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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

Tough Financial Times Ahead for Hospital Labs

THIS YEAR'S MASSIVE HEALTH REFORM LEGISLATION has a ticking financial time bomb for hospital laboratories. Starting October 1, Medicare Part A hospital fees will be reduced by 0.4% for the federal fiscal year 2011. This is expected to reduce Medicare Part A spending by $440 million in 2011 compared to 2010.

As go the finances of the hospital, so go the finances of the laboratory. I predict that, during the upcoming budget planning cycle, many hospital laboratories will be asked by hospital and health system administrators to spend less in 2011 than they did in 2010.

This will intensify the budget squeeze already experienced by hospital labs. As a consequence of the painful economic recession which commenced in 2008, during the past two years, most hospital laboratories were forced to cut costs, defer important capital expenditures, and contain spending below the level of prior years.

Thus, my prediction of further financial belt-tightening for most hospital laboratories means 2011 will be the third consecutive year where budgets are barely adequate to support the year-over-year increase in the volume of lab tests flowing into the laboratory. You might say that hospital laboratories are caught between the hammer of increased lab test utilization by physicians and the anvil of reduced institutional budgets.

I suspect most of you readers already know at least one obvious response to a shrinking hospital laboratory budget. That response is to identify and develop new and independent sources of revenue from laboratory testing services. For most hospitals, a laboratory outreach testing program can be a significant source of additional specimens and new revenue.

Thus, it is a bit ironic that the funding cuts for Medicare Part A hospital services in 2011 and beyond may actually trigger a surge in laboratory outreach testing activity throughout the country. After all, a growing volume of outreach specimens not only brings in additional revenue to the lab and its parent hospital, but—because of economies of scale—that additional lab test volume contributes to lowering the average cost per test in the lab. In turn, that reduces hospital inpatient testing costs, which is a budget-positive outcome.

Pathologists and lab managers should expect budget planning discussions to intensify during the coming weeks as hospital administrators respond to the reduced Medicare Part A payments they will receive in 2011. TDR

Labs Hope to Renegotiate 1.75% Medicare Fee Cuts

Some labs to be unfairly hit by five consecutive yearly 1.75% cuts in Medicare Part B lab test fees

CEO SUMMARY: As Congress crafted its reform of the nation's healthcare system last year, it asked healthcare providers to contribute substantially to the cost of the Patient Protection and Affordable Care Act. The lab industry will see a 1.75% cut in reimbursement for Medicare Part B patients in each of the next five years—a cut expected to save $5 billion in federal spending. However, for labs that serve a heavy population of Medicare Part B patients, this cut is overly burdensome. Lab groups are approaching Congress to develop a more equitable formula.

ENACTMENT OF THE MASSIVE HEALTH REFORM LEGISLATION last March means that the clinical laboratory testing profession is set to see a 1.75% reduction in the Medicare Part B laboratory testing fees in each of the five years from 2011 through 2015.

"Lawmakers estimated this cut in Medicare Part B lab test fees would save $5 billion in federal spending," observed Mark S. Birenbaum, Ph.D., Administrator of the A**merican Association of Bioanalysts** (AAB) and the **National Independent Laboratory Association** (NILA) in St. Louis, Missouri. "But for labs that have a heavy population of Medicare Part B patients, this cut is overly burdensome."

As the law stands now, those smaller independent clinical laboratory companies—which often have a mix of Medicare patients that can be 40% to 70% of their total patient mix—will bear an unfair share of this *de facto* tax. Thus, the five-year reduction in Medicare Part B lab test fees has a disproportionate negative financial impact on these independent labs.

By comparison, larger laboratories often have a patient mix where Medicare patients represent about 15% or less of total revenue. For these labs, the five-year cuts in Medicare funding represent a much smaller financial impact.

In recognition of the unfair aspects of the current health reform law, several lab industry groups initiated new discussions with congressional lawmakers. "To avoid the severe impact this Medicare Part B fee cut will have on all laboratories—espe-

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

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cially those laboratories that have high Medicare volume and serve the most vulnerable beneficiaries—AAB, NILA, and the **American Clinical Laboratory Association** (ACLA) are working with Congress this summer," stated ACLA President Alan Mertz.

Protect Patient Access

"Our goal is to convince Congress to scale back these cuts for all laboratories," noted Mertz, "so that they are at a level that is more proportionate to the size of the laboratory sector and will not endanger Medicare beneficiary access to critically important laboratory services."

"NILA believes that the bill's cuts of 1.75% in Part B lab fees—scheduled for each of the next five years—are not proportional within the laboratory industry and are clearly not equitable," explained Birenbaum. "The problem is that each 1.75% cut will apply only to Medicare Part B laboratory testing, which comprises less than 14% of the total clinical laboratory market.

"It means these Medicare Part B fee cuts fall most heavily on laboratories with a higher-than-average percentage of Medicare Part B revenue," he said. "By contrast, those laboratories with below-average percentages of Medicare Part B revenues—which includes the large, national corporate laboratories—bear the lightest burden.

Medicare Part B Billing

"In fact, one large reference laboratory does virtually no Medicare Part B billing and therefore contributes almost nothing to healthcare reform," added Birenbaum. "Yet that large laboratory stands to benefit substantially from the additional laboratory testing generated by the 31 million individuals who were previously uninsured and will now have insurance coverage under healthcare reform.

"By taking the 1.75% cuts only from Part B Medicare, Congress is getting funds for healthcare reform from a very small segment of the industry that represents only 13% to 14% of the total amount the nation spends on lab testing," he explained. "When you do that, clinical laboratories that have a larger percentage of their business from Part B—sometimes as high as 70%—obviously are going to bear a much bigger burden under this bill as it stands. Meanwhile, labs that have very little Medicare Part B business do not pay their fair share.

"Given this inequity, we are now seeking a way to equal out everyone's contribution among those labs that do more Part B testing and those labs that do less Part B testing," Birenbaum said. "We are certainly willing to do our share; we just want to make sure it's fair.

Agree On One Proposal

"Capitol Hill has responded with the message that the lab testing industry needs to get together and agree on one proposal instead of a number of different proposals," noted Birenbaum. "Lab industry groups are working on that right now. We want to develop one proposal that we can advance as an industry. If the proposal needs to be modified, AAB and NILA will work with the other industry lab groups to modify it and keep working on it."

Mertz said it may be possible to reopen negotiations with Congress in an effort to find a way to reduce the burden of the lab cuts by scaling it back and stretching it out. "It's important to remember that the $5 billion cut over 10 years in the bill was offered as the only alternative to two far worse proposals," he explained

"The first such funding idea was institution of a Medicare co-pay of 20%," recalled Mertz. "The second funding idea was to collect $7.5 billion over 10 years through a new annual federal tax on all laboratory testing revenue. Under this proposal, the Treasury Department would calculate each laboratory's share of the $750 million annual tax and send it the tax bill.

Senator Brown's Election Helped Derail Hopes To Revise 1.75% Cut in Medicare Lab Test Fees

JUST AS CONGRESS WAS PREPARING to vote on the Patient Protection and Affordable Care Act, voters in Massachusetts foiled the Democrats' plan by electing a Republican. In a special election on January 19, Senator Scott Brown was elected to fill the seat vacated when Democrat Edward Kennedy died on August 25, 2009.

Mark S. Birenbaum, Ph.D., Administrator of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) in St. Louis, Missouri, explained that Brown's election forced the Democrats to revise their plans for passing the healthcare reform act.

Considering Proposals

"In the fall of 2009, we had a commitment from legislators on the hill that they would work with us to come up with a formula that would more equitably produce the funding from labs to finance healthcare reform," Birenbaum recalled. "We understood that the lab testing industry didn't want the [$750 million annual] tax that was being discussed.

"Our goal was to develop a funding formula that didn't rely exclusively on cuts to lab test reimbursement for those labs that do a lot of Medicare Part B work," he explained. "For labs that do a large percentage of Part B work, multi-year cuts of 1.75% in Medicare fees threatens their financial viability.

"At the time, we got agreement from eight of the 10 lab groups in the clinical laboratory coalition that something needed to be done about these five 1.75% cuts," said Birenbaum. "Those eight groups signed the letters we wrote on this subject. These letters were then sent to the Senate and to the House in December and January.

"The lab organizations described the inequity of the funding proposal," he stated. "Members of Congress recognized that this tax created an imbalance that would unfairly put a larger burden on one group of clinical labs—those labs that perform a higher proportion of testing for Medicare patients.

"We planned to work with the House–Senate conference committee to come up with something that would be more equitable," noted Birenbaum. "But that all changed when Scott Brown was elected as a Republican Senator for Massachusetts.

"His election altered the voting balance in the Senate and caused Congressional leaders to use a totally different process to pass the health reform bill," he continued. "That is why the bill never did go to a House-Senate conference committee where key differences between the House and Senate versions would be resolved.

"Instead, the legislation as passed by the Senate was locked in place," commented Birenbaum. "Like other industries, the laboratory testing industry was essentially frozen out of the ability to go to a conference committee, where typically many important issues can be discussed and worked out. It is then that a final, revised version of the bill is presented to the Senate and House for a final vote.

Looking For Better Solution

"Thus, after the bill was passed and signed into law, our coalition of clinical laboratory organizations was left with only one option—to continue negotiations and develop a more equitable proposal that would treat all laboratories fairly while raising the funds Congress expects from the laboratory testing industry," declared Birenbaum.

"That is what we are doing now," he concluded. "We are working to come up with some way to mitigate the burden that the pending five years of 1.75% cuts will have on those clinical labs that have a large percentage of Medicare Part B lab testing."

Health Reform Bill Initiates Cuts in 2011

WITH ABOUT 2,700 PAGES, the Patient Protection and Affordable Care Act of 2010 is a comprehensive piece of legislation. Further, the bill has many different provisions that will be not be instituted until future years.

To understand what is in the bill, it is often simpler to consult the summaries of the legislation produced by various committees in Congress. What follows is a description of the Medicare Part B laboratory test fee reduction of 1.75% per year. This description was developed by the House Energy and Commerce Committee Republican staff:

(H.R. 3590 as Revised by H.R. 4872)

Medicare: Start date for the Secretary to reduce the annual inflation update to Medicare payments for providers paid through the clinical laboratory test fee schedule by 1.75 percentage points for 2011 through 2015. (Sec. 3401)

The link to this document can be found at *http://republicans.energycommerce.house.gov/Media/file/News/042110_Health_Law_Timeline.pdf.*

Evidence that even the lawmakers recognize the complicated language in the bill comes from this statement that precedes the summary of the bill's provisions:

DISCLAIMER: *This document represents the best efforts of the Energy and Commerce Committee Republican staff to describe the substantive provisions and effective dates of the legislation. Because of the lack of clarity, internal inconsistencies, and ambiguity in the text, many provisions will inevitably be subject to dispute or alternative interpretations.*

"The proposal to require a 20% co-payment would have meant an immediate 20% reduction in Medicare lab test reimbursement for all labs in the nation," Mertz noted. "That would be the equivalent of $20 billion over 10 years. This proposal would also have caused a significant increase in the administrative costs a lab incurs when it bills and tries to collect the Medicare 20% co-payment.

"During the summer of 2009, discussions with Congress were ongoing," he continued. "At that time, the lab community worked quite well together to successfully get the 20% Medicare co-pay taken out of the Senate Finance Committee bill.

➤$750 Million Lab Tax Idea

"However, as soon as the 20% co-pay proposal was removed from the bill, the Senate Finance Committee added a new proposal for a permanent tax on all laboratory testing revenue," said Mertz. "This new, all-encompassing laboratory testing tax was designed to produce $750 million per year. Estimates were that this permanent new tax on laboratory testing would probably be 2% to 3% of every laboratory's total revenue from lab testing services.

"As proposed, every source of lab testing revenue would be included in the proposed annual laboratory tax," emphasized Mertz. "The tax base would cover clinical lab work, pathology, Medicare, non-Medicare, and all government and private contracts. Worse yet, this permanent tax on total laboratory revenue would have started this year and lasted forever!

"Lawmakers were designing this annual lab tax so it would generate $7.5 billion over 10 years—and the tax rate was to be increased by whatever percentage was required to collect that $7.5 billion," he observed. "However, projections showed that the net revenue overall to the government as a result of this lab tax would only total about $5 billion.

"This disparity between the $7.5 billion in taxes collected versus $5 billion in net revenue is because government bud-

Moody's Predicts that Not-for-Profit Hospitals Will Suffer from Medicare Funding Cuts

HAVING AGREED TO $155 BILLION in reduced Medicare funding during the coming years, the hospital industry is likely to find itself financially strapped. That's the opinion of financial analysts at **Moody's Investor Services**.

Just a few weeks ago, Moody's released a report on the financial outlook for the nation's not-for-profit hospitals. The findings were not optimistic. Moody's started with the announced federal fiscal year 2011 Medicare budget, which includes a 0.4% net reduction in inpatient hospital rates.

The Moody's analysts wrote that the planned cuts are "an unambiguous credit negative for not-for-profit hospitals and a key driver to our maintaining a negative outlook for the industry. Starting October 1, hospitals will see an overall $440 million less in payments and it was noted that a reduction in federal funding is "an extremely rare event."

Moody's believes it will be a tough environment for the hospital industry. On one side are the reductions in Medicare fees, Medicaid reimbursement that is typically less than the cost of providing care, and the slow economy, which has reduced the volume of patients.

On the other side, Moody's noted that, in recent years, many hospitals have successfully ratcheted down costs in supplies, deferred capital spending, and improved laboratory productivity. However, it is not likely that hospital administrators can continue cutting enough costs to offset lower reimbursement from Medicare.

One consequence of this financial squeeze is that hospital labs will be given even tighter budget restrictions than during the recent recession years. This will hamstring the ability of hospital labs to spend capital to build their clinical capabilities. It also means that it will be tougher for lab industry vendors to enjoy increased sales volume.

geters estimated that so many labs would have to lay off workers, shut down, or file bankruptcy as a result of this devastating new tax, that the government would simultaneously lose about $2.5 billion in other taxes on incomes and profits that they would otherwise collect without the new lab tax," noted Mertz.

New Medical Device Tax

"This is not pure conjecture, as a similar new tax on medical devices did make it in the final bill," he added. "That industry is now bracing itself for a permanent new 2.3% federal tax on all sales of medical devices." *(See TDR, March 29, 2010.)*

Birenbaum admits that there are many hurdles to overcome before any interested lab industry groups could succeed in gaining repeal of the five consecutive 1.75% Medicare Part B lab test fee cuts—scheduled for 2011 through 2015—and replace them with a more satisfactory funding proposal. "It's definitely worth doing," he stated. "However, it will be an uphill battle for any healthcare group that attempts to renegotiate funding cuts as they now stand in the law.

"Generally you have to offer an alternative way to pay for it," Birenbaum concluded. "That is what we are working on now. If the Senate Finance Committee is receptive, we hope to do something and action could take place, possibly in the next few months." TDR

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Pathology Records Found At Massachusetts Dump

Thousands of patient records from four hospitals sent by pathology billing company to a public dump

CEO SUMMARY: Pathologists at four Massachusetts hospitals got a powerful reminder recently that a breach of protected health information (PHI) can occur at any time for the most unexpected reason. Earlier this month, the* Boston Globe *reported that the pathology reports and patient information for tens of thousands of individuals had been found unshredded and left at a public dump. The news caused the four hospitals and their pathology groups to scramble to stay ahead of events.

IN MASSACHUSETTS, A MAJOR BREACH of patient privacy involving tens of thousands of pathology reports and billing records has suddenly thrust four hospitals and their pathology groups into the media spotlight.

The episode is a timely warning to all pathology groups and clinical laboratories about the consequences from a breach in patient privacy that involves "protected health information" (PHI), as defined in the recent HITECH legislation. *(See TDR, March 29, 2010.)*

Disclose Breach of PHI

One of the requirements mandated by the HITECH bill is that, in the event of a breach of PHI, the provider must take certain steps. These steps can include notification of the local, regional, and even national media with news of the breach, along with details to inform patients whose PHI may have been involved in the breach.

In this case, it was a media outlet, the *Boston Globe*, which discovered the patient privacy breach on July 26. It alerted the hospitals it believed were responsible for the patient records found at the public dump site. The *Boston Globe* then published its story about the incident on August 13, 2010.

Identified in the press stories about the breach of patients' protected health information were the following hospitals and pathology groups:

- In Holyoke: **Holyoke Medical Center** (159 beds) in Holyoke; **Pioneer Valley Pathology Associates, P.C.**
- In Dorchester: **Caritas Carney Hospital** (159 beds), independent pathology group.
- In Milford: **Milford Regional Medical Center** (121 beds); **Milford Pathology Associates**.
- In Milton: **Milton Hospital** (81 beds); **Milton Pathologists, Inc.**

The story starts on July 26, when a photographer for the *Boston Globe* visited the public dump transfer station in Georgetown, Massachusetts. While there on personal business, he saw a "huge pile of paper 20 foot wide by 20 foot long."

Curious as to why such a large volume of paper was not being recycled, he walked

over to the pile. Upon closer inspection, he determined that the paper was made up of unshredded records that included "pathology reports with patients' names, addresses, and results of breast, bone, and skin cancer tests, as well as the results of lab work following miscarriages."

Hospitals Were Contacted

He took samples of the reports back to the *Boston Globe*. After contacting the four hospitals, the *Globe* printed a story about the incident on August 13. News of the privacy breach attracted widespread attention throughout Massachusetts.

It was quickly determined that the company that did private contract billing for the pathology groups at the four hospitals was responsible for sending the unshredded paper patient records to the Georgetown public dump. Named in press accounts was **Goldthwait Associates** of Marblehead, Massachusetts.

The *Boston Globe* reported that "Goldthwait was purchased around June 1. The new owner's lawyer, Anthony Turco, said the new owner took records only from 2010, and any older records would have been disposed of by the former owner, Joseph Gagnon." When contacted by the *Globe*, Gagnon declined to comment.

Pathology Billing Company

Pathologists using Goldthwait's pathology billing services were surprised to learn of the improper disposal of the patient records. For example, pathologist John Blanchette, M.D., who works at Holyoke Medical Center, told the *Globe* reporter that his pathology group "had an understanding that they [Goldthwait] know how to dispose of medical records. We've done business with this company for 22 years and we're pretty upset about this. Everything as far as we knew was fine."

The number of patients whose records may have been compromised is significant. At Holyoke Medical Center, officials

800,000 Patient Records Breached at MA Hospital

PATHOLOGY RECORDS are not the only source of a patient privacy breach in Massachusetts. On July 20, news sources reported that **South Shore Hospital** in Weymouth had acknowledged that 800,000 patient files were missing.

South Shore Hospital CEO Richard Aubut stated that a vendor serving the hospital could not account for back-up data files containing information on 800,000 patients, physicians, employees volunteers, donors, vendors, and other business partners. The records covered a period between January 1, 1996 through January 6, 2010.

The hospital, in a statement on its web site, wrote that "South Shore Hospital's back-up computer files were shipped for offsite destruction on February 26, 2010. When certificates of destruction were not provided to the hospital in a timely manner, the hospital pressed the data management company for an explanation. South Shore Hospital was finally informed on June 17, 2010, that only a portion of the shipped back-up computer files had been received and destroyed."

Aubut says that the hospital will write a letter to each individual affected by this privacy breach. It has posted a sample of the letter on its web site. The hospital noted that it had no evidence that information on the back-up computer files was improperly accessed. However, it recommends a credit report for any individual whose information may have been compromised. The hospital has also stopped the off-site destruction of its computer files.

Because media notification may be a necessary step for certain types of privacy breaches involving the "protected health information" (PHI) of patients, there will be a larger number of public disclosures as these events occur.

estimate that the number of their patients is between 16,000 and 24,000. Milton Hospital officials state that their estimate is that 8,000 to 12,000 patients were involved in the privacy breach. It is believed that the records primarily cover the years 2007 through 2009.

Recommended Steps

For pathologists and clinical laboratory managers, there are several important insights and lessons to be drawn from this particular breach of patient privacy now unfolding in Massachusetts.

First, it is essential to conduct an internal review of existing policies, procedures, and operating practices that involve the collection, use, storage, and disposition of confidential information about patients.

The design and execution of this review is best done utilizing the input of an attorney or other expert in the field of patient privacy. Changes instituted by the HITECH Act are significant and labs should not take a "do it yourself" approach to assessing their current policies and work procedures to identify gaps or vulnerabilities that make a breach of protected health information (PHI) possible.

Second, informed by the findings of this assessment, the clinical laboratory or pathology group should take steps to address the deficiencies identified.

The third step is to update all company policies, handbooks, and operating procedures. This documents how the laboratory has proactively worked to protect the PHI to which it has access and handles.

Train The Lab Staff About PHI

Fourth, all employees should undergo training on the current standards and requirements for securing PHI. Not only does this mean that the lab staff will be up-to-date on the latest requirements of the HITECH Act, but is also documentation that laboratory management was proactive in establishing policies and training staff to properly handle PHI.

The fifth step is to develop the crisis response plan and designate a team to step up and handle the issues involved should a breach of PHI occur. The discovery of unshredded paper pathology reports and patient records at a public dump illustrates how suddenly a laboratory or pathology group could find itself facing television and newspaper reporters.

Pathologists and clinical laboratory managers may also find it useful to visit the web sites of the four hospitals involved in this PHI breach. In this context, the current episode provides a case study of how other providers are interpreting the requirements of the HITECH Act.

Each hospital has posted a public notice that can be reached from the home page. Typically, the statements posted provide specific details on the how the PHI was breached and why there is the possibility that a patient's confidential information may have been compromised.

Advising Patients

These hospital statements notify patients that they may want to take certain actions. These actions include putting a security freeze and/or a fraud alert on their credit reports, asking for a copy of their credit report, and how to file a complaint with the Federal Trade Commission.

Since the new provisions of the HITECH Act took place, this is one of the first public disclosures of a major PHI breach that involves pathology or clinical laboratory organizations. Thus, it is a timely warning and alert to senior laboratory leaders about the importance of being prepared to address a breach of protected health information.

In Massachusetts, four pathology groups are dealing with the consequences of a privacy breach that may involve 35,000 to 40,000 patients. A timely internal review and assessment of how PHI was handled and protected would have been simple insurance to help prevent a breach of this nature from happening. TDR

Industry Update

Lab Manager Training Program Coming to Four Cities This Fall

WHEN IT COMES TO PREPARING the next generation of laboratory managers to assume leadership roles, pathologists and lab administrators have few options. That is about to change.

This fall, in four different cities, workshops will be conducted specifically to provide your laboratory's most promising management talent with the knowledge and tools they need to step up and contribute immediately to your lab's success.

Opportunities to learn basic, advanced, and sophisticated management methods that focus specifically on clinical and pathology laboratories have been almost non-existent during the past. This four-city workshop series fills that vacuum. It offers laboratory organizations a useful resource to advance the understanding, capability, and confidence of their most promising managers, administrators, and directors.

The training will be led by Jeff Smith. Currently he provides leadership development services for **Slone Partners** and **Titan Management University**. During the 2000s, Smith was key team member in the transformation of the management culture at top-performing **Carilion Laboratories** in Roanoke, Virginia.

Don't Short-Change Training

"In today's tough financial environment, many labs short-change the training and development of their most promising managers," observed Smith. "That is self-defeating, because having a management team of confident, trained, and motivated people is the single biggest factor in a laboratory's clinical and financial success."

"This two-day lab managers' training workshop is a solution to finding the time and the expertise needed to train the most promising management talent in your laboratory," noted Robert L. Michel, Editor-In-Chief of THE DARK REPORT and organizer of the lab managers' workshop series. "Best of all this special lab managers' training is designed and conducted by an experienced lab leader."

Teams Can Train Together

To reduce travel requirements and to make it easier for teams of lab managers to attend and train together, identical two-day workshops will be conducted in these four major population centers:

- Baltimore (October 12-13, 2010)
- San Francisco (October 26-27)
- Chicago (November 2-3)
- Miami (November 16-17)

During the first day of the lab managers workshop, participants will learn important basics and get hands-on experience at using these effective tools. The first step is to help participants learn to identify their personal management style, along with the techniques to flex their style to meet the needs of the teams, management peers, and the boss in their laboratory.

Next comes training in how to recognize the laboratory's working culture, along with specific ways to identify the strengths and dysfunctions of that working culture. Participants will then learn methods and approaches on how to apply their leadership and management skills to help people move forward and achieve more. This will include insights on how to motivate the different generations, includ-

ing Baby Boomers, Generation X, and Generation Y.

The balance of day one focuses on how to align the performance of the lab team with the organization's goals and objectives. Here is where the rubber meets the road and those emerging leaders on your lab's management team learn how to manage people. That means retaining the most productive staff members while getting the wrong people off the bus.

More Productive Lab Teams

Day two builds upon this knowledge. Participants will learn the secrets of coaching—along with how to develop others on the lab team into effective coaches. Learning modules teach goal setting and how to monitor progress toward these goals.

This knowledge-packed day ends with succession planning methods and information about career planning. The goal here is to help your laboratory's top management talent understand how to use all this information to contribute more in the laboratory while preparing themselves for higher levels of responsibility as they demonstrate proficiency.

"Every lab faces the same challenges," noted Michel. "Many of the most experienced managers are preparing to retire. Yet, because of reduced budgets, the laboratory's most promising management talent often don't get the resources or time required to sharpen their own skills.

"This is a lab industry first," he continued. "It's an affordable, fast way to give your lab's most promising manager prospects much of the essential knowledge, instruction, and confidence they need to return and contribute more to your lab's success." TDR

Details and registration for "Transforming Clinical Lab Middle Managers into Top-Performing Team Contributors!" can be found at: http://www.darkdaily.com/management-training-for-clinical-laboratory-managers.

Helping Lab Managers Build Leadership Skills

THIS SPECIAL CLINICAL LABORATORY MANAGERS WORKSHOP is designed to help your up-and-coming leaders unlock their full potential, while teaching them how to motivate and lead others in your laboratory. These are skills and outcomes that every enlightened boss wants for the ambitious managers on their team.

In each of four cities, the identical two-day workshop will be presented. Every day, start and finish is 8:00 a.m. and 4:00 p.m. Curriculum will address four basic management areas:

First, an overview of culture; how managers can shape and transform culture; along with proven tools to achieve these outcomes.

Second, team dynamics; how to identify leaders in your lab; specific techniques for engaging these emerging leaders; effective ways to achieve greater productivity and improve staff harmony and morale.

Third, essentials of coaching; creating coaches among your lab's most promising managers, how to unleash the power of coaching.

Fourth, the management and career development path, ranging from goal-setting and succession planning to sustaining the improved performance of your lab managers.

Dates and locations are:

October 12-13, 2010
Hilton Baltimore BWI Airport Hotel

October 26-27, 2010
Hilton San Francisco Airport Hotel

November 2-3, 2010
DoubleTree Chicago O'Hare

November 16-17, 2010
Hilton Garden Inn Miami Airport Hotel

For Details and to Register:
www.darkdaily.com

More Hospitals Now Use Point-of-Care Test Devices

Norman Regional Health System uses POCT to advance patient care in several clinical areas

CEO SUMMARY: Point-of-care testing (POCT) continues to gain acceptance in hospitals across the nation. One factor in this trend is improved technology for both the POC assays and the POC systems, each of which contributes to a more accurate and reproducible POC test result. But an equally important factor is tight management of a hospital's POC testing program by its clinical laboratory team. Norman Regional Health System provides insights about what is needed to be successful with POCT.

EXAMPLES OF PROGRESSIVE HOSPITAL LABORATORIES that support extensive use of point-of-care testing (POCT) in diverse clinical settings are becoming more common.

This is true of **Norman Regional Health System** in Norman, Oklahoma. It has made POCT the centerpiece of its laboratory service since it opened a new Long-Term Acute Care (L-TAC) facility five years ago. Use of POC tests solved several problems that are familiar to most pathologists and hospital laboratory directors.

"Our 50-bed L-TAC facility was a remodeled nursing home and there wasn't space for even a small laboratory," explained Danny Myers, Director of Laboratory Services for Norman Regional. "Also, for the purposes of establishing an on-site laboratory, it is a low volume facility. That makes it difficult to justify the capital expenditure and staffing costs of a lab in that facility."

There was another unique challenge to servicing this L-TAC facility from the hospital core lab, which is located only about two miles away. "Though routine lab tests can be sent by courier to the central lab, the route between the L-TAC facility and the hospital crosses a railroad track," observed Myers. "The problem is that mile-long trains regularly come to a complete stop on that track and nowhere in town is there a single underpass or bridge that crosses the railroad track.

"Encountering a stopped train on that track can delay our couriers by 30 minutes or more," he added. "This situation may soon change, as the city recently commenced construction on an underpass."

Clinical Need For POCT

Independent of the courier transport issue was a basic clinical requirement. "About two-thirds of the patients at the L-TAC facility are on ventilators," said Myers. "Physicians and nurses constantly do blood gas tests to determine adjustments to the ventilators. Point-of-care testing was the only solution that made sense for the facility."

To open the facility, Norman Regional purchased four i-Stat POC testing devices, one for each wing. "The L-TAC staff runs blood gasses and chem-8 tests on the

device, although this POC device is capable of doing more," said Myers. "The staff also do glucose testing and dip-stick urine testing at their facility. For everything else, our hospital is their reference lab."

POCT Used In Several Areas

The L-TAC is not the only service in the Norman Regional system that uses POC testing. "We have POC devices in the ER, surgery and recovery, ICU, and the NICU," Myers explained. "The NICU uses more POCT than the other clinical areas within the hospital.

"The clinical staff likes the fact that it requires only a heel stick to do blood gasses, chem-8s, and ionized calcium tests on the POC device," he said. "With critical babies, a fast answer is important. The other significant benefit is that, were these tests to be done in the core lab, a venipuncture would often be required. That's not preferable when treating these tiny babies."

Testing for specific situations is the primary use of POCT in other clinical departments. "For example, the ICU only uses their POCT device when a patient crashes and they need fast results on blood gasses and chem-8 tests," he explained. "The OR and recovery room use the POC device for coagulation tests and blood gasses."

Successes And A Setback

Norman Regional's ER provides examples of both a POCT success and a setback. "Our emergency room uses the i-Stat to run the first troponin test on patients that present with chest pain, though subsequent troponins are sent to the central laboratory," noted Myers. "This has been a successful use of POCT.

"That was not true of our experience with POC testing for CKMB and myoglobin testing," he recalled. "Our emergency room doctors lobbied for a POCT device that would do CKMB, myoglobin, and troponin. The salesman had done a good job convincing them that it would improve patient care.

"Despite our lab's concerns about the accuracy of this POCT analyzer, we agreed to purchase these devices, at a price of $64,000 each, plus the cost of reagents," continued Myers. "This turned out to be an expensive mistake!

"The devices were accurate most of the time, but a few exceptions came back to bite the ER physicians," he added. "The challenge lies in the fact that these tests have very narrow ranges of normal.

"When there is too much variation, the operator gets false positives," Myers explained. "Acting on those POCT results, the physician ends up taking patients to the cath lab who aren't having a heart attack."

Devices Now Sit On A Shelf

"After a couple of those incidents, the ER physicians stopped using these particular POCT devices," stated Myers. "Now these $64,000 devices sit on a shelf in my office.

"Meanwhile, the ER docs went back to relying on troponin tests using the i-Stat," he added. "They combine this with the EKG results to determine if chest pain is the result of a heart attack."

On balance, both Myers and the health system's clinical staff are happy with the current use of point-of-care testing. Myers summarized the key reasons behind the success of POCT in his health system.

"First, from day one, we diligently monitored the program every step of the way," Myers stated. "Two laboratory staff members are dedicated to the functions of POC monitoring and performance improvement.

"Together, they spend about 20 hours of each week on routine POC maintenance and monitoring," he commented. "They are immediately involved if: 1) there are problems with a POCT device; or, 2) we purchase a new POCT device; or, 3) if additional staff must be trained.

"Second, our laboratory staff members regularly perform correlation testing on the POCT devices," noted Myers. "This ensures that the test results from the POCT devices match the test results from the central lab. To date, we've found the POCT systems we use to be very accurate.

"Third, we monitor the cost of POCT testing," he stated. "POC testing is an expensive proposition," he observed, "since a POC assay can be four times or more the cost of doing that same test in the central laboratory.

Maintain Cassette Inventory

"One way to monitor the cost of POC testing is for our laboratory staff to maintain the reagent cassette inventory," said Myers. "They also handle the necessary calibration any time a POC device is repaired or a new device is purchased."

Excessive utilization of POCT has not been a problem at Norman Regional. "If the situation demands quick turnaround times, the right POC test can be worth the cost. Across Norman Regional, our clinical staff has generally been conservative with their use of point-of-care testing.", he said.

"Fourth, and likely the two most important factors in a successful POC testing program are training and security," said Myers. "Our POC devices are linked to our computer system in the laboratory, and they require a user code to operate.

"Before our laboratory issues a user code to a staff member, he or she has to undergo comprehensive training and show proficiency with the POCT device they will use," he explained. "Every three months, our laboratory conducts a review of the POCT devices.

"If it is determined that a particular user is abusing the privilege or having continuing problems using the POCT device correctly, he or she will be locked out of the system," explained Myers. "Even physicians must go through POCT training, show proficiency, and obtain a user code."

How New POC Tests Are Vetted at Norman

EACH REQUEST FOR A NEW POINT-OF-CARE TEST (POCT) at Norman Health System triggers a rigorous review and approval process.

"When a hospital unit wants approval to use a new POC test, they must submit a formal request through the POC Test Committee," stated Danny Myers, Director of Laboratory Services. "This group of 12 hospital staff is chaired by a pathologist. It includes other physicians, nurses, and technologists. The committee carefully reviews the medical necessity of POC testing. They also weigh the cost of using a POC test against the patient benefit."

Myers added that the proper selection of the POC assay and testing system is an important factor. "For our purposes, the i-Stat is a good little device," he noted. "It is very accurate and very reliable. But that will not be true of all the POCT systems currently sold in the market."

Overall, Myers gave satisfactory marks to the POC test program at Norman Regional. "It's turned out to be worth the investment in terms of better patient care," he said. "But POCT success requires more than just a capital investment. There must be a commitment by administration and the hospital laboratory to devote staff time necessary to monitor the program and manage use of POCT. Without leadership from laboratory management and staff, it just wouldn't work."

Norman Regional's success demonstrates that hospital laboratory managers can safely use POC testing in their facilities, under the right conditions. With careful selection of devices, proper testing, and a security and monitoring system, POC testing can be a valuable clinical tool. TDR

—Karen Branz

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HIEs Boost Fortunes of Community Hospital Labs

➤Regional health information exchange (HIE) is a win-win for labs, docs, and patients

➤➤CEO SUMMARY: Regional health information exchanges (HIEs) are becoming more common. In Southern Indiana, the HealthLINC HIE is boosting the value that the community hospital laboratory provides to physicians. At the top of the list is expedited turnaround of laboratory test results, often within just two to three hours. Another major goal is for the HIE to support integration of patient care. HealthLINC, in Bloomington, Indiana, is also connected to HIEs in Indianapolis and Cincinnati.

DIFFERENT FORMS of health information exchanges (HIEs) are becoming operational across the United States. Local clinical laboratories and pathology groups are learning how to support the needs of these HIEs to accept and distribute laboratory test data.

One thriving example is **HealthLINC**. This non-profit heath information exchange operates in southern Indiana. HealthLINC demonstrates how electronic information sharing can contribute to improved patient care. At the same time, an HIE like HealthLINC can be used by community hospital laboratories within the network to deliver real time laboratory test data from inpatient, outpatient, and outreach testing to all physicians participating in the HIE.

Established in 2007, HealthLINC is based in Bloomington. It integrates communication among providers while speeding delivery of laboratory, radiology, physician notes, and many other allied health test results via an electronic clinical messaging system.

HealthLINC's network currently connects two hospitals, one lab and 254 physicians in a seven-county region. Included is bustling Monroe County, which is home to **Indiana University**, and the city of Bloomington.

"Doctors can schedule patients sooner for follow-up, because they get lab test results so much faster—often within two to three hours," stated Todd Rowland, M.D., the Network Director at HealthLINC and President of **E-Health Consulting, Inc.** "Before HealthLINC became operational, it was common for physicians to schedule patient follow-up visits in two to three weeks to ensure laboratory and other test results would be back.

➤Faster Access To Lab Results

"Our HIE accelerates information sharing and allows physicians to be more responsive to patient needs," emphasized Rowland. "This is particularly true when a patient is anxious about the results of a diagnostic test."

"There's no installation or special equipment needed," observed Rowland. "For a physician to access data in a patient's EMR, all that is required is for the physician to log in. Our application pro-

vides security in complete compliance with Health Insurance Portability and Accountability Act (HIPAA) rules."

"Clinical messaging changed the way we do business here in our laboratory," said Kelli Wesley, MT, Client Services Manager at the laboratory of 297-bed **Bloomington Hospital**. "There's much more collaboration across the clinical services in the hospital.

Positive Changes In The Lab

"For example, the HealthLINC system makes it possible for the laboratory, the imaging department, and allied health areas to access information on a patient from all the providers—not just the lab," noted Wesley. "It's easy to use and saves time and paper.

"This is quite a change," she continued. Before HealthLINC, our laboratory regularly hand-delivered or faxed lab test results to physician practices. Now our laboratory electronically posts lab test results directly to the patient record. Among other benefits, it means that staff at the referring physicians' offices no longer must match up paper lab test reports with the right patient's health folder."

Wesley noted that the HIE has generated savings for her hospital from two sources. "Internally, use of HealthLINC has increased collaboration among the departments in the hospital, including the laboratory," she stated. "Externally, our hospital lab can use the real-time electronic connectivity of the HIE to better serve outreach physicians who are also in the network.

"The feedback we get at our lab is that the quality of care is better," noted Wesley. "Doctors need to know a patient's history—no matter where that patient receives care.

"HealthLINC also hooks our hospital and our laboratory into the electronic health network used in Indianapolis," she explained. "This is another benefit in patient care, because Bloomington-area patients are routinely referred to specialists in Indianapolis. With the HIE, all the laboratory test data on these patients is immediately available to those specialists.

"Our healthcare community here in Southern Indiana is more wired than most of the country," continued Wesley. "Based on our experience with an HIE here, I believe that, as healthcare providers across the country are electronically linked, it will save unnecessary procedures and people will get better care."

Wesley pointed out that HealthLINC has been good for business at her laboratory and suggested that a regional HIE can help hospital laboratories and small independent laboratories better compete against the national lab companies. "Large commercial labs have provided on-line lab test results for some time," said Wesley. "HealthLINC now gives us the same capability. Plus, physicians like the fact that our hospital laboratory LIS has inpatient lab test results, which they can view in the patient's electronic medical record."

Another example of how a community HIE integrates all classes of providers is HealthLINC's partnership and integration with **HealthBridge**. Healthbridge is one of the nation's earliest, largest, and most successful EMR networks.

Partnering With HealthBridge

Launched in 1997, HealthBridge connects 28 hospitals, 5,500 physicians and 17 health departments in the tri-state region and the greater Cincinnati area. It is a member of the **National Health Information Network** (NHIN).

HealthBridge provides technology and data management services to HealthLINC. "The HealthBridge data center hosts HealthLINC on its servers and deploys technology via 'cloud' computing with EMR Lite, an off-the-shelf, Web-based software application from **Axolotl Corporation**," explained Rowland.

"Leveraging Healthbridge technology was very cost-effective and saved time," he said, "This enabled us to rapidly deploy the HIE here in our community.

"As a trend, the use of health information exchanges is still in its earliest stages," noted Rowland. "Currently, only some 80-plus EMR networks operate nationally. However, that is expected to change rapidly because of federal incentives to encourage physicians to adopt electronic medical record (EMR) systems and federal grants in support of HIE development and expansion."

A federal stimulus grant is helping Rowland grow HealthLINC, which he plans to expand to 10 counties. Another goal is for the network to be financially sustainable by the end of next year. Rowland noted that HealthLINC offers several functional modules, including Clinical Messaging and ePrescribing.

"Currently, hospital data centers subsidize the cost of connecting physician practices to the diagnostic results management sources," noted Rowland, "That's because doctors are unlikely to pay for a test reporting service that simply replaces the 'free' fax service.

"Hospitals have been willing to subsidize this service because it provides incredible efficiencies for their data centers, and makes it likely the physicians will send them their lab work," he added. "Federal incentives for physicians to adopt and use electronic medical records (EMRs) will be a positive factor in helping further improve the integration of health data and healthcare services."

➤Good For Hospital Labs

In communities where a health information exchange like HealthLINC has become operational, community hospital laboratories have benefited from the capabilities and features enabled by the HIE. It is an early example of how and why adoption and use of HIEs in similar communities may be favorable to hospital laboratories in the longer term. TDR

—P. Kirk

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Physicians' Offices Like Benefits from HealthLINC

USE OF HEALTHLINC IS PRODUCING worthwhile benefits, both in improving patient care and in reducing the cost of care. Physicians and staff members are enthusiastic about the introduction of the health information exchange (HIE).

"I'm able to call my patients from home once I get information from the hospital, which is great," said Lisa Jerrells, M.D., a Bloomington family practitioner. "If I'm concerned about a patient, I can send them home, confident that—later in the evening, I will have immediate access to patient data and can call my patient at any time."

Quick turnaround of diagnostic reports can affect both physician and patient satisfaction. "The benefits of clinical messaging are numerous, but number one is accessibility to patient labs," said Beth Hash, Office Manager at **Ageis Women's Health Care** in Bloomington, one of the first practices to participate with HealthLINC. "Back before we had clinical messaging, we had to call medical records at the hospital to obtain them, then wait for them to be faxed.

"Now we can just go in [to the patient's electronic record] and view all the relevant clinical information," explained Hash. "Also, when our doctors are at the hospital, they can access patient records kept in our office and enter clinical updates to those records."

Staff in physician offices quickly learned to use HealthLINC's capabilities to streamline routine operations, "Clinical messaging is vital to our practice, and we use it daily," said Charlene Hardesty, Practice staff and Coordinator at **Clarion CV Surgeons**. "It allows me to customize reports. I can sort out what information I need. In turn, that saves both paper and time that was formerly spent tracking down paper patient files."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

With the goal of developing biomarkers useful in diagnosing a variety of cancers, **Pathwork Diagnostics, Inc.**, and **Novartis AG** announced a research partnership on July 30. It is an early example of a collaboration between a diagnostics company and a pharmaceutical company for the specific purpose of producing assays for use as "companion diagnostics"—diagnostic tests that can identify whether a patient will benefit from a specific therapeutic drug. Last October, Novartis entered a similar commercial partnership with **Orion Genomics LLC** to jointly identify and develop epigenetic biomarkers.

MORE ON: *Pathwork*

Redwood City, California-based Pathwork Diagnostics offers a cancer "Tissue of Origin" test that utilizes microarray technology from **Affymetrix Inc.** to measure the expression levels of more than 2,000 genes. Last June, Pathworks announced that the FDA "had cleared the Pathwork Tissue of Origin Test for formalin-fixed, paraffin-embedded (FFPE) tissues. The FDA clearance allows the Tissue of Origin Test to be broadly utilized on common clinical FFPE tumor specimens from both community and research hospitals and paves the way for additional FFPE-based cancer tests on the Pathwork platform."

MYRIAD GENETICS REPORTS GROWTH IN REVENUE, PROFIT

In closing its fiscal 2010 year on June 30, **Myriad Genetics, Inc.**, reported that full-year revenues had increased 11%, to $362.6 million, compared to $326.5 million in 2009. Most pathologists and clinical laboratory managers do not realize that annual revenue at Myriad now exceeds a third of a billion dollars. Its BRCAnalysis test was responsible for $82 million of the company's fourth quarter revenue of $93.9 million. Myriad's genetic risk tests for colorectal cancer and uterine cancer generated an additional $7.3 million in revenue for the quarter.

GENE SEQUENCING COMPANIES FILE IPO DOCUMENTS

It may be the final push in the race to be first to achieve the $1,000 whole human genome sequence. This summer, both **Complete Genomics, Inc.,** and **Pacific Biosciences** filed S-1 registration documents as a first step to initial public offerings (IPO). Complete Genomics hopes to raise $86 million. Pacific Biosciences seeks $200 million.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 13, 2010.