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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

PAML's "Magic Touch" with Hospital Lab JVs

IMAGINE FOR A MOMENT THAT ONE OF THE TWO BLOOD BROTHERS inked a deal: 1) to set up a series of hospital laboratory joint ventures with a multi-billion health system that operated 50 to 100 hospitals in 15 to 20 states; and, 2) to be a primary source of esoteric and reference testing to all those hospitals. Wouldn't that be a major event among Wall Street analysts and investors?

I'll bet it would. We would see a flood of commentary praising the shrewd strategy of the blood brother executives to partner up with hospitals. There would be rosy projections about increased specimens and revenue that would accrue from sequentially establishing commercial lab/hospital lab joint ventures in different markets—each done with the full support of the parent health system.

Armed with that thought, consider the lead story in this issue of THE DARK REPORT. **Pathology Associates Medical Laboratories** (PAML, owned by **Providence Health & Services** of Seattle, Washington) now has $6.8 billion **Catholic Health Initiatives** (CHI) as an equity owner and an agreement with CHI—which operates 78 hospitals in 20 states—to: 1) set up a series of hospital laboratory joint ventures with CHI hospitals; and, 2) be a primary source of esoteric and reference testing to all those hospitals.

This is a remarkable accomplishment for any lab organization in the United States. It validates the investment PAML has devoted to creating its "better mousetrap" of a high-service laboratory joint venture business template. With six successful, long-running, and ongoing hospital lab joint ventures under its belt *(see page 5)*, PAML is poised to enter new regions of the United States and help its hospital partners build profitable laboratory outreach programs.

Lest anyone think this is a unique or one-off business deal between PAML and Catholic Health Initiatives, I would remind our clients and long-time readers of **MountainStar Clinical Laboratories** in Salt Lake City. This is a laboratory joint venture between PAML and three hospitals owned by **HCA, Inc.**, the $24.4 billion, for-profit hospital company. Started in early 2008, it is another example of a large hospital operator that sees opportunity in PAML's laboratory joint venture business model.

Not since the days of **International Clinical Laboratories** (ICL) in the 1980s has a lab company in the United States been as effective as PAML in developing laboratory joint ventures with hospitals. It seems that PAML has a "magic touch" in offering hospitals the right value proposition for JVs. TDR

Catholic Health Initiatives Signs Pact with PAML

Goal is to pursue hospital lab joint ventures in multiple regional markets served by CHI hospitals

CEO SUMMARY: In concept, it is a simple deal. Catholic Health Initiatives (CHI), the nation's second largest Catholic health system, is taking a 25% equity position in Pathology Associates Medical Laboratories (PAML). However, the consequences may be significant. PAML now has an open door to develop laboratory joint ventures with the 78 hospitals operated by CHI. It also is positioned to become the primary esoteric and reference testing partner for the CHI hospitals.

THERE'S A NEW INVESTOR AND PARTNER at **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington. It's a business move that positions this regional laboratory powerhouse to expand nationally.

Last Tuesday, **Providence Health & Services** of Seattle, Washington, which owns PAML, announced a new agreement with **Catholic Health Initiatives** (CHI) of Denver, Colorado. CHI will assume a 25% equity position in PAML.

This deal brings together two big health systems. Providence operates 27 hospitals and 35 non-acute care facilities in the western United States. Catholic Health Initiatives is the nation's second largest Catholic health system. It operates 78 hospitals and 40 non-acute care facilities in 20 states. CHI has annual revenue of $6.8 billion.

Laboratory testing services are at the heart of this unprecedented new business relationship. Both Providence and CHI recognize the importance of further expanding their clinical services in the outpatient/outreach sector. For outreach laboratory testing, both health systems will utilize PAML as one vehicle to accomplish that goal.

The new agreement between Providence and Catholic Health Initiatives benefits PAML in three ways. First, it creates access for PAML to establish laboratory testing joint ventures with CHI's 78 hospitals in 20 states. In turn, this may help PAML become a national laboratory organization. That's because CHI's hospitals are located in states ranging from Washington and Oregon on the west coast, all the way to Pennsylvania, New Jersey, and Maryland on the east coast.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes *THE DARK REPORT* plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

Second, with Catholic Health Initiatives as an equity owner, PAML gains improved access to the capital it needs to expand. This is an important benefit, since it is difficult for an operational unit of a not-for-profit health system to raise money by borrowing or selling equity.

Reference Testing Source

Third, the agreement positions PAML to become a primary source of reference testing for CHI's 78 hospitals. Not only would this contribute to seamless service in laboratory joint ventures between PAML and CHI hospitals, but it would create an opportunity for PAML to market itself more widely as a national reference laboratory.

"With the agreement finalized, we expect the next steps will quickly take place," noted Noel Maring, Senior Vice President and Chief Marketing Officer at PAML. "For example, market studies and joint venture business plans involving specific CHI hospitals are already in place. Implementation at these laboratory joint venture sites is ready to begin immediately.

"At this time, PAML expects to have operational laboratory joint ventures in 10 new markets within the next 36 to 48 months," explained Maring. "This demonstrates the confidence our new partner has in the strategy of using lab outreach testing to expand its presence in the outpatient/outreach marketplace. It also positions PAML for rapid growth."

Lab's Strategic Value

At its core, the significance of the new agreement between Providence and Catholic Health Initiatives is the strategic value of laboratory testing. For pathologists and clinical lab administrators, this development affirms that some health system administrators recognize how their hospitals can leverage outreach laboratory testing to achieve a wider strategic objective.

"Both Providence Health and Catholic Health Initiatives recognize the strategic necessity of expanding their clinical services into the outpatient and outreach sectors," stated Maring. "Since 1980, annual growth in outpatient procedures has been at double digit rates, compared to single-digit growth rates in inpatient procedures.

"It means the largest number of patients never get to the hospital, but are seen in doctor's offices and similar ambulatory settings," he continued. "Innovative health systems understand that success in the future will come from being able to provide a continuum of care that includes outpatient and ambulatory services as well as inpatient services.

"For hospitals that want to build clinical service bridges into these outreach environments, laboratory testing is a proven strategy," observed Maring. "This is why Catholic Health Initiatives recognized how a laboratory joint venture can support and advance this strategy.

Established Track Record

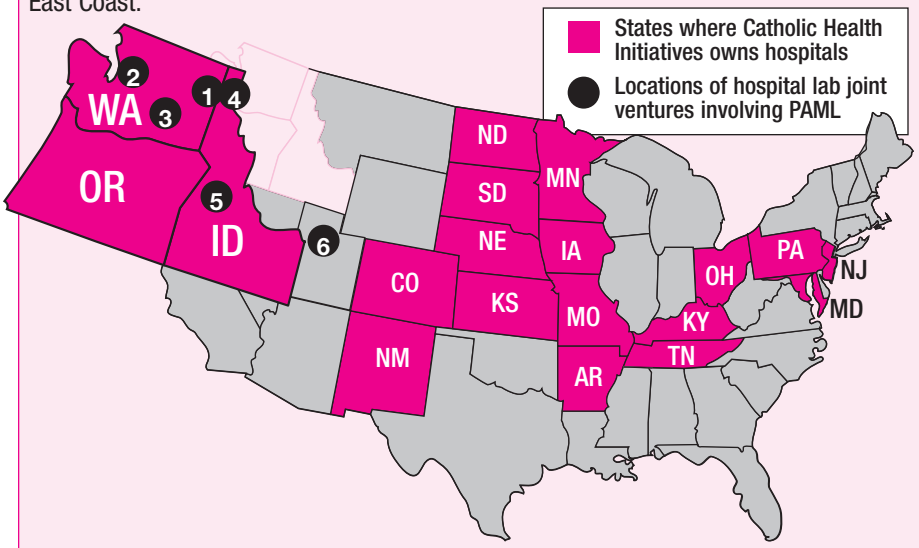
"Further, when it comes to establishing and operating lab testing joint ventures with hospitals that generate substantial cash flow to the hospital partner, PAML has a track record that is unmatched over the past 15 years," added Maring.

"In our lengthy discussions and negotiations with CHI officials, it was clear that they understand how laboratory joint ventures can help individual hospitals achieve wider strategic goals," he said. "These extend beyond the substantial revenue and cash flow produced by a successful, growing hospital lab outreach program.

"A well-run laboratory outreach testing program helps the hospital forge tighter professional relationships with physicians in the community," explained Maring. "It also introduces an electronic lab test ordering and results reporting capability between the hospital and the physicians' offices. This electronic link is often used to allow the physician to access other information systems within the hospital."

Deal with Catholic Health Initiatives Positions PAML to Grow into a National Laboratory

THIS MAP IDENTIFIES THE EXISTING LOCATIONS where Pathology Associates Medical Laboratories operates hospital laboratory outreach joint ventures. The six operational laboratory joint ventures are found in Washington, Idaho, and Utah. The 20 states shown in color identify where Catholic Health Initiatives (CHI) operates hospitals. This map illustrates why PAML now has the potential to become a national laboratory. That's because CHI operates hospitals in states that include the West Coast, the Rocky Mountains, the Midwest, the Midsouth, and the East Coast.



PAML's Existing Joint Ventures with Hospital Labs

1 PAML
Spokane, WA—Founded 1990
Providence Sacred Heart Medical Center

2 PACLAB NETWORK LABS, LLC
Olympia, Tacoma, Seattle, Everett, Bellevue, Kirkland, Renton, WA—Founded 1996
PAML (Bellevue, Seattle, Olympia)
Providence Health System–Washington
Providence Everett Medical Center
Providence Centralia Medical Center
Franciscan Health System
St. Josephs Medical Center
St. Francis Hospital
St. Clare Hospital
Stevens Healthcare
Evergreen Healthcare
Overlake Hospital & Medical Center
Valley Medical Center

3 TRI-CITIES LABORATORY, LLC
Kennewick, Pasco, Richland, WA—Founded 1997
Lourdes Health Network
Kennewick General Hospital
Kadlec Medical Center

4 ALPHA MEDICAL LABORATORY, LLC
Coeur d'Alene, ID—Founded 1995
Kootenai Medical Center

5 TREASURE VALLEY LABORATORY
Boise, ID—Founded 1999
Saint Alphonsus Regional Medical Center

6 MOUNTAINSTAR CLINICAL LABS, LLC
Salt Lake City, UT—Founded 2007
St. Marks Hospital
Lakeview Hospital
Ogden Regional Medical Center

In fact, sophisticated use of information technology (IT) is one secret behind the success PAML has demonstrated in developing, operating, and sustaining multiple laboratory outreach programs with different hospitals over the past 15 years. PAML believes that sophisticated use of information technology (IT) is a powerful way to differentiate its laboratory services from other lab competitors in the market.

"That is true," responded Maring. "Our laboratory joint ventures with hospitals are organized around two principles. One, the hospital laboratory should emphasize its core competency, which is lab testing. Two, PAML should provide all the support services that wrap around the actual step of performing the test.

"That means PAML provides and manages everything but the actual testing itself," he added. "This division of duties plays to the strength of each partner in the lab joint venture.

Soup To Nuts JV Support

"PAML is responsible for sales, marketing, courier services, customer services, coding, billing, collections, and reporting on operational performance," stated Maring. "Next comes our trump card. We have an informatics backbone that links these functions to the hospital laboratory, the hospital LIS, and the client physicians served by the outreach program.

"PAML has invested heavily to build this informatics platform. It supports every aspect of laboratory operations and service," noted Maring. "We took **Microsoft Corporation's** Customer Relationship Management (CRM) software product and customized it for the unique needs of a clinical laboratory. All our different software systems in the lab interface with the CRM.

"This home-grown informatics solution is called Joint Venture Advantage," he continued. "It will be an integral part of each laboratory joint venture developed with Catholic Health Initiatives.

"Keep in mind that JV Advantage gives our joint venture labs a 'high touch' capability," stated Maring. "We consistently perform at a 5+ Sigma level in many functions at our laboratory. Five Sigma means 230 defects per million events.

Competitive Advantage

"Because most competing labs still struggle to operate at 3 or 4 Sigma—66,800 and 6,210 defects per million events, respectively—our outreach physician clients quickly recognize the superior service we provide. In turn, that generates competitive advantage to our hospital lab joint venture," commented Maring.

Lab administrators and pathologists should not underestimate the potential of PAML's new agreement with Catholic Health Initiatives. PAML has a proven track record in creating and operating dynamic hospital laboratory joint ventures. These JVs consistently return ever-growing cash flow back to the hospital partner. They also contribute to reduced inpatient testing costs because of the growing test volume.

For its part, Catholic Health Initiatives offers 78 hospitals located in 20 states as potential joint venture partners. As Maring noted, based on development work already completed prior to the signing of the agreement, PAML expects the CHI relationship will allow it to expand into 10 new regional markets over the next 36 to 48 months.

Potential For More Lab JVs

Plus, CHI is not the only iron in the PAML fire. PAML is now ending the second full year of its hospital laboratory joint venture with **MountainStar Healthcare Network** in Salt Lake City, Utah, a health system owned by **Hospital Corporation of America** (HCA). *(See TDRs, December 10, 2007 and March 3, 2008.)* It would not be a surprise if the success of the MountainStar JV encouraged other HCA hospitals to initiate a laboratory joint venture with PAML. TDR

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Guest Commentary

FDA Advisory Panel Convenes To Assess Whole Slide Imaging

By Martin Perry

Editor's Note: Guest writer Martin Perry attended the FDA's advisory panel on digital pathology conducted earlier this month. He is CEO of The Perry Group and has extensive experience in imaging and healthcare. He offers his insights from the FDA proceedings on digital pathology imaging.

DIGITAL PATHOLOGY CONTINUES to gain acceptance at a steady but measured pace. The **Food and Drug Administration** (FDA) acknowledges these developments and is prepared to regulate emerging digital pathology technologies.

This FDA message was clear at the two-day Advisory Panel meeting which took place on October 22-23 in Gaithersburg, Maryland. The meeting was conducted by the Panel for Hematology and Pathology Devices, which is part of the Medical Devices Advisory Committee.

The objective of the two-day meeting was to provide input to the FDA panel about the current status of the industry and its expectations of the future. The panel also reviewed how digital pathology imaging is being used by pathologists alongside conventional light microscopy, along with the challenges of bringing digital whole slide images (WSI) into mainstream use.

Digital Pathology Images

There was discussion about the hardware and computer monitors used to view digital pathology images and the ability of these devices to support an accurate diagnosis. The advisory panel consisted of well-known physicians and scientists currently engaged in some aspect of digital imaging, as well as an industry representative.

Presenting to the panel were FDA scientists, physicians with practical experience in the technology, and executives from companies developing and selling digital scanning products and digital pathology systems.

At the outset, FDA officials stated—in no uncertain terms—that it intended to regulate the use of digital pathology devices and it would not classify them as exempt under 21 CFR864.9 rules. While there have been no known instances of a negative impact on patient care to date, the FDA is wary that incorrect use of this new technology could result in serious consequences to patient care and outcomes.

"Gold Standard" Microscope

While the many advantages of digital pathology were described by the experts who spoke at the meeting, these speakers also emphasized several common points. For example, it was noted that the microscope has been the "gold standard" for use in rendering a diagnosis for the past 100 years. However, the microscope is not subject to a standard itself.

As noted by one presenter, the standards used today may be considered an "artisan standard" at best, subject to the preferences of the user. How then does a valid comparison of performance come about, given the variability inherent to the configuration of a microscope, i.e. optics, illumination, centration, etc.?

Even maintenance and day-to-day adjustments of the standard microscope come into play. There was discussion about the need to develop a microscope slide "phantom" to test microscope performance. This phantom would be trans-

latable to whole slide pathology imaging applications, as was done in radiology.

In developing this new "gold standard," what considerations should be given to the definition of the pathologist's role as an integral part of the standard? Towards this end, the participation of the **College of American Pathologists** (CAP) was mentioned by at least one presenter during the discussions and, in conversation, seemed to be a point of agreement.

Performance Characteristics

There was discussion among the speakers and the panel about the need to establish performance characteristics for monitors, image sensors, and the basic optics used in digital imaging systems. The types of training to be provided by the manufacturers and interoperability between different systems were also recognized as issues. Several speakers recommended that DICOM might be part of the solution.

One insight that emerged was that the FDA appears to studying the lessons learned in radiology as that specialty adopted digital mammography systems and made the transition away from film. At that time, radiology had well-established and detailed standards to guide the transition from film-based images to digital images. Currently, pathology lacks a comparable set of standards as existed in radiology

Integrated Work Flow

Productivity and workflow issues were considered during this FDA meeting. It was recognized that digital systems would not go mainstream unless they are designed to integrate easily into the daily workflow of the pathology laboratory. Both manufacturers and users acknowledged the necessity of making digital technology convenient, reliable, and cost effective for the long term. For example, one obstacle to widespread adoption has been the time required to scan a slide. However, scan times have decreased dramatically in recent years.

On the supply side, manufacturers of current and future digital pathology products were well represented. They expressed their views and expectations to the panel quite clearly. For now, only the FDA knows what course it will ultimately follow in regulating digital pathology products and systems.

Some industry experts point out that the less stringent 510(k) approval process, rather than the more stringent PMA (Pre-Market Approval), would allow faster implementation. However, FDA officials offered no comments on their thinking on this matter. Industry expressed its willingness to work with the FDA. Many would prefer that industry and users, not governmental regulation, should control the process.

Pathology Globalization

Of course, globalization of pathology testing services was not overlooked. On that count, one presenter remarked that the United States lags behind other countries, notably Sweden, in the implementation of whole slide imaging. The attendance of suppliers from Europe, Canada, and Asia indicates the keen interest to participate in the growth of the U.S. market. Some speakers urged the FDA to help the industry grow by adopting a regulatory approval path that would be less stringent.

By itself, this first public meeting of an advisory panel to evaluate whole slide imaging in pathology confirms its growing presence in the clinical marketplace. It is expected the FDA Advisory Panel will schedule future meetings to explore other issues, including image analysis and its use in whole slide imaging, standards for data storage of images, and validation studies.

Interested parties can visit the FDA website to obtain transcripts and audio recordings of the proceedings. The URL is *www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm.* TDR

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Health Info Exchange (HIE) Helps South Bend Lab

Lab gets many advantages from working with Michiana Health Information Network

CEO SUMMARY: Across the country, there are many efforts to create Regional Health Information Exchanges (HIEs). This has the potential to change the way laboratories connect electronically with referring physicians. This is true in South Bend, Indiana, where the Michiana Health Information Network (MHIN) has operated for 10 years. It turns out that MHIN has been beneficial to the area's major laboratory. South Bend Medical Foundation reports it has gained competitive market advantage from MHIN.

IF THERE IS A POSTER CHILD for a healthcare trend that has yet to catch fire, it is the effort to create effective regional health information exchanges (HIEs). After a decade of effort, few regions of the United States have a viable HIE in full operation.

The HIE concept is simple. Hospitals, physicians, laboratories, and other providers would feed patient data into a central data repository. In turn, that repository would essentially become a universal electronic patient health record (PHR) for residents of the region.

Implementing the HIE concept has proved challenging. Who pays to develop and operate the HIE? What common format will be used for the health data streaming in from different providers? These and other issues have proved complex to solve. Thus, of the estimated 150 HIEs in the United States, only a handful have become fully operational and deemed a success.

One such successful HIE is the **Michiana Health Information Network** (MHIN) in South Bend, Indiana. The 10-year-old MHIN is an economically self-sustaining organization. Serving 10 counties across northern Indiana and southwestern Michigan, MHIN has more than 1,000 physician clients, seven hospitals, and four outpatient imaging centers, along with nursing homes, ambulatory surgery centers, hospice care providers, and public health agencies. It also has four laboratories as clients, including the **South Bend Medical Foundation** (SBMF) and three small hospital lab systems.

MDs Want Lab in Network

SBMF was a founder of MHIN and recognized that MHIN could be the source of competitive advantage for this regional laboratory. "This has happened in two ways," noted Bob King, M.S.A., Senior Vice President at SBMF. "First, MHIN helps to keep large national labs from taking specimens out of town. Second, local physicians like the fact that SBMF is part of MHIN and is feeding both hospital inpatient and outreach lab test data into the MHIN repository. These physicians insist on having SBMF in their managed care contracts."

SBMF's relationship with MHIN offers lessons for pathologists and lab directors

nationwide. It demonstrates how an HIE can become a source of competitive advantage for local labs. It also is a working example of how a well-designed HIE can support better provider access to patient health information, including lab test data.

A Longitudinal EHR

"What we do for labs is store patient-centered data in a repository so that providers can look at laboratory data from as far back as 1999 all the way up through to today," explained Tom Liddell, MHIN's Executive Director. "Essentially we distribute that data via print, fax, a Web-based messaging application, or even on paper. For the past 10 years, most of our physician clients can access the data from the Web and store it or print it.

"That was our first generation of service," continued Liddell. "Starting about three years ago, we built an integration service where a practice can receive patient data electronically. That data comes from multiple hospitals, radiology centers in the area, and from SBMF. We like to say 'we provide something for everyone.'

"It was in the mid-1990s when the concept of an integrated regional health information network was first discussed," he said. "Great community support helped us make that concept a reality. And, from the earliest days, one of our biggest supporters has been the lab, the South Bend Medical Foundation."

SBMF is an integrated regional laboratory and pathology group that employs 23 pathologists and around 800 employees in a clinical lab in South Bend. It also owns the equipment and employs the staff at hospital laboratories in South Bend. In 2008, SBMF did 1 million billable tests and about 30% of the total volume is from the outreach business.

"We are a hybrid lab," noted King. "Through our central laboratory and hospital labs in South Bend, SBMF provides hospital inpatient testing services.

"Of course, SBMF provides lab testing services to office-based physicians in our primary service area in and around South Bend," he added. "Next, we offer reference testing to a wider geography, serving about 1,000 physicians in northern Indiana and about 50 hospitals in Indiana, in Southwest Michigan, and a bit into Ohio and Illinois.

"Does being a part of MHIN give us a competitive advantage?" King asked. "The short answer is yes. We have always believed that we are in the information business, not just the lab business. So anything we can do to enhance the presentation of our lab results improves our service levels and gives us competitive advantage.

"SBMF presents a longitudinal report that includes inpatient and outreach laboratory results and other patient data that goes back 10 years," said King. "This capability will help us continue to be a competitive lab player in this market.

"Repeatedly over the years, referring physicians tell us they appreciate access to the rich and full patient test data that they get from us," explained King. "The practical benefit is these same physicians are among our strongest supporters when negotiating with managed care companies.

"They will speak up and encourage the various health plans to include us in their networks and they express their concern if we are not in their contracts," he observed. "In a competitive environment, it's significant to have those allies on our side."

Docs Want Top Lab Service

SBMF also has another card to play to maintain competitive advantage in South Bend and the surrounding communities. Its participation in the Michiana Health Information Network supports faster turnaround time for outreach lab test reporting. "SBMF has faster turnaround time for reporting many outreach test results," stated King. "Local physicians

Survey Shows More Health Information Initiatives Are Exchanging Data and Cutting Costs

MORE PHYSICIANS, HOSPITALS, AND HEALTH PLANS are exchanging health data electronically. This trend is helping to reduce the cost of care, according to a survey from the nonprofit **eHealth Initiative** (eHI) in Washington, D.C.

Most operational regional health information organizations are actively handling laboratory test data. The report, "Migrating Toward Meaningful Use: The State of Health Information Exchange," is part of eHI's Sixth Annual Survey of Health Information Exchanges and was released in July. It includes responses from 150 community-based health information initiatives and shows a nearly 40% increase in the number of advanced or operational initiatives exchanging information.

According to eHealth Initiative, the 2009 survey determined that the number of health information exchange initiatives reporting operational status this year was 57, up from 42 initiatives last year. More health information initiatives were exchanging data, the report said. Specifically, operational health information exchange initiatives were reporting the use of:

- Laboratory data increased to 49 initiatives, up from 26 in 2008
- Outpatient laboratory data increased to 45, up from 25 in 2008.
- Data on outpatient episodes increased to 43, up from 23 in 2008.
- Radiology results increased to 39, up from 23 in 2008.
- Data on emergency department episodes increased to 36, up from 27 in 2008.

In addition, 40 initiatives reported cost savings resulting from health information exchange. Cost savings were identified in the following areas:

- Reduced staff time spent on handling lab and radiology results (26 operational initiatives).
- Reduced staff time spent on clerical administration and filing (24).
- Less spending on redundant tests (17).
- Decreased costs for chronic care patients (11).
- Fewer medication errors (10).

expect us to deliver a certain level of service. But that was not always true for SBMF.

"Back in late 1980s and early 1990s, national labs were taking samples out of town and SBMF was not meeting their level of service," he recalled. "But we knew that, working closely with MHIN, we could fight to keep that business by having a better turnaround time.

"That's why SBMF was an original supporter of MHIN when the first organizational meetings took place," recounted King. "We believe strongly that lab services should be delivered at a local level and we wanted to demonstrate that SBMF could improve patient care by faster delivery of lab test results.

"As noted earlier, this is one reason why our physician clients support us," he said. "But they also support us because they know they can get a complete lab test record from us at any point when they are providing care.

"In our conversations with physicians and payers, they repeatedly tell us that what we have here with MHIN is a highly efficient system that helps to eliminate a lot of duplication of orders," he stated. "If the primary care physician sees a patient who was recently discharged from a local

hospital, that primary care physician can see all the activity that any specialist or hospital has delivered for that patient over the past 10 years. They know what labs have been ordered in the past and can use that information to treat that patient effectively without the need to order duplicate or unnecessary tests.

"Having this data on hand leads to the question of whether the costs of lab testing in our market are lower than they are in other regions," King continued. "We would like to think so. Empirically we have a sense that the health system pays less for lab testing in and around South Bend compared to other communities. But we have not been able to fund a study on that issue because it would be an expensive study.

"We also would like to quantify whether we can transmit lab test data more efficiently than other labs through the use of MHIN," he said. "One way we're evaluating that concept is to monitor each call coming from a physician's office or a client.

"We log more than 1,000 incoming calls a day from clients looking for lab results," he continued. "Because we log every call, we know our high volume users who make such requests. We then focus on getting better connectivity through MHIN to that client. Over time, we evaluate if the call requests then decrease.

➤Fewer Couriers

"We believe that number is dropping, but we are not sure," he said. "We have reduced the number of printers we maintain in the field. We've also reduced the number of couriers delivering lab test reports in the morning because we now send results through the MHIN system.

"MHIN's capabilities have changed long-standing practices and helped us to become more cost effective," commented King. "For example, 10 years ago, we had couriers deliver reports in the morning and pick up samples in the afternoon. The morning report drop-off no longer happens because the lab results are reported over MHIN.

"We do know that MHIN delivers value, because we avoid duplication of services," King explained. "We sometimes ask physicians, 'What if you didn't have access to the MHIN data?' The answer is that the treatment protocols would be different because providers would then do a lot more tests.

"In that way, it shows that the leadership of the laboratory strongly supports doing the right thing clinically," he added. "In some places, there may be a culture of providing more services because doing so helps to bring in more revenue. But that's not the case here."

Among the keys to success for MHIN are its three most popular services. "First is a messaging service that allows anyone on the network to connect with anyone else on the system. Second is a repository that is basically a longitudinal electronic health record (EHR) for every patient," said Liddell. "And third, we provide services to integrate different systems, which means taking data from all the different systems and moving them into the physicians' EHRs or vice versa and taking that data from physicians and moving it into the community repository. Those three core main services drive what we do."

The experience of the Michiana Health Information Network and South Bend Medical Foundation demonstrates how a regional health information organization can help local laboratories improve their value proposition and competitive advantage. That's particularly true because this relationship has a 10-year operating history.

THE DARK REPORT is looking for other examples of operational HIEs and would like to hear from clinical labs and pathology groups that have experience participating in these arrangements.

TDR

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New Privacy Breach Law Requires Labs to Respond

HITECH legislation passed last February creates new compliance steps for privacy breaches

CEO SUMMARY: There were plenty of headlines about the passage of HITECH last February because of how it expanded funding for electronic medical records. But lesser known are new requirements that providers, including labs and pathology groups, must now take specific compliance actions in response to breaches involving protected health information (PHI). Enforcement of these new requirements by the Department of Health and Human Services begins on February 22, 2010.

MUCH IS KNOWN ABOUT THE STIMULUS BILL signed last February and how it included money to advance electronic patient records. But most laboratory executives and pathologists remain unaware of important new notification requirements for reporting breaches of patient privacy.

These requirements are contained in the Health Information Technology for Economic and Clinical Health act (HITECH). HITECH was part of the American Recovery and Reinvestment Act (ARRA) which became law last February.

"HITECH details healthcare providers' responsibilities in regard to breaches in patient privacy," said Elizabeth Sullivan, Associate Attorney at **McDonald Hopkins, LLC**, of Cleveland, Ohio. "On February 22, 2010, the **Department of Health and Human Services** (HHS) will begin to enforce these new requirements. Clinical laboratories and pathology groups should review their existing compliance programs before that date to make sure they comply with the new rules.

"This law turns out to be more nuanced than it appears when you read it the first time," she observed. Sullivan was speaking last week at THE DARK REPORT'S audio conference titled "New Legal Issues and Regulatory Changes and Their Potential Impact on Clinical Laboratories and Pathology Groups."

"The HITECH legislation contains several elements about which labs and pathology groups should become informed," explained Sullivan. "One major new requirement is, whenever a breach of privacy involves 500 or more residents of a state, the provider must notify a prominent media outlet of the breach.

Reporting A Privacy Breach

"Similarly, when a privacy breach involves more than 500 residents of a state, another requirement is that the provider must immediately contact the Secretary of Health and Human Services to report the breach," added Sullivan.

"Determining whether an entity is required to notify individuals of the breach is the first step that the provider must take," she said. "When the breach involves more than 500 hundred residents of a state, determining the appropriate media outlet for disclosure can also pres-

ent a challenge. It varies from case to case. It is important that providers covered under this statute know how to recognize what action to take in a specific situation."

Sullivan stressed that one reason that the HITECH legislation makes compliance more complex is the nuance involved in identifying breaches that require notification. "Determining whether the breach requires notification is only a starting point toward compliance," said Sullivan. "A 'breach' is the acquisition, access, use, or disclosure of protected health information that is not permitted under HIPAA. This involves protected health information, or PHI, as defined by the law.

Risk Assessment Of Breach

"These notification requirements only apply when unsecured PHI [any PHI that is not encryted or destroyed] is breached," she noted. "To determine whether notification is required, the interim final rule gives entities the opportunity to assess the risk of the harm that could result from the breach. The challenge is to determine whether the risk of harm from the breach rises to a level that requires notification.

"Here is where the law offers only broad guidance," she observed. "Only breaches of unsecured PHI, posing a 'significant risk of financial, reputational, or other harm to the individual' require notification."

"Therefore, it is the provider's responsibility to make a judgment call," said Sullivan. "HITECH's interim final rules give several examples of differing levels of risk. For example a breach disclosing that an individual was treated at a hospital without any more information poses less of a risk of harm than a breach disclosing the types of procedures or the patient's diagnosis.

"Similarly, a breach of PHI to another covered entity poses less of a risk than a breach to a non-covered entity which is not obligated to safeguard PHI," noted Sullivan. "Thus, a confidential lab report mistakenly faxed to the wrong doctor's office would carry less of a risk of harm than the same report mistakenly faxed to, say, a bank or tire store. Any breach that could lead to identity theft is considered high risk.

"Once the lab or pathology group identifies that a breach of patient privacy has occurred that requires notification," she noted, "the next step is to determine whether the breach is so extensive that it requires the provider to notify a major media source in addition to making individual notifications. In both instances, the Department of Health and Human Services must be notified. If the breach involves more than 500 residents of a state, HHS must be notified immediately.

"Clinical labs and pathology groups should review their current policies for safeguarding PHI," she advised. "Particular attention should be devoted to the lab's internal notification process when a breach is discovered, since entities have a limited time period to notify individuals of a breach under the new rule."

Lab industry vendors and business partners should take note that the HITECH and HIPAA statutes may include them in specific instances. "Business associates working with the lab are also at risk," warned Sullivan. "That is because HIPAA-covered entities and their business associates are subject to the new breach notification rule."

These highlights about the new compliance requirements contained in HITECH demonstrate the need for all clinical laboratories and pathology groups to develop appropriate policies for their own organization. Only about four months remain before HHS begins enforcing the new law. TDR

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Interested to Learn More?

These and other new legal and compliance issues were discussed in detail by Elizabeth Sullivan and attorneys Jane Pine Wood and Richard Cooper. The full 90-minute audio conference is available on DVD. Visit *www.dark-daily.com* for details and how to order "New Legal Issues and Regulatory Changes and Their Potential Impact on Clinical Laboratories and Pathology Groups."

Genomics Update

Physicians in Survey Recognize Lack of Genetic Test Knowledge

MOST PHYSICIANS BELIEVE they are inadequately informed about pharmacogenomics (PGx) and how to utilize genetic tests. That's the finding of a survey of 10,303 physicians and reveals an opportunity for pathologists and clinical lab professionals to fill an unmet need.

In fact, only 10% of the 10,303 physicians responding to the survey believed they have adequate education about such testing. By contrast, 98% of respondents said having patients' genetic test results would be useful when making treatment decisions. Titled "The National Pharmacogenomics Physician Survey," the study was conducted by researchers from **Medco Health Solutions** and the **American Medical Association** (AMA). The findings were presented last month at the 59th Annual American Society of Human Genetics (ASHG) Meeting.

Need For More Education

This survey provides pathologists with a baseline perspective about the existing level of physician knowledge and use of pharmacogenomics testing. Among responding physicians, the survey showed there was a lack of formalized PGx training; only 26% had either medical school or postgraduate PGx education. But notably, survey results revealed that those physicians who were well informed about PGx tests were twice as likely to order or recommend them as those who were not.

"The results of this survey make complete sense—physicians who feel well-informed about genetic testing or have had previous pharmacogenomics (PGx) training are far more likely to have ordered these tests or recommended them to their patients," commented E.J. Stanek, Pharm.D., Senior Director, Personalized Medicine, for **Medco Health Solutions, Inc.**, one of the researchers. "What makes less sense is the dearth of formal PGx education available to physicians. According to the survey, only a little more than one in four physicians had any type of PGx training in either graduate or postgraduate schooling.

"Despite this knowledge gap, there is wide acceptance that pharmacogenomics has a potential role in patient care, with almost unanimous agreement among physicians that a patient's genetic profile may influence drug therapy," Stanek added. "While the number of physicians who had ordered or recommended PGx tests was small (13%), that figure is actually quite significant since, if extrapolated to include all U.S. physicians, it would indicate that approximately 50,000 physicians who care for a large number of patients have engaged in this type of testing. It is also quite encouraging that many physicians who had not yet adopted PGx testing anticipated that they would be doing so in the very near future."

"The survey clearly identifies the need for increased pharmacogenomic education and training opportunities for physicians to accelerate the use of PGx testing—a critical step toward improving patient safety and outcomes," concluded Stanek.

These are welcome developments for pathologists and lab managers. It is evidence that physicians will value the education and clinical consultation on genetic and molecular testing that labs can provide. TDR

DC Area Labs Busy Hiring Subspecialist Pathologists

➤AFIP staffs up with five new hires, while local pathologists speculate about events at AIPL

➤➤CEO SUMMARY: When a mass exodus of at least 15 civilian subspecialist pathologists left the Armed Forces Institute of Pathology (AFIP) to join the newly-formed American International Pathology Laboratories (AIPL) in September, it triggered a number of consequences for both labs, along with a slew of rumors. AFIP reports that it is maintaining services and has hired five new pathologists to work during the interim before AFIP's transition to the Joint Pathology Center. At AIPL, no official statements have been made about recent events.

THERE'S A WHO'S WHO OF SUBSPECIALIST PATHOLOGY TALENT on the roster of the newly-opened **American International Pathology Laboratories** (AIPL) in Silver Spring, Maryland, a business division of **Bostwick Laboratories**.

In fact, of the 16 AIPL pathologists listed on its web site, at least 13 came directly to AIPL from the **Armed Forces Institute of Pathology** (AFIP). Acting in an opportunistic fashion because of planned changes at AFIP, Bostwick Labs recruited civilian pathologists from AFIP with the promise to build them a new laboratory facility in Silver Spring. *(See TDR, August 31, 2009.)*

However, the opening of AIPL's new laboratory facility has not been a totally happy story of new jobs for pathologists and a new laboratory service offering high quality subspecialty pathology services. Among the reasons is that Bostwick Laboratories' gain was seen by many pathologists in the region as an immediate loss for the Armed Forces Institute of Pathology.

Rumors are flying throughout the pathology community in Washington, DC. After AFIP said it lost 15 pathologists to AIPL, wagging tongues spread the rumor that, because of this loss of staff, AFIP would no longer be taking new cases. That rumor is false.

➤AFIP Issued Public Statement

AFIP refuted this rumor several times, including a public statement issued last Thursday, October 29, that said AFIP would absolutely continue to receive and process pathology consultation cases. "The AFIP proudly continues to serve our beneficiaries and customers as we have done ever since our founding in 1862," AFIP said.

For its part, AFIP lost 15 pathologists to the new venture. That represented about 15% of its 100-member staff of pathologists, said Colonel Jo Lynne Raymond, DVM, AFIP's Chair, Department of Veterinary Pathology and Deputy Director. In an interview with THE DARK REPORT last week, Raymond said, "We are operating as normal now and our director, Florabel Garcia Mullick, M.D., ScD, FCAP, has said her number one continual focus is to provide expert medical care to our beneficiaries."

Also, in response to the departure of the 15 pathologists, AFIP recently announced the hiring of additional pathologists. AFIP officials were not aware of any pathologists who may want to leave AIPL and return to AFIP.

AFIP To Transition In 2011

"AFIP is not recruiting pathologists for any permanent positions," stated Colonel Raymond. "That's because, under the Base Realignment and Closing Act (BRAC) of 2005, both the AFIP and **Walter Reed Army Medical Center** in Washington, D.C., will be closed in 2011. At that time, AFIP will transition to become the **Joint Pathology Center** (JPC).

"With these events ahead, we are focusing on maintaining the patient care mission during the transition," commented Colonel Raymond. "We did have staff leave, but we had absolutely no degradation in services and we back-filled some of the key positions with short term contracts. As a result, we continue to support our customers."

Over at AIPL, the opening of the new laboratory division appears not to have gone as smooth as planned. A variety of rumors are circulating among pathologists in the area. To help separate fact from fiction, THE DARK REPORT spoke to Richard Bostwick, J.D., who serves as Corporate Counsel for Bostwick Laboratories. He declined to comment at this time.

21 Pathologists To Join AIPL

Several facts indicate that the opening has not been fully compatible with management plans. On September 8, 2009, Bostwick Laboratories issued a press release announcing the opening of the laboratory facility at American International Pathology Laboratories. In this press release, it identified 21 pathologists by name who were joining AIPL. It also stated "other colleagues are scheduled to join later this year."

Yet, on the AIPL web site, currently only 16 pathologists are listed. Assuming this is accurate as of this date, then either some AFIP pathologists who planned to join AIPL started and then quit, or never started. A comparison of the list of pathologists announced as starting in the press release indicates 10 pathologists who currently are not shown on the roster at the AIPL web site.

The fact that 10 pathologists identified in September as part of the AIPL medical staff are not there today would indicate

AFIP Beefs Up Roster, Hires Five Pathologists

LAST WEEK, the Armed Forces Institute of Pathology (AFIP) announced it had hired five pathologists who were previously employed at AFIP. They had worked in specialty pathology departments as staff pathologists and would now return to manage those departments.

Sharda Sabnis, M.D., who served as a pathologist for 30 years and retired in 2006, returned as Chief of Nephropathology. She is responsible for consultation work, including signing out cases.

Other returning pathologists include Russell A. Harley, M.D.; Edina Paal, M.D.; Linda Murakata, M.D.; and Hala R. Markhlouf, M.D., Ph.D. Collectively, these pathologists have more than 140 years of pathology training and experience.

Harley is now Chair of the Department of Pulmonary and Mediastinal Pathology at AFIP. Paal will serve as a pathologist in the Department of Endocrine and Otolaryngologic-Head and Neck Pathology.

Murakata will be Senior Pathologist for the Division of Hepatic Pathology. She will sign out liver cases, and handle the department's administrative duties.

Hala R. Markhlouf, M.D., Ph.D., now serves as Acting Chief for both the Department of Hepatic and Gastrointestinal Pathology and Division of Gastrointestinal Pathology.

that there is some substance to the rumors now circulating around laboratories in the area. For example, a pathologist who asked not to be named, heard that the volume of specimens coming into AIPL was not as high as the business projections, which she thought were predicated on the expectation that case referrals would follow the subspecialist pathologists as they left AFIP and started practicing at AIPL.

"I wonder if AIPL assumed that, because each of the AFIP pathologists was a recognized subspecialist expert, case referrals from long-time clients would quickly follow them from AFIP to AIPL," said this pathologist. "However, the word I hear is that, in the weeks since AIPL began handling cases, the influx of case referrals has been below what was projected.

"In my case, I've referred specimens to AFIP over the years," continued this pathologist. "My lab has received letters and telephone calls from AIPL asking me to switch my referrals to their laboratory. However, I don't want to switch. I have a lot of loyalty for AFIP."

Contract Terms

A second rumor making the rounds is that some of the newly-hired pathologists were displeased with terms of their contracts. One source claiming knowledge of the situation told THE DARK REPORT that some of the newly-hired pathologists were looking to leave because AIPL required them to pay the first $500,000 in any losses from medical malpractice cases.

"A malpractice deductible of $500,000 is very high, especially when you consider that the average malpractice case is only $250,000 to $300,000," said this source. "I was told that the pathologists who left AFIP to go to work at AIPL were not aware of the malpractice payment requirement until after they arrived at AIPL. Maybe because of lengthy employment at AFIP, they were not concerned about malpractice issues. In that sense, these pathologists may have been a bit naïve.

"I believe this issue surfaced when one pathologist got his pay stub," continued the source. "He saw a deduction for insurance and asked about it. The answer was that he agreed to that amount when he signed the contract. So these malpractice premiums were being deducted from his salary. But, with the pathologist assuming responsibility for the first $500,000 of malpractice liability, that would put most of the premium burden on the pathologist, leaving the laboratory with a significantly smaller premium."

Unfolding Situations

THE DARK REPORT notes that these rumors are unconfirmed and readers should note that fact. Collectively, the rumors do mirror the attention that pathologists in the Mid-Atlantic states are giving to the unfolding situations at both AFIP and AIPL. It is extremely uncommon for 15 to 20 pathologists to leave one laboratory organization en masse and travel across town to begin working at another laboratory competitor.

What adds further interest to this story is the 150-year history of the Armed Forces Institute of Pathology. Pathologists across the country have utilized the services of AFIP for years. The sudden loss of a large number of subspecialist pathologists at AFIP becomes a factor in their decision to refer cases. So it is not surprising that many pathologists are following the events in Washington, DC.

Fast-Growth Strategy

Similarly, the fast-growth success of Bostwick Laboratories since its founding in 1998 has also been watched by many pathologists across the country. Therefore, the press release announcing the hiring of 21 subspecialist pathologists and the opening of a new laboratory division caught the attention of many pathologists, who are curious as to whether this business strategy will prove successful for Bostwick Laboratories. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Digital microfluidics and lab-on-a-chip technologies are being combined to create a new way to measure breast estrogen levels in women. An interdisciplinary group at the **University of Toronto** developed a lab-on-a-chip technique to analyze blood and breast tissue to identify women at risk of breast cancer. "Breast estrogen levels in women at risk are not routinely measured because conventional techniques require large tissue samples obtained through invasive biopsies," observed Noha Mousa, M.D., a clinical fellow in the University of Toronto's Department of Obstetrics and Gynecology.

MORE ON: *Estrogen*

The research team is working to develop less-invasive methods that avoid the need for a tissue biopsy. Moreover, because of the micro-technology used, a point-of-care testing device might be the end product. "The new methods we've developed may someday facilitate routine screening of clinical samples for analysis of hormones," stated Aaron Wheeler, Ph.D., Director of the Wheeler Microfludics Lab in the Department of Chemistry. "We applied this technique for the first time to analyze hormones in tiny clinical samples—we looked at blood, serum, and breast cancer tissue. We developed methods to move droplets of several different kinds of reagents... to extract hormones and purify them—all on a device that can fit into the palm of a hand."

PREDICT LABS TO BE SWAMPED BY FLU TEST TIDAL WAVE

US News & World Report is predicting that the coming surge of seasonal flu cases may not just overwhelm the ability of the nation's labs to handle the increased number of flu tests, but it could also create delays in turnaround time for testing involving other diseases. This could potentially put patients at risk. In its story, *US News & World Report* also called attention to the shortage of trained laboratory professionals, noting that the inadequate supply of skilled labor constrains the ability of most laboratories to cope with the expected high demand for flu and other tests when the flu season hits this fall.

TRANSITIONS

• Rina Wolf has joined **XIFIN, Inc.**, as Vice President of Commercialization Strategies, Consulting & Industry Affairs. She will consult with labs to help them "commercialize new molecular diagnostic assays and optimize their pricing and reimbursement strategies."

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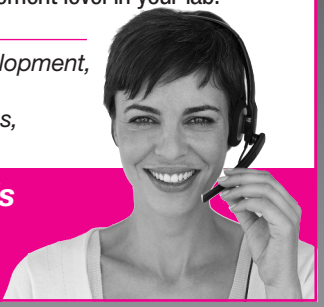

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