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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

Of 88305-TC and Other Bad News for Pathology Labs

BY NOW, VIRTUALLY ALL PATHOLOGISTS ARE AWARE of the announced cut in Medicare reimbursement for the technical component (TC) of CPT 88305. Effective on January 1, 2012, Medicare will pay 52% less for this CPT code.

From the prior level of $69.78, the new reimbursement will be $33.70. As news of this development rippled across the anatomic pathology profession in recent weeks, a variety of comments surfaced.

Pathologists and their practice administrators are attempting to determine what financial impact this lower reimbursement will have on their laboratories going forward. Wall Street analysts want to understand which lab companies will be the winners and the losers as a consequence of this draconian reduction in an important pathology CPT code.

The bad news about 88305-TC comes on the heels of this summer's decision by Medicare carrier **Palmetto GBA** to implement a new policy governing Medicare claims for prostate cancer biopsies. The new policy represents about a 50% reduction in reimbursement for a 12-core prostate biopsy. *(See TDR, August 27, 2012.)* Of course, to these reimbursement cuts must be added the expected reduction in Medicare Part B Clinical Laboratory Fees for fiscal year 2013. When all the formulas are calculated, the overall Part B fee cuts will total about 5%.

These developments call to mind an important point that our Editor, Robert L. Michel, has been making in his public presentations. He notes that, whenever there is not enough money available to pay for healthcare, government health programs do one or more of three things:

1) Pay less to providers.

2) Restrict access via guidelines.

3) Refuse to cover new and/or expensive health services, drugs, lab tests.

Thus, we can see all three dynamics at work in recent years as they pertain to clinical lab and pathology testing. Reduction in fees for 88305 and Medicare Part B lab testing is number one above. The new policy guidelines for Medicare prostate biopsy claims involve restricting access is number two on Michel's list. The fact that Medicare is only now working to implement 100 new molecular CPT codes after years of feet-dragging illustrates principle three above. My prediction is that we are seeing the front edge of more and deeper Medicare cuts yet to come, using the three approaches listed above. TDR

First-Mover Labs Reveal Success with Lean & QMS

Timing aligns with Institute of Medicine's call for all providers to become "continuous learners"

CEO SUMMARY: There is good news for those clinical labs and pathology groups currently operating robust Lean, Six Sigma, and process improvement programs. The Institute of Medicine's new report calls for all healthcare providers to rapidly transform themselves into 'continuously learning' organizations. These developments met with a welcome reception at the recent Lab Quality Confab, where pathologists and lab administrators discussed their labs' innovations.

IT SHOULD BE BIG NEWS in the lab industry that the **Institute of Medicine** is calling for all healthcare providers to become "continuously learning" organizations. For early-adopter labs and pathology groups, this creates an opportunity for them to gain competitive advantage over their slower-moving peers.

The Institute of Medicine (IOM) issued this recommendation on September 6, 2012. That is when it publicly released its latest report, titled "Best Care at Lower Cost: The Path to Continuously Learning Health Care in America."

Authors of the IOM report state that the American healthcare system will not meet the challenges of increased clinical complexity and the skyrocketing cost of healthcare unless it radically changes the status quo. Specifically, the IOM says that healthcare providers, including clinical labs, must become much faster at identifying useful technologies and innovations outside healthcare and adopt them with deliberate speed.

Authors of the IOM report wrote that "Achieving higher quality [health]care at lower cost will require fundamental commitments to the incentives, culture, and leadership that foster continuous 'learning,' as the lessons from research and each care experience are systematically captured, assessed, and translated into reliable care."

The IOM also wrote "Americans would be better served by a more nimble healthcare system that is consistently reliable and that constantly, systematically, and seamlessly improves."

This new call to action by the IOM was acknowledged by speakers at the

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

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Sixth Annual *Lab Quality Confab* that took place earlier this month in San Antonio, Texas. "The timing and direction of this important new report by the Institute of Medicine is deliberate," stated Robert L. Michel, Editor-In-Chief of THE DARK REPORT during his keynote address at *Lab Quality Confab*.

"Healthcare policymakers at the IOM are admitting that the pace of innovation within the American healthcare system is inadequate and needs immediate redress," he stated. "Lab executives and pathologists should not ignore this new call to action by the IOM. Instead, they should obtain a copy of this report and incorporate its recommendations into their lab's strategic planning process."

In calling attention to the importance of the IOM's new report, "Best Care at Lower Cost," Michel reminded the *Lab Quality Confab* audience of how the IOM's 1999 report "To Err Is Human" signaled a major policy shift that continues to the present time.

Policy Recommendations

"Both 'To Err is Human' and 'Crossing the Quality Chasm: A New Health System for the 21st Century' which IOM published in 2001, contained policy recommendations that unleashed powerful forces of change that continued into the present," observed Michel. "As one example, think of how accreditation guidelines evolved to require hospitals and other providers to measure patient satisfaction, then demonstrate improvement in these measures over a defined period of time.

"However, most of us would acknowledge that, even within progressive hospitals and physician practices, substantial cultural and institutional barriers still act to slow down the pace of innovation and change," he continued. "A careful reading of 'Best Care at Lowest Cost' reveals that the IOM predicts failure of the American healthcare system if it continues on its current trajectory.

"On the other hand, there is time and opportunity to turn this around," added Michel. "The IOM makes the argument that hospitals, physicians, and other providers must develop an organizational culture of innovation and a willingness to go outside healthcare to identify new technologies and new management methods.

Medicine's Complexity

"Only then does the IOM believe the American healthcare system will be able to cope effectively with the growing complexity of medical care and the demand for health services that already exceeds the capacity of the system to meet this demand," emphasized Michel.

It is Michel's view that the IOM's new report is intended to cause a fundamental change in the management mindset of all providers, large and small. "Traditionally, hospitals and physicians have been slow to adopt new technologies and new management models that have already gained wide acceptance by other major industries," he observed. "By issuing this report, the IOM is attacking that status quo."

These newest calls to action by the Institute of Medicine will be considered good news by any hospital or laboratory organization that currently has Lean and process improvement programs in place. These providers are already moving down the path of continuous improvement.

Looking Outside Medicine

Further, these clinical labs and pathology groups actively go outside healthcare to identify "best practices." They want to incorporate these "best practices" to meet the challenges of improving clinical quality while reducing and eliminating errors.

One example of going outside laboratory medicine and healthcare was presented at *Lab Quality Confab* by keynote speaker Richard J. Zarbo, M.D., D.M.D. He is Senior Vice President and Chair of Pathology and Laboratory Medicine at **Henry Ford Health System** in Detroit,

Michigan. There are four acute care hospitals and 32 medical centers in this health system.

The theme of Zarbo's presentation was the adoption of single piece/small batch workflow in histology and surgical pathology at Henry Ford Health. His pathology lab handles 80,000 surgical pathology cases and 85,000 cytology cases each year.

Zarbo's laboratory team is using the work principles first described by Henry Ford, and the management principles of W. Edwards Deming, known as the "Henry Ford Production System." These were the methods that inspired Taichi Ohno, of **Toyota Motor Corporation** and resulted in Toyota's just-in-time (JIT) and Lean manufacturing successes.

The Lean journey for anatomic pathology at Henry Ford Health began in 2004. It is now in its eighth year. During his presentation, Zarbo showed the specific steps the lab team took to reduce the number of steps between accessioning and case sign-out by 31%—with equal gains in the reduction in average turnaround time, reduction of errors, and improvement in quality.

Vacuum-Sealing Tissue

But what caught the full attention of the audience at this year's *Lab Quality Confab* was how the Henry Ford pathology department went outside of healthcare to borrow the technology used to vacuum-seal food and apply it to vacuum-sealing tissue specimens at the point of collection.

"What does Kielbasa sausage, pathology staff safety, and pre-analytic tissue specimen quality have in common?" asked Zarbo during his presentation. He then showed a photo of a vacuum-sealed package of Kielbasa sausage as is commonly found in a supermarket. Next to this was a photo of a colectomy tissue specimen, also in a vacuum-sealed plastic bag.

Zarbo had a ready answer to his question. "By having the surgical team vacuum-seal and refrigerate the tissue specimen before transport to the pathology laboratory, we are reducing the use of formalin, widely-acknowledged to be a dangerous chemical," he pointed out. "Reduced exposure to formalin makes it safer for staff working in operating rooms and in histology."

Zarbo also noted that there are direct cost savings that result from using vacuum-sealing for tissue specimens. "By not using formalin at all, we save money for those specimens," he said. "Also, we can use much smaller amounts of formalin within the vacuum-sealed tissue container should it be necessary to use formalin with a tissue specimen."

The other innovation happening with the pathology laboratory at Henry Ford Health is the use of rapid, formalin-free microwave processing. This allows the lab to produce a continuous flow of small batches of processed specimens. It also means that the tissue, because it is preserved, can be used for molecular and genetic testing.

ISO 15189 Accreditation

There were several sessions at this year's *Lab Quality Confab* on the topic of ISO 15189 and how its quality management system (QMS) provides a more effective foundation for ongoing continuous improvement in the laboratory organization.

For example, keynote speaker Kathy McCloy, the Quality Assurance Director at **Laboratory Corporation of America**, discussed the lessons learned from implementing CAP 15189 across five different lab testing facilities. In fact, LabCorp is further along in its understanding and use of 15189's QMS than any other public laboratory company in the United States.

Another laboratory which recently earned accreditation to ISO 15189 is **Nationwide Laboratory Services**, based in Ft. Lauderdale, Florida. Marvin Lessig, M.D., Medical/Laboratory Director, provided insights into how adoption of the QMS is helping the lab staff establish an organizational culture of continuous

improvement. This directly contributes to improved workflow, better quality, and reduced costs. There are additional benefits that accrue from the reduction and elimination of errors, as well as enhanced morale and greater productivity of the laboratory staff.

➤'Continuous Learning'

From THE DARK REPORT'S perspective, there are additional threads that connect the Institute of Medicine's call for "continuous learning," a growing interest in adopting a QMS by hospitals and other providers (via ISO 9001 certification, for example), and the need by healthcare regulators for better tools to ensure the safety and quality of medical care in this nation.

Take the statements of the **Food & Drug Administration** (FDA) about its interest in regulating laboratory-developed tests (LDT). Since the early 1980s, the FDA has required medical device manufacturers to follow good manufacturing practices (GMP).

GMP and QMS are close relatives. Thus, it is reasonable to speculate that one way that the FDA could establish an acceptable regulatory framework for LDTs would be to incorporate a QMS, like ISO 15189, into whatever final regulations it promulgates. After all, in making such a decision, the FDA would have the credibility of the fact that ISO 15189 has been chosen by a steadily growing number of countries as the basis for medical laboratory accreditation and/or licensure.

➤IOM Puts Down A Marker

That is not to overlook the most important development. The Institute of Medicine has put down its latest marker by publishing "Best Care at Lower Cost." This is the newest attempt to change health policy and motivate all providers—including clinical labs—to adopt the principles of "continuous learning." This is another powerful reminder that labs would be well-served to adopt Lean and similar management methods sooner rather than later. TDR

Institute of Medicine Lists Sources of "Poor" Healthcare

IN ITS LATEST REPORT, the Institute of Medicine (IOM) provided examples to highlight the service and performance gaps within healthcare, compared to non-healthcare industries that have been much faster to be innovative and adopt new technologies.

Below is a partial list of items that the IOM provided as examples to show how far behind the American healthcare system is, compared to other industries:

On use of information technology...

- 20% of patients reported that test results or medical records were not transferred from one place to another in time for an appointment.
- 25% of patients said their healthcare provider has had to re-order tests to have accurate information for diagnosis.

On managing complexity...

- 229 other doctors are involved in treating the average primary care physician's Medicare patients.

On making healthcare safer...

- 1/3 of hospitalized patients are harmed during their stay.
- 1/5 of Medicare patients are re-hospitalized within 30 days.

On improving transparency...

- 63% of patients don't know how much their care costs until they receive their bill.

Promoting teamwork and coordination...

- 50% of adults report problems with care coordination, notification of test results, and communication among their doctors.

Partnering with patients...

- Less than half of patients receive clear information on the benefits and the trade-offs of treatments for their conditions.

Decreasing waste, increasing efficiency...

- 1/3 of healthcare expenditures—an estimated $750 billion—don't improve health.

OURLab Founder Lays Out New Business Strategy

Fundamental changes in lab marketplace trigger move to merge lab company with OPKO

CEO SUMMARY: For OURLabs of Nashville, Tennessee, it was the host of changes in the lab testing marketplace that motivated it to go looking for a partner. Its recently-announced merger with OPKO Health, Inc., of Miami, Florida, creates opportunities for OURLab pathologists to do more in therapeutics and pharmaceutical development. OURLab will also be able to leverage its sales force to sell OPKO's proprietary diagnostic tests, including a test panel designed to detect prostate cancer.

THERE'S A NEW BUSINESS STRATEGY at **OURLab** of Nashville, Tennessee. It's the reason the pathology lab company entered into an agreement to merge with **OPKO Health, Inc.**, of Miami, Florida.

On October 19, OPKO issued a press release announcing "an Agreement and Plan of Merger" with **Prost-Data, Inc.**, the owner of OURLab. Through a series of mergers, Prost-Data/OURLab will become a "direct wholly owned subsidiary" of OPKO, a public company (NYSE: OPKO).

The parties announced that OPKO would pay $9.4 million in cash, and $30.6 million in shares to Prost-Data. The deal is expected to close by year's end.

To learn more about the details of this transaction, THE DARK REPORT caught up with Jonathan Oppenheimer, M.D., the founder of **Oppenheimer Urologic Reference Laboratory** (OURLab). He discussed the business strategies which led to the agreement to merge with OPKO.

"The market for lab testing services has changed dramatically since OURLab was founded in 1996," noted Oppenheimer. "In response to these changes, there was an increased need for us to find a partner.

"This merger is important for OURLab because it creates the opportunity to use our existing resource base in three new ways," he explained. "First, because of proprietary diagnostic and therapeutic technologies at OPKO Health, our clinicians will be engaged in activities that go beyond laboratory medicine and pathology.

New Growth Opportunities

"Second, it leverages our sales force by giving them more products to sell," noted Oppenheimer. "Third, in addition to our work in diagnostic medicine, we can now get involved in the development of pharmaceuticals, which is a fast-growing area of medicine today."

Post-merger, Oppenheimer, currently CEO of OURLab, will become CEO of OPKO's diagnostics division. Oppenheimer cited fundamental changes in the lab testing marketplace as contributing to the strategic decision to find a partner.

"As medical professionals, our primary responsibility is to patients," he said. "We can't serve patients if we are not taking care of the bottom line of our business.

"In a business, the first obligation is to make a profit and that is where medical providers have a built-in conflict," he added. "As a physician, you shouldn't profit at the expense of your patients. You should profit by helping your patients. People want to pay for clinical value and this merger allows us to do that.

"Frankly, I don't know how any private lab company today can avoid being bought up by bigger lab companies or hospital systems," Oppenheimer said. "The big box lab companies such as **Laboratory Corporation of America** and **Quest Diagnostics Incorporated,** are very good at winning exclusive managed care contracts. They are so good at acquiring contracts that it's difficult to compete against them.

"The deeply-discounted pricing offered by these lab companies to win and hold their managed care contracts is one reason why so many payers view the work of laboratories as a commodity," he added.

Hospitals Are Buying Labs

"Another reason lab medicine is a difficult business today is that hospitals and hospital networks are buying private labs and physician practices," said Oppenheimer. "Because those lab specimens now go to the hospital system, that cuts the supply of specimens on which private national labs depend."

Oppenheimer acknowledged that the change in reimbursement for prostate biopsies in seven states served by Medicare contractor **Palmetto GBA** is just one more example of how the lab marketplace is changing. (*See sidebar this page*).

"OURLab has not seen a decrease in the number of biopsies it does or in the number of vials from this policy," noted Oppenheimer. "But it has seen a downward trend in revenue from those biopsies as a result of this new policy. And it's likely that this policy is being felt more severely at the urology groups that operate in-office pathology labs."

Change in Prostate Biopsy Billing Affects Claims

ONE REASON LABS may be seeing reduced reimbursement for prostate biopsies is a change in policy that Palmetto, GBA, announced in August. The nation's largest Medicare contractor, Palmetto serves seven states: California, Hawaii, Nevada, North Carolina, South Carolina, Virginia, and West Virginia. (*See TDR, August 27, 2012.*)

Effective August 7, Palmetto limited the number of prostate biopsies that may be reported for CPT code 88305 to four services. To report five or more prostate biopsies, providers must use G0416 with one unit of service. The effect of this policy is to cap reimbursement for a 12-core prostate biopsy at about 47% of its former level.

"Pathology labs that have operations in jurisdictions that Palmetto serves have definitely been affected," said Joe Plandowski, Co-founder of **In-Office Pathology** of Lake Forest, Illinois. "That policy was implemented in August, which means that labs billed for prostate testing under the new rules in September. So it is only in recent weeks that labs would begin getting their rejection notices. It is likely that labs in those seven states probably had a decrease of about 50% in Medicare revenue from prostate biopsies."

OPKO has a proprietary assay called the 4Kscore test that may eventually cause a decrease in prostrate biopsy testing, added Oppenheimer. OPKO launched this test in Europe. It is used to predict the probability of positive biopsies in men suspected of having prostate cancer. OPKO believes it could reduce the number of unnecessary prostate biopsies by 50% or more. This would benefit patients but would reduce lab revenue because of the need for fewer biopsies. TDR

—By Joseph Burns

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Lab Market Update

BRLI's Spanish-Language Lab To Serve Hispanic Americans

2010 census tallied 50.5 million Hispanic Americans and BRLI's new lab division wants to meet their needs

THIS MONTH, **Laboratorio Buena Salud**, a new division of **Bio-Reference Laboratories Inc.** (BRLI), becomes the first national laboratory for Spanish-speaking patients.

BRLI, of Elmwood Park, New Jersey, says that all services will be customized to the Hispanic community and business will be conducted in Spanish. This includes patient and physician interactions. This is a smart business strategy for three reasons.

First, the Hispanic population in the United States is large and growing. Second, implementation of the Affordable Care Act means thousands of previously uninsured Hispanic Americans will soon have access to health insurance. Third, a minimal investment is required for BRLI, as a traditional clinical lab, to begin serving these patients.

Large, Growing Presence

In 2010, the U.S. Census reported 50.5 million Hispanic Americans in the United States. At 16.3% of the population, this is the nation's largest ethnic or race minority. By 2050, there will be 132.8 million Hispanic Americans, or about 30% of the population.

"Laboratories are not bricks and mortar," explained Marc D. Grodman, M.D., BRLI's President and CEO. "Labs are defined by the markets they serve and by their client service staff, sales and sales support professionals, and customer service representatives. To serve a Spanish-speaking population, we recruited and trained Spanish-speaking staff members.

"With this staff, we can offer Laboratorio Buena Salud as an Hispanic-first service in areas around the country where there are large Spanish-speaking populations," continued Grodman. "This includes Arizona, California, Florida, New Jersey, New York, and Texas.

"Our support staff now includes 30 Spanish-speaking customer service representatives," he said. "This lab's website is in Spanish, including support for online ordering and reporting. Patient education materials and results reports also are in Spanish.

"The other key element of this strategy is that we are now a bilingual laboratory," continued Grodman. "Those patients using BRLI, GenPath Oncology, and GenPath Women's Health can speak to us in Spanish or English.

"As a service business, we should be sensitive to the needs of Hispanic Americans," he commented. "In many places, health plans, physicians, and other providers are already dedicated to serving Spanish-speaking patients.

"As a clinical laboratory, we want to become an integral member of these communities and make it convenient and comfortable for Spanish-speaking individuals and families to take care of their clinical testing needs," concluded Grodman. TDR

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Regional HIE links hospitals and physicians

Memorial Hermann's Health Info Exchange Helps Lab Outreach

CEO SUMMARY: In Houston, Memorial Hermann Healthcare System has put together a health information exchange (HIE) to serve the Houston market. By design, this HIE not only gives physicians immediate access to a wide variety of patient data, but also supports the type of workflow required for Memorial Hermann's new accountable care organization to succeed. Memorial Hermann's laboratory outreach program is using the HIE to forge closer clinical relationships with physicians in the community.

THERE IS A NEW CATEGORY OF PLAYER in the American healthcare system. It is the health information exchange (HIE) and it has the potential to be both an enemy and a friend to local clinical laboratories and anatomic pathology groups.

Lab executives should view HIEs as both a consolidator of patient data—including laboratory test results—and an integration platform that supports new models of tightly integrated clinical care, including accountable care organizations (ACO) and medical homes.

For both reasons—as clinical data consolidator and as clinical workflow integrator—it is essential that every clinical laboratory and pathology group have an understanding of how HIEs can enhance their labs' competitive position even as the HIE can make it easier for competing labs to also do business within the communities served by the HIE.

Aware of this dual nature of threat and opportunity, a prominent academic center in Houston, Texas, recently launched its own HIE as part of its strategy to be a clinical and workflow leader within its service region. Early evidence shows that this HIE is creating new opportunities for the medical center's laboratory outreach program to build market share while delivering greater value to the physicians and other clients it serves.

It was in August 2011, when **Memorial Hermann Healthcare System** publicly announced that the **Memorial Hermann Information Exchange** (MHiE) was operational. A distinguishing factor about this HIE is that it is provider-owned and provider-operated.

"Here at Memorial Hermann, we developed MHiE to achieve several goals that range from clinical to operational," stated Robert Weeks, MHA, Administrative Director for Information Technology at Memorial Hermann. He was speaking at THE DARK REPORT'S *Executive War College* last May in New Orleans, Louisiana.

Weeks brings an interesting perspective to his current job. He has 22 years of healthcare experience. He started as a paramedic in the emergency room and later worked as a phlebotomist before going into health information technology.

Plumbing For ACOs

"The reason I got into healthcare was to improve patient care," observed Weeks. "Thus, when I talk about the MHiE, I explain that this technology is all about improving patient care. At the same time, these developments in information technology provide the plumbing for accountable care because they enable providers to improve the transitions of care from one setting to another."

In fact, improved workflow is one secret contributing to the effectiveness of MHiE. Lab executives should take note of Weeks' comments on this subject. "MHiE allows us to improve workflow in ways that were previously not possible," he declared. "We launched this MHiE system on August 1, 2011, so it is still relatively new.

"Today, MHiE is connected to 15 Memorial Hermann hospitals and seven ambulatory facilities," he continued. "Via informed consent, more than 317,000 patients have agreed to participate in this system. MHiE has exchanged more than 100,000 continuity of care documents (CCDs).

"MHiE sends and receives data with providers and others outside the walls of the hospital. For example, when a participating patient transitions from the ER to primary care, a consented CCD goes to the primary care physician," emphasized Weeks.

"When community healthcare providers become exchange members with MHiE, any provider using a standards-based informatics system can both send and receive patient data," he continued. "In the absence of a certified EMR, MHiE can be viewed via secure web screens. MHiE exchange capabilities include orders, results, documents, images, and CCDs.

"Having demonstrated that we can transmit all of these documents, it's important to know that an HIE is not about moving documents," stated Weeks. "MHiE improves workflow by allowing us to deliver key clinical information to caregivers where and when they need it. By delivering the data needed by providers, we promote clinical excellence, improve both clinical integration and the patient experience, while at the same time we are reducing operating costs.

Point Of Care Support

"From a strategy standpoint, we are using innovations in technology to improve the delivery of information," he said. "In that way, our MHiE contributes to improved clinical care. This is true whether you are in the laboratory, a provider of inpatient or ambulatory services, someone doing billing, or as a patient.

"Pathologists know that lab test results are highly important," continued Weeks. "Thus, delivering these data to physicians when they need it is critical to their ability to make timely and accurate decisions, about patient care. MHiE delivers those results in a timely way. At the same time, it keeps costs down by preventing the need for repeat, redundant testing.

"How our clinicians use MHiE may sound simple as I describe it, but that overlooks the complexity and hard work it takes to keep all the parts working smoothly," he noted. "As of today, MHiE remains the only live HIE in Houston. Also, for the past seven years, our facilities have made national lists of the 'most wired' hospitals.

"Keep in mind the scale of this endeavor," continued Weeks. "Memorial Hermann is the largest healthcare system in Texas. This includes 23,500 employees and 4,500 physicians on staff who work in 15 major facilities. Across the greater Houston metropolitan area, we serve another 9,500 referring physicians. Add to this a number of retail operations.

"Memorial Hermann also has a large laboratory outreach program, and 30 patient service centers doing lab draws," he stated. "In our outreach lab program, we do 800,000 lab transactions each month.

"We contract with three pathology groups," added Weeks. "There are nine hospital-based laboratories that run approximately 1.5 million to 1.8 million lab tests per month.

"Our efforts to achieve a high degree of clinical integration across our systems go back 15 to 20 years," Weeks commented. "Our hospital clinical systems can talk to registration and billing systems and vice versa.

"We'll spend the next 15 to 20 years achieving that same degree of interoperability outside of our walls," he said. "Developing that capability further will allow us to support the ongoing development of our accountable care organization. Its formation was announced earlier this year.

"Use of our MHiE to support the ACO is significant," Weeks stated. "It will help us migrate from a fee-for-service payment model to a reimbursement model that is more like capitation—where we will get paid *once* to provide *all* services needed by every patient in the ACO.

Better Patient Management

"Most hospital administrators want to stay on the fee-for-service side where they can bill for volume, procedures, lab tests, and for having patients in hospital beds," offered Weeks. "But most of healthcare is starting to move toward tight management of every patient. That means volume and procedures are no longer the key to reimbursement."

Weeks acknowledges that the era of the ACO has not yet arrived. "Right now, our health system has one foot on the dock and one foot in the boat," Weeks explained. "That means we are learning as we go.

"For example, as an ACO, we need to identify our at-risk population and man-

How Memorial Hermann Uses Technology To Improve Patient Care and Reduce Cost

IN A FEE-FOR-SERVICE HEALTHCARE SYSTEM, the more tests and procedures that are done each day, the more providers and health systems can bill. But fee-for-service payment will soon give way to other forms of reimbursement that do not pay for increased volume of services.

Forward-looking health systems are seeking more efficient ways to deliver care in anticipation of these new reimbursement arrangements. "Let me provide you with an example of how the Memorial Hermann Healthcare System uses its health information exchange (MHiE) technology to increase efficiency and improve care," stated Robert Weeks, MHA, Memorial Hermann's Administrative Director for Information Technology.

"A 10-year-old girl in Beaumont, Texas, has a complex facture of her hip and femur," he explained. "It's a weekend and she needs to be transported by air ambulance. On the phone to arrange the transport, the staff in our Emergency Department asks if the Beaumont facility has any images of the girl's injuries. The answer is, 'yes,' and we ask the hospital to send the images over our image gateway.

"Before the helicopter with the 10-year-old patient arrives, the images are transmitted to us and displayed on the large screens in our operating room," he noted. "The images also are stored in our Picture Archive and Communication (PAC) System.

"When the patient lands, she is wheeled directly into the OR for surgery," he said. "There was no need for additional images, thus saving time and costs. This is a real example and the patient had the surgery, then was sent home after getting the appropriate therapy.

"We didn't need to do additional imaging nor repeat imaging that had already been done," he pointed out. "Thus, besides not adding to the cost of care, we didn't needlessly expose this patient to more radiation. This is just one case, but it shows how we already use technology to control costs and improve care at the same time."

age those patients," he said. "That's why we have case and care managers who monitor and engage patients.

"Here is where timely access to data is essential," stated Weeks. "For instance, care managers working with diabetes patients need to identify which patients have had their hemoglobin A1c test done in the past six months and which have not.

"Today we use technology to derive such alerts from hospital, ambulatory, and HIE data," Weeks added. "In the example of the diabetes patient who needs a hemoglobin A1c test, if that alert is not on an ambulatory care manager's list, a printed alert is sent to the clinic where the patient is scheduled to visit next.

"This example shows how Memorial Hermann currently uses lab data to improve care," emphasized Weeks. "After all, when there are gaps in the data, there are gaps in care.

"Don't overlook the fact that, to do this well, we have to get data from outside the walls of the hospitals," he stated. "That requires us to connect to a wide variety of electronic medical record (EMR) systems so that any affiliated physician can get clinical lab, radiology, and hospital data.

"MHiE is the informatics plumbing to support this and it is already in place," Weeks continued. "Currently, we have integration with a number of EMR systems and other health informatics products. That number increases as we achieve integration with additional vendors' products.

"Some specific examples show the importance of integrating with as many

informatics systems as possible," he said. "We currently host about 500 physicians on the **eClinical Works** EMR in our data center. Other physicians use **GE's** Centricity EMR. We have a strong partnership with University of Texas Physicians, who use the **AllScripts** EMR. These EMRs are connected through MHiE today."

Since 2007, Memorial Hermann has partnered with **RediClinics** to operate rapid-access clinics in retail locations throughout Houston. As many as 30 of these clinics connect through MHiE and access lab test data and other patient information via this channel.

"We are also taking steps to create connections with post-acute care agencies, community clinics, federally-qualified health centers, and other types of health providers who serve our patients," Weeks said.

Access To Lab Test Data

"Whenever a participating patient moves from one setting or one physician to another, the structured clinical care document is passed along with them," noted Weeks. "In serving physicians across different care settings, we need to feed lab test data in a useful way. It is true that different physicians will use lab test data in different ways. So, before we could pass along the lab results, we had to decide how we wanted to display the lab data.

How To Display Lab Data

"Take the example of a patient who stayed in the ICU for 30 days," explained Weeks. "Just that ICU stay may have generated thousands of lab test results. By default, do physicians want just the latest lab tests or all 30 days of tests?

"Keep in mind that it is a little thing like this that determines whether sending the data is a nuisance or clinically relevant," he said. "Next, our laboratory had to decide if we wanted to push lab test data out to providers or keep it here and let providers come and pull that data from us. We decided on the pull model."

In the short time since MHiE has been operational, the laboratory outreach program at Memorial Hermann has used the MHiE's capabilities to deliver more value to referring physicians. This is producing two benefits.

First, it increases the loyalty of physicians using the outreach laboratory. Second, it positions the Memorial Hermann outreach lab as the preferred resource for supporting its parent organization's nascent ACO. And there is more to come.

Enhancing MHiE Features

"Looking ahead, we are actively working on a number of ways to improve the MHiE," noted Weeks. "For example, we are adding additional sections to the CCDs for family and social histories.

"We are also doing a gap analysis on which types of physicians' notes would best supplement the data we have in the CCD data section of MHiE," he added. "We want to determine whether some providers may want us to add ER notes, discharge summaries, or progress and consult notes."

Regional HIEs Already Helping Hospital Labs

IN RECENT YEARS, REGIONAL HEALTH INFORMATION EXCHANGES (HIE) have proved to be helpful to local hospital laboratories wanting to expand their outreach business.

THE DARK REPORT has provided coverage of these developments, including:

- **HealthBridge**, Cincinnati, Ohio, (*See TDR, October 17, 2011.*)
- **Central Georgia Health Network** (CGHN), Macon, Georgia, (*See TDR, September 6, 2011.*)
- **HealthLINC**, Bloomington, Indiana, (*See TDR, August 23, 2010.*)
- **Michiana Health Information Network**, South Bend, Indiana, (*See TDR Nov. 9, 2009.*)

HIE's Diagnostic Exchange System Serves Outreach Physicians with Lab and Radiology

ONE PRIMARY FUNCTION of Memorial Hermann Healthcare System's Memorial Health Information Exchange (MHiE) is the ability to enable outreach physicians to send lab test orders and to receive lab test results.

"The MHiE Diagnostic Health Exchange functions as a router between a physician's EMR system and Memorial Hermann Outreach Services," said Robert Weeks, MHA, "MHiE makes our diagnostic and therapeutic test results immediately available to the referring physicians who are members of our HIE. Even if these physicians do not have an EMR, every exchange member has access to an online web portal that allows them to submit lab orders and view results anytime from anywhere.

"We developed this orders-and-results exchange with **LifePoint Informatics** of Glen Rock, New Jersey," he explained. "It's primarily for our lab outreach business that now serves more than 9,000 outreach physicians who use MHiE.

"Currently MHiE can fully connect to many EMR products," continued Weeks. "That enables us to receive electronic orders in our labs and then send electronic results back to our ordering physicians. It's a significant system that manages 800,000 lab outreach transactions each month.

"We also have a companion system called the MHiE Image Gateway," observed Weeks. "This is an image exchange system that handles radiology orders and results. It is the only operating image exchange in Houston.

"MHiE Image Gateway is connected to 15 of our own hospitals and more than 34 other facilities located within 100 miles of Houston," he said. "It allows physicians to receive electronic radiology test results, access radiology image links via a secure portal, and view transcription documents.

"Recently, we enabled a feature allowing physicians to enter radiology test orders directly in the EMR and let patients schedule a visit to a radiologist as well," noted Weeks. "Also, we're developing the ability to access our secure web portal via mobile devices.

"We intend to leverage this experience and our capabilities in handling digital images," predicted Weeks. "When pathologists begin sending and receiving digital images, MHiE and our lab will be able to accommodate those images."

In several ways, the ongoing development of Memorial Hermann's HIE directly benefits the laboratory outreach program. "We anticipate that continued growth in the number of providers who are in the network and using MHiE will open the door for our laboratory outreach program to become their lab test provider," said Weeks. "We can deliver added value via MiHE and that helps us differentiate our lab in a competitive marketplace."

THE DARK REPORT observes that Memorial Hermann Healthcare System provides an early case study of one strategy to achieve clinical integration within a regional market. Memorial Hermann is using MHiE as the integrator of informatics. MHiE then becomes one cornerstone for further development of Memorial Hermann's ACO.

At the same time, the capabilities of MHiE are being leveraged by Memorial Hermann's lab outreach program to deliver more value and gain new clients. That appears to be one significant short-term benefit. Over the long term, as the Memorial Hermann ACO becomes fully operational, it is this same informatics integration that positions the lab outreach program to be the ACO's primary lab test provider. **TDR**

—By Joseph Burns

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More Medicare Auditors Are Targeting Clinical Labs

To identify fraud, Medicare programs use private contractors to audit providers, labs

CEO SUMMARY: For labs and all healthcare providers, the risk of an audit is growing because the number of auditors seeking overpayments is rising. In their efforts to eliminate waste and make the Medicare and state Medicaid programs more efficient, federal officials have introduced several different audit programs in recent years. A consultant who helps clinical labs and pathology groups respond and appeal the assessments of these private auditors provides insight and advice.

MEDICARE AUDITS CONDUCTED by private contractors are proving to be contentious and frequently based on inaccurate interpretations of the law. This situation is creating new compliance threats for the clinical laboratory industry.

"Growing numbers of clinical labs and pathology groups are becoming ensnared by the expanding host of Medicare audit programs, of which the Recovery Audit Contractor (RAC) program is probably best known," observed Christopher P. Young, CHC, President of **Laboratory Management Support Services** (LMSS), in Phoenix, Arizona.

"With the number of auditors seeking Medicare overpayments rising, the risk of any clinical lab or pathology group experiencing an audit similarly increases," added Young, who provides regulatory guidance to lab managers, pathologists, and compliance officers. "It is all because Medicare officials, in their efforts to eliminate waste and make the federal Medicare and state Medicaid programs more efficient, have introduced multiple new contractor audit programs."

Young listed four separate Medicare audit programs that allow private contractors to audit the records of providers to identify situations where the Medicare program was improperly billed. These include: Recovery Audit Contractor (RAC) program, Comprehensive Error Rate Testing (CERT) program, Zone Program Integrity Contractors (ZPICs) program, and the Medicaid Integrity Contractors (MICs) program.

Extrapolating from Samples

"People tend to focus on the RACs, but any of these contractors can review a sample of laboratory claims and then extrapolate to determine what a lab owes," he explained. "In such situations, it's imperative that you review any and all correspondence from these auditors carefully, because these contractors are frequently wrong!

"Many lab directors will recall how, back in 2010, RAC auditors in the Pacific Northwest sent demand letters to many pathology labs because the auditors were interpreting the technical component (TC) grandfather rule incorrectly," he

said. "It took months of dogged determination for these pathology labs to challenge the RAC auditor's demands and prevail upon appeal to the Medicare program. *(See TDR, August 15, 2011.)*

"Similarly, on January 1, 2011, the **Centers for Medicare and Medicare Services** (CMS) implemented the rule requiring that labs have a physician sign each paper laboratory requisition," continued Young. "However, this rule was never implemented because it was based on an error in the manuals and later withdrawn. Yet, later in the year, CERT auditors started questioning why labs were not getting requisitions signed by referring physicians." *(See TDR, January 18, 2011.)*

Negotiate Favorable Outcome

"Both of these issues were resolved in labs' favor, but it required considerable effort for labs to appeal, to document, and to negotiate a favorable resolution," he stated. "One problem with the RAC audit program is that the auditors are paid on a contingency fee basis. The CERT, ZPICs, and MICs auditors are not paid in this manner."

Young has several recommendations. "First, labs need to prepare in advance for Medicare audits conducted by private contractors by putting programs in place to protect themselves," he advised. "Every laboratory should have a strategy for how to respond when a demand letter or a request for records arrives from a federal auditor.

"Second, be aware that the request for records may not reveal the specific target of the audit," commented Young. "If an auditor sends a demand letter to your lab, however, that letter will spell out precisely what you need to do if you review the information carefully.

"Third, it is most important to recognize that any request for records or a demand letter could turn out to be a big problem for the lab," Young continued. "For this reason, labs should not let *any* request for records or a demand letter go by without careful examination. And, it would be best to get professional advice in such situations.

"My fourth point is this: even if you think it's not worth the trouble to appeal it, don't just make a repayment and hope that it's over. That could be a grave error," he added. "Labs need to ask: 'Would I have some additional liability if I just refund the money?'"

"When a lab simply refunds the amount of money assessed by the auditor, it is essentially agreeing that its actions in how it billed the Medicare program for those specific claims were wrong,"

Congressional Committee Looking at RAC Auditors

ARE FEDERAL AUDITORS ACTING appropriately when auditing healthcare providers? That's a question that the members of the U.S. Senate Finance Committee want to answer.

The committee has asked the Government Accountability Office to study the audits being done in the Medicare program, according to the **Clinical Laboratory Management Association (CLMA)**. In a memo to members, CLMA asked members to provide examples of a variety of poor behavior on the part of private auditors including the following:

- Letters from auditors who use poor or unclear writing, cite inaccurate information, or have typographical errors;
- Examples of over-reach, such as when auditors searched through trash or made burdensome requests for information, for example, by asking for hundreds of records;
- Lack of coordination by the contractor such as when different auditors would ask for the same documentation from various sources; and
- Failure to follow proper procedures or current rules.

emphasized Young. "That is why your lab should fully understand these issues first. Engaging a consultant or lawyer to assist in this process can avoid much trouble later in the appeal process.

"That leads to my fifth point: You need to be deliberate with your response to the request for records and/or the demand letter—but do not delay!" declared Young. "Your laboratory needs to respond quickly, in an appropriate way. That is because, once you've received the request from the private Medicare auditor, that auditor expects the lab to answer within a specified number of days.

"And, rest assured, the auditors will not go away unless and until you act to resolve the issue," he said. "That is why it is essential that your lab has a procedure in place so that every such letter or communication does not get buried somewhere in the lab, but rather is quickly brought to the attention of management.

"I have seen cases where an auditor's request for records was received in one department of the laboratory," explained Young. "None of the staff handling that letter understood the importance of bringing it to the attention of management. Enough time went by that, when lab management finally became involved, it had missed the deadlines for a timely response or appeal.

Auditors Make Mistakes

"Point number six is to always keep in mind that—just as we saw with the RAC audits regarding the TC grandfather clause for pathology claims—these auditors often make mistakes," added Young. "All too often, it turns out that the auditors failed to correctly understand or interpret the regulations. Laboratory billing is a complex process.

"Another source of mistakes made by auditors is that they do not apply current regulations," he stated. "In these cases, because the laboratory team is much more familiar with the current regulations, it can provide the proper documentation to support its appeal."

Young believes that the various Medicare audit programs are likely to be an ongoing part of Medicare compliance for all providers. "There is pressure on the Medicare program to become more efficient and to root out sources of fraud," observed Young. "For that reason, all providers should expect to see these audits continue into the future."

Young also noted that a lab that appeals its audit findings has a very good percentage chance of winning its appeal. "In June, CMS reported that the RACs determined that Medicare overpaid 903,372 claims last year and that providers appealed only 56,620 of those claims," he said. "Yet, out of those 56,620 claims, 24,548 (or 43.4%) were decided in the provider's favor. In other words, if a laboratory believes it has a strong case, then it should appeal." TDR

—By Joseph Burns

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Pathology Group Appealed Its RAC Audit with Success

It was during 2010 when **InCyte Pathology, Inc.**, of Spokane, Washington, underwent a RAC audit of certain Medicare claims. Following the successful resolution of these issue, The Dark Report interviewed Tom Rehwald, InCyte's Chief Financial Officer (CFO). *(See TDR, August 15, 2011.)*

Rehwald offered four lessons learned in working with the private RAC auditor to resolve the issues identified in this case. His advice included these points:

- Hire a lawyer or someone knowledgeable to challenge the RAC audit findings.
- Know the issues in question.
- Recognize that you may know more than the RAC auditor knows.
- Listen closely and be respectful.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Only one clinical lab industry vendor made the inaugural list of the *Modern Healthcare's* fastest-growing health companies. It was **Sysmex America**, of Mundelein, Illinois. Sysmex ranked number 26 on a list of 40 healthcare companies. *Modern Healthcare* reported that Sysmex's 2011 revenues of $229.6 million represented a growth rate of 161.1%!

MORE ON: *Sysmex*

Such rapid growth during the past year is notable. That's because Sysmex America, a division of Japan-based Sysmex Corporation, is an *in vitro* diagnostic (IVD) manufacturer with a major presence in the routine, high-volume sector of clinical diagnostics. Routine testing has only grown at low single-digit rates over the past 15 years. Thus, the 161% growth in revenue indicates that Sysmex America has hit upon a winning combination of diagnostic technology, performance, price, and service that appeals to clinical labs here in the United States. Because of this growth, Sysmex America has just relocated into a bigger corporate office complex in Lincolnshire, near Chicago's O'Hare Airport.

NEOGENOMICS REPORTS 42% RISE IN SPECIMENS

In reporting its third quarter earnings, **Neogenomics, Inc.**, of Ft. Meyers, Florida, extended its double-digit growth streak once more. It reported 42% growth in specimen volume, 26% increase in revenue, and a 22% increase in EBITDA (earnings before interest depreciation, taxes, and amortization). Revenue for Q3-12 was $14.2 million, compared to $11.3 million in Q3-11. Neogenomics provides specialized cancer genetic testing services and has introduced several proprietary molecular diagnostic assays. The end of the TC Grandfather clause took effect during the quarter. "...our sales force spent a significant amount of time in the quarter educating existing clients about the TC Grandfather expiration rather than acquiring new clients," stated CEO Douglas Van Ort in the company's press release about third quarter earnings.

TRANSITIONS

- **Kellison & Company** of Cleveland, Ohio, has appointed Scott Liff as President, Business Development. Liff has held executive positions with **SmithKline Beecham Clinical Laboratories** and **John Muir Health**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how researchers, after studying 19 published studies, determined that physicians in the United States fail to follow up as many as 62% of clinical laboratory test results and 35% of radiology results, thus missing critical diagnoses.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, December 10, 2012.

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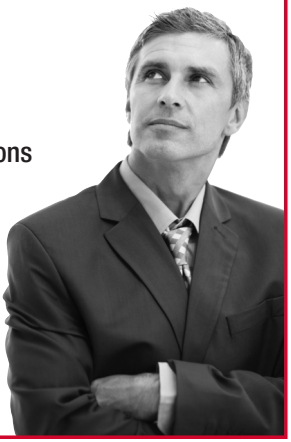
CALL FOR SPEAKERS & TOPICS!

2013 will bring big changes to the lab testing industry! Significant cuts in Medicare reimbursement for anatomic pathology take effect. FDA action on Laboratory-Developed Tests (LDTs) looms. A new Congress must tackle tough healthcare issues. You're invited to send us your suggestions for session topics. We're now selecting speakers for the upcoming 18th Annual ***Executive War College on Lab and Pathology Management***. Contact us at: rmichel@darkreport.com



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UPCOMING...

- ***The Dark Report Walks Halls of Congress with NILA: How Election May Change Healthcare and Labs.***
- ***Predicting What's Next for Laboratory-Developed Tests: Lab Quality Confab Speakers Offer Informed Predictions.***
- ***Hitting Clinical Home Runs with Point-of-Care Testing: How Hospital Lab Used POCT to Improve Outcomes.***

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