is our ability to maintain the long-term relationship we have had with the pathologists from Metro Labs," emphasized Wachter. "We anticipate that the new structure will allow us to work more efficiently with the pathologists on Genesis-related issues."

This lab acquisition is an early example of how many hospitals and health systems are expected to develop the integrated clinical services needed to support ACOs in their communities. TDR

—Joseph Burns

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Lab Acquisition Doubles Test Volume at Genesis

AS A RESULT OF A LAB ACQUISITION announced July 1, Genesis Health System of Davenport, Iowa, doubled its lab test volume almost overnight. Genesis has five hospitals serving patients in 12 counties in two states, and each hospital has a clinical lab.

"Metro Labs ran the labs in 252-bed Genesis Medical Center, East Rusholme Street, and at 174-bed Genesis Medical Center, West Central Park," noted Keith Wachter, MT(ASCP), the Director of Lab Services for Genesis Health System. "Genesis was already operating the labs in three facilities: 150-bed Genesis Medical Center, Illini Campus in Silvis; and critical access hospitals of 11 beds in DeWitt, Iowa, and 22 beds in Aledo, Illinois. All Genesis facilities are called Genesis Medical Center.

"Combined annual volume at the two Davenport hospital labs is about 800,000 billable lab tests," stated Wachter. "The volume at the Illini Campus in Silvis is 600,000 billable tests annually, and the two critical access hospitals do about 100,000 billable tests each per year. Therefore, the total lab test volume has doubled, going from about 800,000 tests to 1.6 million tests per year."

BlueCard Policy Causing Clinical Labs to Go Unpaid

Blues plans are sending payments to patients, but patients are not paying their lab providers

CEO SUMMARY: Clinical laboratories doing lab test work for Blue Cross Blue Shield patients using their BlueCard benefit are no longer being paid by the Blues plans. Some Blues plans are sending those reimbursement checks directly to their members with instructions for the patient to use those funds to pay their lab bills. Instead, most patients are keeping the money. This policy is having a particularly detrimental effect on labs that provide testing in support of pain management.

DURING 2012, the **Blue Cross Blue Shield Association** (BCBSA) implemented major changes in its long-established Blue Card program. Now the consequences of those changes are becoming visible. *(See TDR, July 16, 2012.)*

Clinical laboratories are reporting a number of unintended consequences as a direct result of the changes to Blue Card policies. In some cases, patients are being negatively affected by the implementation of these revised policies.

For decades, the BlueCard program was a simple and effective benefit for members of Blue Cross Blue Shield (BCBS) plans because it allowed members of one state BCBS plan to access care when they traveled or lived outside their home BCBS state.

Under the changes that went into effect in the BlueCard program in October 2012, regional Blue Cross Blue Shield plans have been issuing reimbursement for clinical laboratory tests directly to the patients. This happens when patients require lab testing and visit a physician outside of their home states for any lab work done on their behalf.

The theory behind this payment arrangement is that the patient will use those funds to pay the laboratory for those lab tests. But the unintended consequence is that many patients do not pay for their lab services after getting a check for such services from their Blues plans, sources told THE DARK REPORT.

Patients Keep the Money

Instead, the patients keep the money. This is particularly concerning for patients who have had drugs-of-abuse testing as physicians monitor their pain management treatment.

At one lab company serving the pain management market, a lab executive stated that the lab sees patients using the money issued to them by the Blues plans to buy drugs. Other labs report that their billing and collections departments are being told by patients that they have already spent that money on consumer products, vacations, or down payments on automobiles.

This situation was predicted last year by several clinical laboratory associations. It is a well-established fact that, when a

health insurer sends the patient a check for money that is meant to reimburse the provider, that provider's bad debt and collection costs skyrocket.

This affects clinical laboratories more than other providers. That is because, unlike a physician who physically sees the patient, laboratories generally have no direct relationship with the patient. This is particularly true when the specimen collection was done in a physician's office.

Pay The Patient Strategy

To be sure, this strategy of paying the patient is not uncommon. In the health insurance industry, it's called "Pay The Member" or PTM, a source told THE DARK REPORT. "Some larger health insurers use PTM according to the benefit design or at the request of the health plan's employer that is the plan sponsor," the source said.

What's new about the PTM strategy today is how the Blue Cross Blue Shield Association has expanded its use as part of the revised policies that took effect last October. These policies were broadly interpreted as an effort by the BCBSA to prevent network physicians from referring patients to out-of-network laboratories.

However, although PTM seems to have been around a while, reports are filtering in from a number of sources that other insurers are using "pay the member" more frequently than in previous years. It is said that **UnitedHealthcare** (UHC), **Cigna**, and **Aetna** are all using PTM more frequently.

One Way To Deter Leakage

One long-time industry observer confirmed these developments. "In 2004, UHC introduced this strategy in select markets," he stated. "At the time, the strategy was designed—as evidenced most recently by the BlueCard changes—to deter leakage to out of network services by forcing laboratory test providers to go to the patient for payment.

"However, in today's healthcare marketplace, there is a new reason to try to force physicians to use only in-network labs and that is the sharp increase in drugs-of-abuse testing," continued this individual. "Health insurance plans are seeing skyrocketing volumes of claims for lab tests associated with pain management. You can bet that health insurers want to force this PTM strategy on those lab companies serving the pain management market as a way to constrain that utilization." TDR

BlueCard Changes Do Impact Patients

IN RESPONSE TO THE NEGATIVE PATIENT IMPACT of the changes made last year to the Blue Card program, the **Center for Lawful Access and Abuse Deterrence** (CLAAD) in Washington, D.C. published an analysis of the situation.

In a recent article, "Insurer Efforts To Reduce Rx Abuse: Life Savers or Money Savers?" on CLAAD's web site (*www.claad.org*), CLAAD said, "Insurers like Blue Cross/Blue Shield and Cigna are experimenting with policies that restrict in-network coverage for lab services—like urine drug testing to verify abstinence or dosing compliance—to a single provider. All others are treated as out-of-network providers, leading to higher deductibles and co-pays, and greater paperwork hassle for patients."

The article explained that, because physicians do not collect payments for lab services, the BCBS plans have been paying patients directly for laboratory services, forcing the labs to collect from the patients.

"These policies award the contracted provider an effective monopoly by driving the non-contracted [lab test] providers out of the market," the CLAAD explained. "Meanwhile, patients trying to sustain a fragile recovery get something incredibly dangerous, an insurance check that should be used to pay medical bills but could otherwise be spent in a moment of weakness."

Report Shows Price Drop for Most Molecular Tests

Medicare contractors seem to be adopting prices developed and posted by Palmetto GBA

CEO SUMMARY: In recent weeks, labs are reporting that Medicare contractors have begun to issue payments for molecular test claims filed—but unpaid—since January 1, 2013. A newly-issued analysis of this situation by Quorum Consulting indicates that, for many molecular assays, Medicare contractors are now paying less than they paid for the same tests last year. In particular, the analysis shows that, for six of 10 common molecular pathology test CPT codes, rates are lower than labs were paid last year.

SOMETIMES, COUNTRY AND WESTERN SONGS have a way of simplifying the most complex issues. "It's All Over But the Crying," a song by Hank Williams, Jr., is an excellent example. The title alone applies quite well to the situation clinical labs face this year regarding payment for molecular pathology test codes.

A growing list of labs are reporting that Medicare contractors are beginning to send payments for molecular test claims filed under the new molecular CPT codes. However, the news is not good for the clinical lab testing industry.

Confirmation of this situation comes from a new analysis issued by **Quorum Consulting Inc.**, a strategic pricing, reimbursement, and health economics firm in San Francisco, California. Data gathered by Quorum from national reference labs show that—for six of 10 common molecular pathology test CPT codes—prices developed by the federal **Centers for Medicare & Medicaid Services** (CMS) are lower than the prices paid last year. The analysis also shows how one Medicare contractor raised preliminary gap fill payment rates on some tests after labs complained earlier this year.

Today (July 8) marked the end of the 60-day period that CMS allowed for labs to submit written comments on the rates proposed for 114 new molecular test codes introduced on January 1, 2013. Plenty of labs probably had much to say about how and why the new prices for molecular tests are too low.

Another source of major dissatisfaction is the fact that Medicare contractors classified an unexpectedly high number of these molecular tests as medically unnecessary. Such determinations mean that Medicare will not reimburse labs for these assays.

New Methods, New Rates

Now that payments are going out and the comment period is closed, the next step comes in September. That is when CMS releases its finalized pricing decisions. It will also begin setting rates for 2014, based on the prices it will release in September.

To set the rates for next year, each of the 114 new molecular pathology codes will be paid at the median of the final gap-fill rates that the Medicare Administrative Contractors (MACs) have determined this year, according to Jacqueline Huang of

Quorum Consulting. This national payment rate, established by the median of the final gap-fill rates, is called the national limitation amount or NLA. After CMS posts the final rates in September, a 30-day reconsideration period will begin, Huang added.

The 2014 rates will be set based on what CMS calls the national limitation amounts or NLAs, Huang wrote. Quorum Consulting prepared a table showing how the NLAs compare with the rates paid last year.

"If the proposed gap-fill rates are finalized with no changes, the table *(see sidebar at right)* identifies the corresponding NLAs for these tests in 2014. The table also identifies the associated payment rates for the 2012 code stacks billed by **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** for these tests," she wrote. "This analysis highlights the similarities and disparities between the historical payment rates and potential NLAs."

Prices Less Than Last Year

The table lists prices for 10 common CPT codes, including 81235, 81255, 81292, and 81243, which Huang noted are potentially lower than the rates paid to Quest and LabCorp last year under the previous code-stack payment rates. Also, Huang reported, "The calculated potential 2014 NLA for CPT 81243 demonstrates an 82% decrease in payment from Quest's historical code-stack and a 90% decrease in payment from LabCorp's historical code-stack."

For six of the 10 tests listed in the table, the NLAs have the potential to be about the same as what Quest and LabCorp were billing last year or is in the range billed by to the two companies, Huang wrote.

In its report, Quorum Consulting also addressed the role **Palmetto GBA** has played in the rate-setting process. Recognizing that Palmetto is one of the influential Medicare Administrative Contractors (MACs) and has the most experience in setting prices for molecular tests, many of the nation's MACs are adopting Palmetto's prices, Huang wrote.

Quorum Analyzes Regional Contractors' Proposed Gap-Fill Payment Rates

IN A NEW REPORT, QUORUM CONSULTING INC. compared current molecular test payment rates. As a baseline, Quorum used 2012 code-stack rates paid to Quest Diagnostics and LabCorp. and the potential rate for next year (columns 1, 2, and 3). For six of 10 common tests, rates next year will drop. Quorum also compared prices Palmetto posted in January with Palmetto's revised prices posted by CMS in May (columns 5 and 6). Except for CPT 81220 and 81243, Palmetto's gap-fill prices have increased since January or stayed the same for these common molecular tests. Also, Quorum Consulting noted in its report that Palmetto increased payment rates for at least one test (CPT 81225) by 136%, compared to the price it first posted earlier in 2013.

Potential 2014 NLAs compared to historical payment rates

Quest 2012 Code Stack Payment	LabCorp 2012 Code Stack Payment	Potential 2014 NLA
$259.10	$53.00	$97.45
$153.80	$248.76	$148.12
$75.88	$349.40	$192.15
$301.92	$533.48	$155.22
$212.64	$265.64	$235.00
$1,132.82	$1,174.62	$1,102.15
$378.82	$349.40	$108.45
$930.52	$2,147.96	$803.28
$183.22	$230.70	$187.42
$348.50	$637.49	$63.79

Comparison of Palmetto's initial to current rates

CPT Code	Code Descriptor	Initial Palmetto 2013 Gap-Fill Rate	Current Palmetto 2013 Gap-Fill Rate
81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (e.g., colon cancer), gene analysis, V600E variant	$57.51	$97.45
81261	IGH@ (Immunoglobulin heavy chain locus) (e.g. leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (e.g. polymerase chain reaction)	$148.12	$148.12
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *4, *8, *17)	$135.26	$319.12
81235	EGFR (epidermal growth factor receptor) (e.g. non-small cell lung cancer) gene analysis, common variants (e.g. exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	$116.25	$225.00
81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (e.g. carcinoma) gene analysis, variants in codons 12 and 13	$225.88	$246.40
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; common variants (e.g. ACMG/ACOG guidelines)	N/A[2]	$800.46
81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g. Tay-Sachs disease) gene analysis, common variants (e.g. 1278ins TATC, 1421+1G>C, G269S)	$93.90	$93.90
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g. hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	$803.28	$803.28
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g. alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (e.g, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha 4.2, alpha20.5, and Constant Spring)	$183.22	$183.22
81243	FMR1 (Fragile X mental retardation 1) (e.g. fragile X mental retardation) gene analysis; evaluation to detect abnormal (e.g. expanded) alleles	$123.00	$60.51

Source: Quorum Consulting

The table includes two sets of Palmetto rates. One set was posted early in the year. That is when clinical laboratories complained about how those rates were too low. Palmetto subsequently raised many of these rates, as the table shows. TDR

—By Joseph Burns

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Lab testing company was serving 900 urologists

Medicare Contractor's Ruling on MolDx Test Causes Lab to Close

CEO SUMMARY: On May 14, Predictive Biosciences learned that its Medicare contractor had determined that one of its three molecular tests for bladder cancer was a screening test. It also never got a determination on its other two molecular tests. Because Medicare is half of the lab's payer mix, and since the company was worried that private payers would follow Medicare's lead, its investors decided to close the laboratory and go out of business on May 31. This is one example of the disruption caused by the Medicare program's bollixed handling of the new molecular CPT codes.

FIVE MONTHS AFTER IT STOPPED getting payment for its molecular diagnostic test claims that were covered by the new molecular test CPT codes, **Predictive Biosciences** (PB) of Lexington, Massachusetts, closed its doors for good.

Its financial collapse was due to the mishandling of the new CPT codes by the Medicare program, according to the company's CEO. More than 10,000 patients are now without a test for bladder cancer as a result of a single non-coverage decision by one Medicare Administrative Contractor (MAC). Further, these patients will now likely undergo an invasive diagnostic procedure.

The big news across the clinical laboratory industry is how the Medicare program botched the implementation of the 114 new molecular test CPT codes that took effect on January 1, 2013. Now, six months later, some labs still await payment for some or all of the molecular test claims they have submitted since January 1. *(See TDRs, April 15, 2013 and May 28, 2013.)*

Two Disruptive Payment Issues

Further, Predictive Biosciences and other labs performing these molecular tests found themselves dealing with issues, one of which was more disruptive than simple non-payment. One issue involves prices posted by Medicare contractors that are lower by 40% or more than what was paid for the same tests in 2012 as code-stacked claims.

Another issue centers around determinations by MACs—and also possibly Medicaid programs and private health insurers—that many molecular tests are medically unnecessary. As a consequence, labs offering these tests are being asked to submit extensive documentation to support the medical necessity, including physicians' clinical notes.

For Predictive Biosciences, what turned out to be the lab company's financial death blow came when **CGS Administrators, LLC**, a Medicare Administrative Contractor, decided one of PB's three molecular assays was a screening assay. Medicare does not reimburse for screening tests.

Once CGS made its decision, Predictive Biosciences had no recourse. Without Medicare reimbursement, the company decided it could not continue to operate and closed on May 31, said PB's CEO Pierre Cassigneul.

Closure of this formerly growing lab company means that more than 900 urologists are unable to use this test and instead must now resort to invasive cystoscopy testing for their patients with bladder cancer. At the same time, a full time staff of 91 professionals was thrown out of work as a result of this negative coverage determination.

Lab Experts Warned Medicare

Many lab industry experts had warned the **Centers for Medicare & Medicaid Services** (CMS) that its failure to properly handle the transition from code-stacked molecular test claims to the new molecular test CPT codes that took effect on January 1 would have far-reaching consequences.

These consequences included disrupting physicians' access to useful molecular diagnostic assays and setbacks in patient care. It was also predicted that investors would cease providing both capital and the resources needed by molecular testing labs to advance molecular and genetic testing to support personalized medicine.

Several of these predictions proved true in the case of Predictive Biosciences. Its investors decided to close the clinical lab company after it learned of CGS's determination that one of its proprietary molecular tests did not meet medical necessity as defined by the Medical Director of the MAC.

"We had three tests for bladder cancer," explained Cassigneul. "These were the CertNDx Bladder Cancer Assays. One assay is used to diagnose bladder cancer, one is to evaluate and grade tumors, and one is for identifying recurrence of bladder cancer.

"All three tests were introduced at the end of 2011 and we have been commercializing them ever since," he continued. "There are 9,000 urologists in the United States. About 900 of them were using the tests. Medicare and private payers were paying us for running these tests."

Since 2011, the company had performed 36,000 tests and had a referral base of about 900 urologists nationwide who had used the tests for more than 10,000 patients. When it closed, PB was running 150 tests a day.

"After January 1, however, Medicare stopped paying for our tests, which was worrisome," observed Cassigneul. "We heard that the Medicare contractor had suspended payments until the new molecular testing codes and publication of the new payment amounts. We heard payment would be okay.

"But by the end of March, we still didn't have any payment from Medicare," he noted. "At that time, I attended a meeting in Washington and heard a representative from Medicare speak. I asked why PB was not getting paid and was told that Medicare had not instructed the contractors not to pay bills. Again, we considered that a positive sign that the non-payment situation would soon be resolved.

"Not long after that, we scheduled a conference call with our Medicare contractor, CGS, which covers our lab in Cleveland, Ohio," Cassigneul said. "On the conference call we were told that CGS had decided not to cover the test.

"This was a total surprise to us because, before this moment, they had never spoken to us and had never asked us for anything—no documentation of any kind!" he recalled. "There was no prior communication with anyone from CGS.

"After the call, we sent CGS a full set of peer-reviewed publications, along with information on how we validated our tests," added Cassigneul. "Unfortunately, we were told that the documentation we submitted didn't mean anything and that the test would remain uncovered.

"Officials at CGS said our test was a screening test," he stated. "It is relevant to also note that—whenever they referred to our three tests—they always called it 'our test' (singular), meaning that they reviewed only one of our three diagnostic tests. That was the specific test used by urologists to diagnose whether the patient has cancer or not.

"Keep in mind that this test is done *only* after there is a symptom, meaning blood in urine," continued Cassigneul. "But they did not agree to that logic and instead said it was a screening test.

"We asked for an explanation and on May 14 we received an email from CGS saying the test was a screening test and so was not covered," he noted. "But we have not received any communication on the other two molecular tests we offer.

No Explanation Given

"From a process standpoint, the May 14 decision by CGS was surprising," observed Cassigneul. "It had been reviewing these tests since January. Yet CGS made a determination that involved just one test and gave no explanation except to say it was a screening test. Our lab had performed this test for urologists for two years and clearly they were not screening tests.

"At that point, we asked what it would take to get a positive coverage decision," continued Cassigneul. "The medical director for CGS told us we would need to have new studies published in a peer-reviewed journal such as the *New England Journal of Medicine* (NEJM) or the *Journal of the American Medical Association* (JAMA). We would also need to have our molecular test written into the clinical guidelines.

"In response, we explained, that getting published in either of those journals and getting written into the guidelines would take years," he said. "We did point out that about 900 physicians were already using this test. CGS stood firm, however, and said that's what it would take to get a positive coverage determination.

National Reference Lab Saw Clinical Utility, Had Marketing Partnership with Predictive

EXECUTIVES AND PATHOLOGISTS at Predictive Biosciences were baffled when they learned that its Medicare contractor had determined that its molecular diagnostic assay for detecting bladder cancer was a screening test. Therefore, it would not meet medical necessity criteria and would not be covered.

The Predictive Bioscience's executive team learned of this decision just as it was announcing a marketing partnership with **ARUP Laboratories**, one of the nation's largest and more successful reference laboratory companies

Based in Salt Lake City, Utah, ARUP had evaluated Predictive Bioscience's tests. It had decided to offer the company's molecular diagnostic bladder cancer tests to its national network of hospitals, healthcare providers, academic medical centers, and military and government facilities around the country.

Under a non-exclusive agreement, ARUP clients could order the CertNDx tests, submit specimens, and receive all results through ARUP. Predictive Biosciences would perform the tests in its CAP and CLIA-certified laboratory in Cleveland, Ohio.

Karen A. Heichman, Ph.D., ARUP's Vice President, Oncology Technology Development and Licensing, said she was involved in the technical evaluation of Predictive Biosciences' tests and in developing the referral relationship.

"We reviewed the technology at the publication level and we spoke with the medical director," stated Heichman. "To us, it looked like the science was sound. These tests were designed to fulfill an unmet medical need.

"That's why it was surprising to learn that the lab testing company had gone out of business," she said. "Predictive Biosciences had hundreds of urologists ordering the test to avoid invasive procedures with cystoscopy.

"This is a great use of molecular testing that benefits patients," added Heichman. "It is important because there is a high incidence of recurrence with bladder cancer. Not having to do multiple repeat cystoscopies is a significant advantage to these patients.

"Plus, the CertNDx tests were not experimental," she explained. "There is clear utility with these tests. You can see that from the clinical uptake in the urology community. That uptake alone showed that the doctors thought it was a useful test.

"Keep in mind that urologists are physicians who normally do procedures," observed Heichman. "For them to utilize a molecular test in place of an invasive procedure shows that this molecular assay does provide something that is clinically useful to both the physician and the patient."

"We were absolutely taken aback by these criteria," recalled Cassigneul. "Our investors decided these requests were unreasonable. They also were concerned that even if we succeeded in getting these publications and guidelines, the reimbursement could be below our cost to run the tests.

"The investors at Predictive Biosciences recognized that it would take at least a couple of years to get articles published in those two medical journals," he said. "They could not afford to keep the product on the market without being paid. That was their concern: We couldn't continue to do the tests without payment.

"We have had several articles published in peer-reviewed publications and six of them were independent studies," explained Cassigneul. "But to get pub-

lished in a peer reviewed journal such as *NEJM* or *JAMA* would require very long and expensive studies and would take at least two years.

"Then there would be no guarantee of a positive determination after all this time and expense," he explained. "And, don't forget, during this entire time, Predictive Biosciences would not be getting paid. The financial position was just not practical.

Reaction of Private Payers

"Medicare represents half of our business," he said. "Virtually overnight, we discovered that half of the business disappeared and it would be a least a couple of years before we would have any hope of getting paid.

"In addition, we were concerned about how private health insurers would react," noted Cassigneul. "They usually follow Medicare on decisions like this. But our investors didn't want to wait to see what the private health plans would do. Thus, because we were losing money, the investors did not want to continue offering these tests with the uncertainty of what payers would do about our tests.

"That is a very tough business proposition," declared Cassigneul. "Given this situation, our investors decided they could no longer support the company.

"What made matters worse, we had no recourse," he added. "CGS is the Medicare contractor for Ohio and we have our lab in Cleveland. It's a CLIA-licensed and CAP-certified lab and because we operate a lab under CLIA, we have to bill the Medicare contractor where the lab is located.

"The most frustrating aspect of this whole situation is that we had one medical director at one Medicare contractor making a decision that one test should not be covered because he felt that the clinical utility had not been demonstrated," explained Cassigneul. "But, in fact, we have 900 urologists using this test routinely and they recognized its clinical utility in diagnosing their patients who showed symptoms consistent with bladder cancer."

Cassigneul discussed how the medical director at CGS had explained the non-coverage decision. "The medical director said hematuria is diagnosed in many ways and usually with a dipstick," he said. "The patient pees in the cup and then a strip is put in the cup. If red blood cells show up, it is positive.

"But since the dipstick tests are not considered very precise and accurate, the Medical Director estimated that the CertNDx test was used as a screening test," he explained. "But that is a specious argument because our test was penalized and it is not the dipstick test.

"We know that blood in the urine is one of the symptoms of bladder cancer," observed Cassigneul. "Yes, it is not exclusively a sign of cancer. But it is one symptom that is almost always present when the patient has bladder cancer.

"That's why it's absolutely crazy to say that our molecular assay was a screening test," he said. "Still, that's the reason given to us by CGS.

"In addition, there's another argument that we never got to make with our Medicare carrier before it made this determination," Cassigneul stated. "It is important and relevant to understand that urologists have the clinical option to do the more invasive cystoscopy and get reimbursed for that, in lieu of ordering our molecular test.

Convincing Urologists

"To change this standard of practice, with its fee-for-service aspect, we had to convince these physicians that our molecular assay is clinically useful," he noted. "In that regard, it was a high hurdle to convince urologists to use our test.

"Clearly they had to see some clinical utility from the test," stated Cassigneul. "That utility was that the test results gave them a clear decision about whether the patient had bladder cancer or not. It was a very actionable type of test.

"Also, patients loved it because it was noninvasive," he noted. "The alternative is

Predictive Biosciences Had Three Molecular Tests: All for Patients with Bladder Cancer

BLADDER CANCER IS MOSTLY a disease that affects older males with a history of smoking. Therefore, Medicare beneficiaries represented half of the patient population served by Predictive Biosciences, said CEO Pierre G. Cassigneul.

After two years, the company was gaining revenue and expected to be profitable next year, he said. "We had started to gain nice traction in the marketplace with our three CertNDx tests. Two of the tests are done with urine and one test is done with tissue.

"The first test is for patients who have blood in the urine, a condition called hematuria and a symptom associated with bladder cancer," said Cassigneul. "A patient gives a urine sample. Our molecular test provides the physician an answer that will be: very high negative, very high positive, or indeterminate. Even the indeterminate answer has a very high predictive value for either positive or negative.

"Our second test involves doing molecular analysis to evaluate the grade of the tumor," he continued. "The third test involves analyzing urine to indicate the predictive risk of recurrence. With bladder cancer there is a very high risk of recurrence and so patients have to be monitored every quarter for that risk.

"Since 2011, our investors collectively had put in $77 million," he said. The investors included **Flybridge Capital Partners**, **Highland Capital Partners**, **Kaiser Permanente Ventures** (the corporate venture capital arm of Kaiser Permanente), **New Enterprise Associates**, and **ProQuest Investments**."

cystoscopy which involves looking for cancerous lesions inside the bladder. This method is like looking for a dark spot in a dark room. It's a very difficult method to find lesions.

"By contrast, our test provides a systematic view about whether there is a lesion," he explained. "Based on the test results, only after the urologist knows there is a lesion, would the patient be subjected to cystoscopy.

"In addition to these frustrations, we were never able to get a clear answer from our Medicare contractor on anything except this one molecular test—yet we have three tests," added Cassigneul. "We asked CGS to provide us with a detailed answer about all three tests. However, all we received was one email about one test.

"None of this adds up. That's why it is so frustrating that this dynamic, growing company fell victim to one particular decision," observed Cassigneul. "And as much as we would like to get the company going again, we do not see how at this point. The studies and publications were sufficient to convince 900 urologists. But if what we have done so far is not enough to convince the MAC medical director, then I don't know what else to try."

The result is that the $77 million investment at Predictive Biosciences will be for naught. In January, although the company was not yet profitable, it was projecting that 2013 would be its best year.

"We had revenue of $1 million at the end of 2011 and that increased to revenue of $4.2 million in 2012," explained Cassigneul. "We were on track to meet our projections to earn revenue of $14.5 million in 2013. In 2014, we expected to achieve our first breakeven and move into the black." TDR

—Joseph Burns

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Managed Care Update

Aetna Threatens to Expel Docs for Out-of-Network Lab Referrals

In letter, insurer reminded in-network physician that Quest Diagnostics Inc. is Aetna's "national preferred lab."

MANAGED CARE PLANS are taking aggressive steps to keep clinical lab testing within their preferred networks. In particular, **Aetna, Inc.**, is earning a reputation as one of the toughest insurers in this regard.

Most recently, in a letter sent to at least one network physician, Aetna warned the physician that, if the doctor continued to refer patients to out-of-network labs, Aetna would take actions against the physician that may include exclusion from participating in Aetna's network.

Signed by Richard J. Gentleman, Aetna's Regional Network Operations Head, the letter also said that the physician in question received a similar warning last year. This is the "second and final notice," Gentleman wrote.

Out-Of-Network Referrals

"In April 2012, we sent a letter requesting that your practice stop referring our members to out-of-network labs," the letter said. "Our claims data shows that this has not happened. The rate your practice refers our members to out-of-network labs has not changed since our initial letter.

"Your patient—our members—pay much more out of pocket when they use out-of-network providers, including labs," he wrote. "Therefore, we again ask that your practice refer our members to in-network providers. Failure to do so will result in one or more of the following actions:

1. *Notice to our members in our DocFind online provider directory. The notice will state that you regularly refer to out-of-network providers, resulting in potentially much higher out-of-pocket costs for your patients.*
2. *A request for an amendment to your agreement.*
3. *The end of your participation with us."*

One way to interpret Aetna's motives in sending this letter to a physician is that the insurer continues to see a significant volume of lab tests go out-of-network. This means that Aetna's joint marketing efforts with its national contract laboratory, **Quest Diagnostics Incorporated**, has failed to persuade certain physicians to stop using out-of-network laboratories.

Assuming that assumption is correct, then Aetna's latest letter could be a sign that, independent of the price of a lab test, some physicians believe they get better service by using an out-of-network laboratory. This marketplace reality is not often discussed publicly by the large health insurers, as it would be an acknowledgement that price is the primary factor when they select their in-network laboratory providers.

In May, THE DARK REPORT reported on a letter Gentleman sent to clinical laboratories saying Aetna would cut the prices it pays for lab tests to a level that is substantionally below Medicare prices, effective July 1. At that time, Aetna spokesman Ethan Slavin said, "We routinely assess our network adequacy and costs by locale or region and adjust as necessary. Our job is to negotiate affordable rates for our members." *(TDR, May 28, 2013.)* TDR

Dark Index

PathCentral Launches Sale of New Anatomic Pathology LIS

Cloud-based software service designed to meet the needs of large and small pathology groups

THERE IS A NEW PLAYER in the market for anatomic pathology laboratory information systems (APLIS). This gives pathology groups a new option when it is time to upgrade or replace their existing APLIS.

It also brings a new competitor into the existing market for anatomic pathology (AP) software. In recent years, the dominant players in that market have been three products. One is **Cerner Corporation's** CoPathPlus. The other two are sold by **Sunquest Information Systems, Inc.**, and are named Sunquest CoPathPlus and Sunquest Powerpath.

On May 28, **PathCentral** of Irvine, California, announced the availability of its APLIS in two versions. Its full-featured product is called AP Anywhere. For smaller pathology groups, PathCentral offers AP Anywhere Express, which it says is a basic system designed to meet the needs of pathology groups with as few as one or two pathologists.

Cloud-Based AP Software

What will be noteworthy for pathologists are two facts about PathCentral's software offerings. First, AP Anywhere is already in use at a number of well-known national pathology companies. Second, this is the only APLIS to offer TC/PC (technical component/professional component) split and it's available as SaaS, or software-as-a-service.

"Because they are cloud-based software offerings, AP Anywhere and its smaller brother—AP Anywhere Express—has certain advantages over client-server software," stated Jaye Connolly, CEO of PathCentral. "One such benefit is that our SaaS service facilitates work on tablets and iPads. This allows pathologists to work literally anywhere."

PathCentral believes its biggest market opportunity is to sell to smaller pathology groups. Of the nation's approximately 3,300 pathology groups, more than 60% are comprised of four or fewer pathologists.

Small Pathology Groups

Small pathology groups have limited capital to invest in software, for example. They also do not need an APLIS that has all the features, functions, and interfaces required by larger pathology groups that may be serving multiple hospitals and a large number of office-based physician clients.

"With continued reimbursement cuts, pathologists in small or start-up practices want a system they can use to grow their outreach business," observed Connolly. "Typically they have contracts with a community hospital and will serve a number of their own clients, which can include specialist physicians such as oncologists and dermatologists.

"AP Anywhere Express was specifically designed to meet the informatics needs of these smaller pathology practices," she continued. "They don't have to invest any capital up front to buy a software system and, as a cloud-based, standalone APLIS, it can immediately be

operational without the need for installation or interfaces with other systems.

"The two cloud-based versions of AP Anywhere have all the same functionality of the client-server version of APLIS that all the larger labs have run for 14 years," Connolly explained. "Thirteen of the top labs in the United States currently use the client-server model of our AP Anywhere.

Long Pedigree in Market

"Those larger pathology lab companies include **Agendia**, **Avero Diagnostics**, **Clarient**, **Genoptix**, **Genzyme, Neogenomics,** and **US Labs**, among others," she said. "While the client-server version works for these companies, software is shifting to the cloud because the SaaS-based versions are easier for customers and software vendors to maintain.

"The cloud-based version of our APLIS is AP Anywhere," explained Connolly. "The smaller version of AP Anywhere is AP Anywhere Express. The difference between the two cloud-based versions is that AP Anywhere Express has fewer modules and is about half the price.

"AP Anywhere Express has many of the same features of AP Anywhere but they are not activated unless the pathology group needs them," she continued. "The express version has modules for accessioning, billing, cytology, management reporting, and surgical. Most small pathology practices only need those five modules.

"The surgical module includes grossing, histology, professional, and transcription," Connolly noted. "A subscription to the surgical module includes those four capabilities."

New Pathology Capabilities

The arrival of a cloud-based APLIS shows how technology can provide new clinical and service capabilities to pathology groups with just a few pathologists. In that sense, PathCentral is building a solution that helps level the playing field for community pathologists. It is providing technology that supports new and different ways for small pathology groups to deliver added-value anatomic pathology services that generate significant revenue. TDR

—By Joseph Burns

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PathCentral Bought Firm With Pathology Software

It was an acquisition of a pathology software company that brought PathCentral into the pathology informatics business. That happened in 2010 when the company acquired **eTeleNext**.

Founded in 2002, eTeleNext was described as "a developer of anatomic pathology systems for the national reference laboratory marketplace."

"PathCentral's strategy was to develop a robust pathology information technology platform that would be based in the cloud," stated Jaye Connolly, CEO at PathCentral. "This software would provide community pathologists with a robust lab information system while at the same time enabling PathCentral to create a professional network that allows pathologists to participate in on-line consulting from anywhere in the world.

"Community pathologists should have the same opportunities to develop their business as larger labs," she continued. "Our professional network was created with the goal of giving them a way to refer cases for subspecialty consultation or offer subspecialty services to other pathologists within the network and generate revenue from these activities.

"Digital pathology images make this easy to accomplish," added Connolly. "When combined with cloud-based services, community pathologists have an opportunity to generate revenue from a variety of sources while still fulfilling their mission to serve the community where they are located."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In China, independent clinical laboratories are in a fast-growth mode. That's the conclusion of **RnRMarketResearch** in a newly-issued survey of the clinical laboratory testing market in China. It estimates this market segment at US$407 million annually. RnR says that three lab companies meet the definition of "large-scale chain-store clinical laboratories." They are **KingMed Diagnostics**, **Adicon Clinical Laboratories**, and **Dian Diagnostics**.

MORE ON: *China*

With lab testing growing at aggressive rates in China, this country has become an important market for *in vitro* diagnostics (IVD) manufacturers. Growth in the Chinese market helps IVD companies offset the slower revenue growth they are seeing in North America and Europe. Labs in these regions are encountering shrinking budgets for lab testing even as utilization is increasing.

ROCHE ACQUIRES CONSTITUTION MED

Roche Holding announced that it would pay approximately $220 million to acquire Constitution **Medical Investors** (CMI) of Westborough, Massachusetts. CMI has developed a hematology instrument system it calls "Bloodhound." The company describes its product as combining "a digital morphologic analyzer, cell counter, and classifier into a single instrument that makes and stains its own slides." CMI was funded by **Warburg Pincus** and founded by Patrick Sullivan and Daniel Levangie, both former executives of **Cytyc Corporation**.

TRANSITIONS

- Robert E. Degnan was appointed as the President and Chief Operating Officer of **Sysmex Canada, Inc.** He will continue in his existing role as Vice President of Commercial Operations for **Sysmex America, Inc.** Degnan formerly held executive positions at **Roche Diagnostics**, where he worked for 23 years.

- **Atossa Genetics, Inc.**, of Seattle, Washington, appointed Michael H. Kalnoski, M.D., as Medical Director. Kalnoski was formerly with the **Puget Sound Institute of Pathology** and has held medical directorships with several hospitals, **PacLab**, and **Quest Diagnostics Incorporated**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 29, 2013.