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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

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More Reimbursement Threats for Lab Testing

WE ARE NOW WELL INTO THE FIRST MONTH OF 2011 and already there are plenty of signs that reimbursement for both clinical laboratory testing and anatomic pathology testing will come under siege from a variety of sources this year.

Take, for example, the rather rapid action by the **Centers for Medicare and Medicaid Services** (CMS) to use the Final 2011 Medicare Physician Fee Schedule Update to issue a final rule that requires a physician signature on paper requisitions for clinical laboratory tests—and puts the laboratory at risk for payment denial if that paper requisition is not signed by the physician. As you will read on pages 3-4, this issue was hashed out back in 2000 as part of the consensus developed by CMS and the Negotiated Rulemaking Committee. Now Medicare bureaucrats are about to cause considerable turmoil once they require enforcement of this rule, with labs as likely financial losers.

Another interesting attack on laboratory reimbursement involves the efforts by a variety of healthcare bodies to address current coding and billing practices for many molecular and genetic tests. (Say "sayonara" to code stacking, for instance.) It is not likely that the resulting mix of reforms—including a list of new molecular test CPT codes—will result in laboratories continuing to file claims and be paid at current rates for many types of molecular tests. If anything, coding experts believe that the coming reforms will reduce the overall payments made to laboratories for molecular and genetic testing.

In fact, as reported first on these pages over the past 18 months, private payers are already gearing up their own pre-authorization programs for expensive molecular and genetic tests. That will bite into the revenues of many pathology groups and regional laboratories if they fail to remain part of the provider networks for these different health plans.

Then comes the consequences of the 2010 health reform legislation. The first 1.75% annual cut in the Medicare Part B laboratory test fee schedule has already kicked in and the clock continues to tick on the January 1, 2013, implementation of the 2.3% federal tax on medical devices that labs will pay when they buy new equipment.

Finally, there are the uncertainties of how clinical labs and pathologists may be paid as health reform addresses services delivered by medical homes and accountable care organizations (ACO). Collectively, these trends indicate a tougher financial future for labs in 2011 and beyond. TDR

Paper Req Signature Rule Contradicts 2001 Actions

Medicare officials say new rule is needed to end confusion about orders and requisitions

CEO SUMMARY: Last year, the Centers for Medicare and Medicaid Services (CMS) used publication of the proposed 2011 Medicare Physician Fee Schedule to introduce new language that would require, as of January 1, 2011, that all paper requisitions for clinical laboratory tests for Medicare patients be signed by a physician or qualified non-physician provider. Public comment was generally critical of the new rule and CMS announced that it would delay compliance with the new rule until the second quarter of 2011.

IT WAS WELCOME NEWS LAST MONTH when clinical laboratories learned that the Medicare program would delay, for 90 days, enforcement of the final rule requiring that physician's signatures be on all paper requisitions for clinical laboratory tests involving Medicare patients. The new rule was scheduled to take effect on January 1, 2011.

However, in seeking to implement the new rule, the federal **Centers for Medicare and Medicaid Services** (CMS) may have a bigger fight on its hands than it expected. Clinical laboratory and pathology associations are coming together to oppose imposition by CMS of the requirement that a paper requisition for clinical lab tests must have a physician signature.

There is a good reason for this opposition. Just nine years ago, a broad coalition of laboratory and healthcare organizations negotiated with CMS on a wide range of issues. One of these issues was the requirement that a physician signature be on paper requisitions for clinical laboratory tests.

Under a mandate that was part of the Balanced Budget Act of 1997 (BBA), CMS convened a Negotiated Rulemaking Committee. Participating in the Negotiated Rulemaking Committee were 18 organizations made up of laboratory and healthcare stakeholders, including the **American Medical Association** (AMA) and the **Medical Group Management Association** (MGMA). This committee met at least nine times with CMS during 2000.

As a result of these meetings—which required unanimous decisions, CMS (then known as HCFA—the **Healthcare**

Financing Administration) agreed with the consensus of the Negotiated Rulemaking Committee that a physician signature would not be required on a paper requisition for a clinical laboratory test.

In its final rule, dated November 23, 2001, and published in the *Federal Register* as 66 FR 58788, CMS did not require a physician's signature on a paper requisition for a clinical laboratory test. CMS did provide guidance that "documentation that the physician ordered the test must be available upon our request."

Thus, just nine years later, Medicare officials apparently decided to ignore the input and the decisions made with the Negotiated Rulemaking Committee during 2000 that directly led to the final rule published in the *Federal Register* on November 23, 2001. That rule did not require a physician signature on a paper requisition for clinical laboratory tests.

These points were emphasized in a letter to CMS Deputy Administrator Marilyn Tavenner. The letter was dated December 3, 2010, and was signed by 29 laboratory and healthcare organizations. The letter stated "...we strongly urge you to delay implementation of this provision by at least one year, until January 1, 2012, allowing for adequate time for all involved parties to discuss the implications of this requirement and clarify the myriad issues surrounding implementation, such as the role of the clinical laboratory in ensuring compliance."

Delay In Enforcement

The new rule was scheduled to take effect on January 1, 2011. However, as noted above, the Centers for Medicare and Medicaid Services announced on December 21, 2010, that it would delay enforcement of this new rule until after the first quarter of 2011.

In the statement posted on its website, CMS explained that it "is concerned that some physicians, NPPs, and clinical diagnostic laboratories are not aware of, or do not understand, this policy. As such, CMS will focus in the first calendar quarter of 2011 on developing educational and outreach materials to educate those affected by this policy."

CMS Posts Statements

Laboratory professionals involved in lobbying CMS on this issue report that CMS officials have not provided a convincing public explanation for their need to change a policy that has functioned smoothly in the nine years since the 2001 final rule was published.

It appears that, at different times, CMS has offered three reasons for this rule change. One reason given was that this rule would encourage adoption of electronic test orders. That certainly is not a benefit that will be offset by the turmoil that enforcement of the final rule will cause for referring physicians and laboratories.

CMS officials gave a second reason: the signature requirement rule will reduce Medicare fraud and abuse and better protect the integrity of the Medicare program. However, federal officials do not provide any convincing evidence that a policy that has worked over the past nine years directly encourages forms of fraud and abuse that the new rule would prevent. As well, the existing rule does require documentation of the need for the test to be available upon request by a carrier.

A third reason is to make the paper requisition signature requirement consistent with the requirement for other physician orders. Since the current system has worked well for providers, for labs, and for Medicare carriers for nine years, this reason may simply represent the bureaucrats' need for order—regardless of the disruption it causes to the honest citizens being regulated.

Few lab managers remember the Negotiated Rulemaking Committee of 2000. Yet those events are directly relevant to the current actions being taken by CMS. TDR

How Labs Should Comply With New Signature Rule

Even with the 90-day delay in enforcement, all laboratories should be taking steps to comply

CEO SUMMARY: Across the nation, clinical laboratories and pathology groups are reacting to the new Medicare rule that requires a physician signature on a paper requisition for clinical laboratory tests. Laboratories using paper requisitions will need to add a signature line, then print and distribute these new requisitions to their clients. Pathologists and lab administrators also recognize that, once again, CMS officials are making a lab the "gatekeeper" to enforce its new rule; otherwise the lab may not be reimbursed by the Medicare program.

MANY EXPERTS IN CLINICAL LABORATORY AND PATHOLOGY BILLING predict that the new Medicare rule requiring a physician's signature on paper requisitions will be disruptive.

The final rule was to become effective on January 1, 2011. However, in the last days of December, the **Centers for Medicare and Medicaid Services** (CMS) said it will delay enforcement of the new rule until the second quarter of 2011.

"CMS states that the new rule is necessary to end confusion about signature requirements associated with its previous attempts to distinguish between orders and requisitions," said John R. Outlaw, CHC, the Chief Compliance Officer for **Pathology Service Associates, LLC (PSA)**. Based in Florence, South Carolina, PSA provides billing and other support services for pathology practices and laboratories nationwide.

"Ironically, to the extent that there is confusion, it is of CMS' own making," observed Outlaw. "Its attempt to end the confusion has only added to the uncertainly about what referring physicians, pathologists, and laboratories must do to comply with the new rule."

"CMS has not issued detailed guidance on how labs and referring physicians should comply with the new rule," noted Outlaw. "In fact, there are many situations where getting an actual physician's signature on a paper requisition may be difficult—if not impossible! Pathologists and physicians have dozens of questions about this wide variety of scenarios.

Paper Requisitions At Issue

"For laboratories and physicians who continue to use paper requisitions when ordering lab tests, the new rule is a major change," he said. "Physicians will be required to include a signed 'order' in the patient record and sign the 'requisition' used to communicate the order to the laboratory. Plus, laboratories will be charged with the responsibility for verifying that each paper requisition includes a valid physician signature.

"What aggravates this situation is that CMS published the final rule in early November, with an enforcement date of

January 1, 2011—just weeks later," explained Outlaw. "That left little time for pathologists and laboratories to understand the final rule and begin educating physicians about the appropriate way to comply with the new requirement for a physician signature on paper requisitions."

Outlaw next observed that CMS has greatly underestimated the major alterations in physician workflow and in-office staff duties that will be required to achieve compliance with the new rule. "To get these physician signatures will require significant changes in workflow, along with increased paperwork and headaches," commented Outlaw. "Labs will need to find ways to do this, as will the referring physicians. What is lacking at the moment is both clear guidance from CMS and an adequate amount of time so that referring physicians can be educated about the requirements of the new rule.

Physicians Need Education

"In its comments on the final rule, CMS said it recognized the need for physician education and was committed to having its contractors start that education," Outlaw said. "But as of now, CMS has not published any guidance on the new rule. All we have is four pages from the *Federal Register* saying the signature is required.

"That leaves laboratories on their own in understanding how to comply with this rule," he stated. "Even worse, and as recently as this week, in a conference call on physician signature documentation requirements, it was reported that at least one Medicare carrier was still advising physicians that signatures were not required on requisitions as long as the underlying order had been signed in the patient's chart.

"Another problem is that the entire burden of compliance falls on the labs," he added. "There is nothing in the CMS rule that requires the physicians to sign the paper requisitions. Nor are physicians at risk in any way if they don't sign. However, if the lab performs the tests ordered by the physician and the paper requisition is not signed, the lab is at risk because Medicare is not likely to reimburse the lab for that claim.

"Thus, once again the lab community is caught in the middle of a compliance issue," Outlaw explained. "Most labs will do the requested lab tests anyway. They have a professional obligation and, practically speaking, they can't *not* do the test—but they will do so knowing full well that Medicare may not pay them for it.

Change in Workflow

"This change in signature requirements also represents a significant change in workflow in hospitals, in physician practices, and in the labs," noted Outlaw. "Many labs provide referral sources with paper requisitions on their own letterhead. However, most of these paper requisitions do not have a place for physicians to sign, since it was not required that they sign paper requisitions for clinical laboratory tests.

"So the paper requisitions themselves will have to be re-designed," he continued. "To comply, new paper requisitions will need to include a signature block for the physician. Next, hospitals and physician practices will have to revisit the paper workflow to make sure that the physician—who is not generally the one completing the requisition—circles back at some point to sign the requisition before the specimen is sent to the lab.

Way To Obtain Signature

"Laboratories will need to rework their workflow in order to ensure that all requisitions are signed," Outlaw said. "They will also need to develop a way to obtain a signature if a paper requisition is received without one.

"According to CMS, a valid 'signature' may be either a handwritten signature or an electronic signature," he added. "Electronic signatures must include language such as 'accepted by,' 'electronically signed by,' 'authorized by,' or 'signed by,'

Attorney Jane Pine Wood Offers Advice to Labs on Compliance with New Medicare Signature Rule

NOW THAT THE MEDICARE PROGRAM WILL DELAY IMPLEMENTATION of the new rule requiring physician signatures on paper test requisitions for clinical laboratory tests, labs and pathology groups have a short window of time to educate staff and physicians about the changes associated with this rule.

"Labs should take several steps to ensure compliance with this new rule," stated Jane Pine Wood, an attorney with **McDonald Hopkins**, based in Cleveland, Ohio. "Laboratories that never had a signature line on their requisition should now add one and reprint their lab test requisition forms.

"A second step is to educate your laboratory staff about the requirements of the new rule," added Wood. "At the same time, laboratories should also have their sales reps and service reps visit physician clients. It is important to provide them a copy of the new rule and discuss the need to comply with its requirements."

Other Types Of Test Orders

Wood did want to call attention to the fact that the signature requirement for a paper requisition for a clinical laboratory test is actually consistent with Medicare guidelines for other types of test orders. "The **Centers for Medicare and Medicaid Services** (CMS) already requires signatures on all tests ordered by a physician," she said. "Until now, clinical laboratory services have been the only exception.

"Having said that, I believe CMS recognizes that labs have many questions about how to implement this rule," she continued. "But philosophically, the lab segment of medicine is not being treated any differently than any other segment of healthcare.

"In fact, I deal with physicians in all the other medical specialties, including primary care doctors," she observed. "These primary care physicians are being audited by Medicare and they get marked down for failure to fully document all aspects of patient care. In that sense, Medicare is being consistent by requiring signatures on paper requisitions for clinical laboratory tests.

Rule Presents Problems

"That said, the new rule does present problems, particularly when a lab handles a high volume of testing each day," stated Wood. "There are also situations where paperwork will lag well behind the test requisition or when an electronic medical record system is used and an outreach program gets a referral from an office-based physician.

"For some of these cases, there is no way to know if a physician actually ordered a test or if someone else ordered the test," she stated. "If it's a hospital inpatient, the lab is fine. But for requisitions originated in a physician's office, it is a difficult challenge for labs that want to protect themselves while ensuring that they get paid.

"I am hopeful that CMS will develop ways to make this rule work for all parties," Wood said. "Further, it is not likely that CMS will back down completely on wanting more documentation. That's because CMS itself has been inconsistent in its rulings over the years. That inconsistency has led to some confusion among labs and is why CMS has muddied all of the waters in terms of the requirements for both clinical labs and for anatomic pathology labs.

"The issue is one of payment, meaning, will labs get paid for these claims," she said. "We hope that CMS will come forward with more guidance, but for now, labs should never delay patient care for paperwork."

etc., followed by the physician's name or digitized signature. Stamped signatures on the paper requisitions are unacceptable.

"Labs have lots of questions about how to implement this requirement," concluded Outlaw. "There are many other practical applications of the lab test order that need to be resolved.

"For example, what happens when a surgeon removes tissue from a patient in the operating room and sends the specimen to the lab?" asked Outlaw. "The surgeon is not going to break scrub to sign the requisition. Thus, is it okay for him or her to sign later? Is there an exception of some sort that could be applied in this case? This is just one of many case-specific questions that CMS needs to answer."

Physicians Remain Unaware

Pathologists at the **Henry Ford Health System** in Detroit are dealing with all the issues identified by Outlaw. "In our city, most pathologists and referring physicians are either unaware of the requirement or confused about how to implement it," said J. Mark Tuthill, M.D., the Division Head, Pathology Informatics, at Henry Ford Health System.

"Last month, I attended a meeting of the **Wayne County Medical Society** and asked a room of about 150 physicians if any knew about this new final rule," he said. "Only one person raised his hand. I asked how many physicians were actually signing their lab requisitions. Again, only one physician raised his hand. That shows why more time for educating physicians about the rule is needed.

"Within our laboratory, we've looked for an information technology solution for this problem," Tuthill added. "We have yet to come up with a viable solution that we can implement rapidly. We recognize that it will probably require a significant change in clinical workflow.

"It's important to note that, in many cases, physicians do not actually order tests in an electronic system—even if they use one," he added. "Often the physician's support staff enters this information.

"Thus, even when orders are done electronically, it may be difficult to get the physician's signature unless the physician allows the support staff to order under his or her name, violating other regulations, such as HIPAA," observed Tuthill.

"Since our laboratory handles more than 1 million outpatient requisitions each year, this is a significant problem for our laboratory," he continued. "I looked through a stack of paper requisitions the other day and not one had a physician signature on it.

"Under our current compliance policies, we accept the fact that an ordering physician is required to be a licensed physician—or a licensed clinical practitioner—and has to be at that level to order a test," said Tuthill. "Before our laboratory will act on an order, we must enter the physician's credentials into our lab system and we are required to report the lab tests results directly back to that physician without an intermediary.

"That is another reason why the new rule is a bit baffling," he continued. "Our laboratory already vets the requisitions we receive. These are valid orders and we report lab test results directly back to the referring physician."

Lots Of Disruption Ahead

Like Outlaw and Tuthill, most lab administrators and pathologists recognize the significant disruption that is about to unfold as laboratories become the primary source of physician education about the new final rule requiring a physician signature on paper requisitions for clinical laboratory tests. Once again, bureaucrats at the Medicare program have taken actions which are counter-productive to patient care and will only add more cost for labs and physicians alike. TDR

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Lab M&A Update

Beckman Coulter and Genoptix Offer Themselves Up for Sale

During December, news reports identified each firm as conducting active discussions with interested buyers

FOR DIFFERENT REASONS, last month two large companies in the lab industry put themselves up for sale. Assuming that both companies are sold, one consequence may be further consolidation in both the *in vitro* diagnostics (IVD) manufacturing sector and the lab testing sector.

It was on December 9, 2010, when news broke that **Beckman Coulter Inc.**, of Brea, California, one of the largest IVD manufacturers in the world, had engaged **Goldman Sachs Group Inc.**, to help it evaluate a potential sale. Financial analysts said that the firm, with a market capitalization of around $4 billion, might fetch a sales price as high as $5 billion.

Then, just four days later, on December 14, news sources reported that the specialty lab testing company **Genoptix Inc.**, of Carlsbad, California, had retained the services of **Barclays Bank Plc** to advise it and manage the sales process.

Different Reasons To Sell

Each company is pursuing a sale for different reasons. At Beckman Coulter, 2010 was a challenging year. It recalled its troponin test during the first half of the year. That test generated sales of about $60 million per year. Then, in September, its CEO, Scott Garrett, resigned unexpectedly.

In the past seven months, Beckman's stock price has traded as low as $43.95 and as high as $78.27. For the full year 2010, Beckman Coulter will report revenue of about $3.6 billion.

For Genoptix, its stock price was trading as high as $39.00 through last spring, then fell to as low as $13.51 in September. That has put its management team under pressure to improve the company's performance and raise its share price.

The market value for Genoptix is estimated at about $369 million. For fiscal 2010, Genoptix is expected to have revenue of about $198 million.

Buyers Are Interested

A number of companies are reported to be interested in acquiring Beckman Coulter. As strategic buyers, the names of **Danaher Corporation** and **Thermo Fisher Scientific Inc.**, have been mentioned. Latest news coverage says that, in a second round of bidding for Beckman, there are two leading bidders. One is made up of **Blackstone Group LP** and **Kohlberg Kravis Roberts & Co.** The second bidder is **Apollo Global Management LLC** and **Carlyle Group**.

In the case of Genoptix, no specific bidders have been identified in press reports. Analysts speculate that the usual suspects are probably looking at Genoptix's financials. That would include **Quest Diagnostics Incorporated**, **Laboratory Corporation of America**, and **Sonic Healthcare, Ltd.**

Were strategic buyers to acquire Beckman and Genoptix, then further consolidation will take place in the IVD and lab testing sectors. Were sales to be made to private equity firms, then each company would continue to operate independently. TDR

CEO Summary: Once it was decided to replace an aging, five-year-old laboratory automation system at the laboratory of Ingalls Memorial Hospital in Harvey, Illinois, the administration at the hospital issued a challenge. It asked the laboratory team to deliver an immediate 10% cost savings upon implementation of its next-generation laboratory automation solution. Because of a rigorous RFP process, the laboratory met that goal and is on track to produce savings to 20% from its new lab automation during its first year of operation.

Nailing Down More Savings When Replacing Older Lab Automation

Pursuing More Benefits From Next Generation Lab Automation

THROUGHOUT THE PAST DECADE, many clinical laboratories adopted laboratory automation, particularly in their high-volume core chemistry and hematology laboratories. Now it is time to replace this aging automation equipment.

This was the problem facing the laboratory at 563-bed **Ingalls Memorial Hospital**, in Harvey, Illinois. In a meeting with her boss late last year, Marilyn Nelson, Director of Laboratory & Cardiac Services, was authorized to replace an aging automated chemistry line—along with clear instructions to achieve significant and measurable operational savings.

"We've used lab automation since 2005, and it was time to move to the next generation system," Nelson said during her presentation at the *Executive War College on Laboratory and Pathology Management* last April in New Orleans. "With our equipment contract expiring, it was time to consider changing to a new system.

"As with many other hospital labs, we are asked to stretch every dollar," she said. "Our procurement process was started with a target goal my boss felt was achievable; that, after purchase and implementation, our lab's goal was to achieve annual savings of 10% and that's what we were to tell the vendors."

Laboratory automation at Ingalls is not a simple proposition. The on-site core laboratory supports the 563-bed hospital and the four ambulatory family care centers in the nearby towns of Matteson, Tinley Park, Calumet City, and Flossmoor.

"We do 1.3 million billable tests each year," stated Nelson. "About 2 million results represent the combined volume of chemistry and immunochemistry tests. Our full-time staff numbers 100 people and the laboratory's gross revenues in 2009 were $82 million. This includes income from a robust laboratory outreach program."

While the research and legwork were performed by a selection team, Nelson organized the request for proposal (RFP) process around five elements. "First, we identified the reasons why we would change our existing laboratory automation arrangement," she noted. "We used these reasons to clearly define our goals for replacing our lab automation.

"Second, we involved as many of the staff in the process as possible," explained Nelson. "Staff input is essential to incorporate our laboratory's individual characteristics in the RFP criteria that must be met by the vendors.

"Third, we used an approach that is definitely not common," she continued. "From the beginning, we involved all necessary parties in the negotiations, particularly those members of other hospital departments who could assist us with the financials.

"Fourth, we planned a structured implementation that included the outlying Family Care Center labs as well as the core lab," she noted. "Fifth, having established our success measures in advance, we intended to follow them diligently."

Better control over laboratory costs was a primary goal. "In recent years, our laboratory at Ingalls Memorial Hospital has experienced strong growth in test volume and revenue," observed Nelson. "However, like the laboratories at many other hospitals, our test volume has grown faster than laboratory revenue. This is why administration wanted the next generation automated laboratory to deliver substantial cost savings.

Seeing Volume Growth

"Projecting these trends forward, with our laboratory adding volume faster than revenue, our goal was to bring in a new generation automation solution that would help us keep lab costs flat or declining," explained Nelson. "One of our assumptions is that reimbursement for laboratory testing will decline steadily from year to year."

Nelson next described the situation within the laboratory. "It was 2005 when we installed automation in our laboratory," she

noted. "This was the **Dade Behring** Streamlab connected to two RXLs and two DPC (**Diagnostic Products Corp.)** 2000 Immulites. Both these companies are now owned by **Siemens Diagnostics**.

Time To Replace Automation

"After five years of use, our existing laboratory automation system had parts that needed replacement due to wear and tear," she stated. "Downtime was becoming more frequent and our five-year contract had expired.

"Since 2005, we've watched the steady advances in software and in lab automation technology," added Nelson. "We've also watched and listened to how innovative clinical labs use Lean and similar process improvement techniques to improve turnaround time, quality, and productivity.

"Our needs were clear," she continued. "For example, the budget for supplies and reagents was in excess of 14% of the total laboratory total budget. That made it an obvious place to look for savings," declared Nelson. "Further, based on the experience of our 2005 lab automation project, we knew there was the opportunity to combine new lab automation with new work flow redesign to achieve improvements in lab test turnaround time, improved quality, and better staff productivity.

Developing a Wish List

"We believed that our new laboratory automation solution could help us do better," she continued. "Included on our wish list were: 1) faster and greater throughput, particularly during peak periods; 2) decreased turnaround times (TAT) for testing cardiac markers; and, 3) an expanded menu of tests performed in the automated laboratory.

"It was also important that this new lab automation support auto-calibration and enable further consolidation of testing," said Nelson. "For example, a second centrifuge would help us to increase throughput, especially if the first centrifuge went down for maintenance or repair.

"The ability to connect additional instruments to the automated line was important," she added. "After we got our Streamlab in 2005, we acquired a Centaur system to allow us to perform a hepatitis panel. This couldn't be connected to the automated line, so we have always operated it as a stand-alone unit.

"It would also be advantageous to put coagulation on our new automated line—something we had not done in 2005," she added. "Auto-calibration was another important feature. Currently, when we get a new reagent order, an extra med tech must handle the calibration.

Buy-In From Lab Staff

"To ensure staff buy-in, we created a selection committee made up of our lab staff," stated Nelson. "The team and the vendors were given a defined list of rules for how communication was to occur throughout the process.

"Another clever twist was that we put our wish list into a grid in order of priority," added Nelson. "This made it always easy for staff and vendors to see which components were most important, such as calibration or a second centrifuge. Each component or capability was assigned a weight.

"At the end of each phase, the grid gave us a point score for each vendor," she recalled. "That grid showed which vendors were likely to move to the next round and which vendors would not.

"On this priority grid, although the selection team had a number of priorities, my prime directive was savings," emphasized Nelson. "And don't forget, my senior administrator insisted on realizing those savings immediately upon implementation of the new automation and laboratory workflow.

"These directives helped everyone—including the vendors—work to develop a solution that produced significant cost sav-

Laboratory Staff and Lab Director at Ingalls Defined Success Criteria for New Automation

BEFORE ISSUING A REQUEST FOR PROPOSAL (RFP) for a next generation laboratory automation system, Lab Director Marilyn Nelson of Ingalls Memorial Hospital, involved the laboratory staff in defining the criteria for a successful new laboratory automation project. The staff's input was combined with management's requirements and used to prepare the RFP that was then distributed to interested automation vendors.

Criteria Identified By Lab Staff

- Minimal/ease of maintenance
- Adequate menu/open system
- No reagent prep
- Load/unload reagents at will
- Small sample volume
- Infrequent and easy calibration
- Handles multiple tube sizes
- Ease of troubleshooting
- Auto repeat and dilutions
- Minimal downtime
- In-house training
- Onboard sample integrity checking
- Plasma required for most tests
- Add on tests while running

Lab Management's Objectives

- Achieve annual cost savings in excess of 10%
- Connect coagulation to automation line
- Solution must include family care center labs and core laboratory
- No hidden costs
- No LIS issues or information system issues
- Vendor must meet timeline
- Broader menu, faster throughput
- Auto calibration and controls
- Consolidation opportunities
- Seasoned implementation team

ings from the first day that the new automation solution went live," she explained.

"Once the specifications were completed, we discussed six prospective vendors," said Nelson. "The team quickly narrowed that number to four. This happened at the first team meeting. At that time, when everyone brought their scores together, it was clear that these four of the six vendors under consideration were the strongest matches for our defined list of goals and needs.

"The selection committee was then told to pare that number down to two vendors," recalled Nelson. "The team could nominate a favorite, but our goal was to have two vendors go into the final phase of the RFP process. Obviously, with two vendors competing for our business, we expected to have improved leverage during negotiations.

"Here is where the time squeeze came into play," she noted. "It was January when we had our two finalist vendors and our goal was to have the new laboratory automation line in full operation by May," she continued. "The final two vendors had to give us confidence they could meet this deadline. Had each vendor ever done a job of this magnitude before? Had they ever replaced an entire system before? How quickly did they do it? What problems did they encounter?

"At this stage, the two proposals varied in terms of the financial options and potential hidden costs," Nelson said. "For many years, our lab has preferred the reagent rental approach. Thus, our con-

tract options were to continue with reagent rental, rent to own, or get a lease.

"We asked the hospital legal staff and the purchasing department to review all the various aspects of leasing. I had the vendors present all the options so that I could show the numbers to the administration. We considered whether to do a capital purchase, a direct lease, a bundled lease, or a rent-to-lease approach.

Identifying Hidden Costs

"With any purchase like this, labs need to be aware of any potential hidden costs associated with the acquisition, installation, and use of new laboratory equipment," she noted. "Examples are construction or remodeling costs, the need to relocate utilities, and add-on charges for freight services

"Each different proposed configuration has unique hidden costs," she continued. "Do we need all the pieces, such as the decapper, the resealer, the alliquoter, and the storage components? Could we connect any pieces that we have now? If we pulled a component out of one proposal, what would it look like if the other company pulled it out too?

"Another hidden cost can be in the interfaces required for the lab information system (LIS)," Nelson said. "Invariably the allotments for interfaces are not at all what interfaces cost. The vendors will say the interfaces cost $10,000, but often your LIS vendor will say it is double that number.

"Get quotes on the necessary interfaces before the contracts are written," she noted. "Then negotiate that number so that it reflects the actual costs. Be sure to also include implementation team requirements and upgrades in the contract.

"Because we knew the laboratory staff would need training, we looked at the training schedule before we made our final decision," explained Nelson. "We also allocated hours to the FTE budget and added time for installation and instrument validation. Then, we calculated the savings based on having each vendor meet our timeline.

"In the end, our lab selected a Dimension Vista system by Siemens," Nelson said. "That meant we were choosing to stay with our incumbent vendor.

"When the decision was made, I credited the staff for a job well done and then we met for a final time with both vendors," she concluded. "The winning vendor wants to know the reasons behind your lab's decision—just as the vendor that wasn't selected wants to know. Make the effort to maintain good relationships, since many things can change between now and when your lab is once again ready to purchase new equipment.

"Because we insisted on getting savings during the implementation year, some savings began as soon as the contract was signed," she stated. "For example, the new contract had lower rates for the reagents used by some of the equipment our lab kept.

"The new laboratory automation system was installed in May, 2010," Nelson observed. "We immediately began to measure the ways in which this new lab automation solution and workflow configuration were meeting our standards for success.

Meeting Expectations

"We wanted to know if the staff and management expectations had been realized and when?" asked Nelson. "Did unexpected costs arise? Are the indicators moving in right direction? Was the support everything we expected? At year-end, and after one year, we will monitor our cost savings and watch for opportunities for additional in-house testing, particularly as we expand our in-house menu of tests."

Nelson reported that the new lab automation system was not fully installed and connected until September 2010. "Some savings started this spring, based on new prices of reagents that went into effect at that time," she said. "For a multitude of reasons, complete installation and

Laboratory Team at Ingalls Took Steps to Tap Vendors' Expertise in Workflow Consulting

NOW THAT THE LABORATORY at Ingalls Memorial Hospital has installed a second-generation automated line, the laboratory has twice benefited from tapping the workflow consulting expertise provided by its lab automation vendor.

"When we installed our first laboratory automation system five years ago, we found that most vendors provide a workflow report," said Marilyn Nelson, Director of Laboratory & Cardiac Services at Ingalls Memorial Hospital, in Harvey, Illinois. "This workflow report can be extremely valuable.

"As part of their agreement, each participating vendor studies your lab's workflow and prepares a report," she explained. "It's free consulting that tells me what's going on in my lab through the eyes of an objective observer. Included are time studies and interviews with each staff member. The vendor's consultant will gather information from phlebotomists, medical technologists, processing staff, and others involved in various work processes in the lab.

"Whenever they identify a problem—even without considering the changes you'll make to accommodate a new system," noted Nelson, "you have an opportunity to ask several important questions. Why is the staff following these procedures? How did we fall into these bad habits?

"This is useful information because it identifies opportunities for improvements at multiple points," she noted. "These workflow improvement suggestions allow you to communicate solutions to the laboratory staff that might have otherwise gone unrecognized or unaddressed.

"Moreover, because these workflow improvement recommendations were identified by the outside experts provided by the vendors, the laboratory staff is more open to this input," concluded Nelson. "That also helps make it easier for staff to then take the steps necessary to fix workflow problems."

operation of our new automated line took longer than planned.

"Despite this delay, we still realized savings and we anticipate saving about 20% in fiscal 2011, which began October 1," noted Nelson. "It looks like our costs will be near 20% lower in 2011 versus 2009-10 and our turnaround time has improved dramatically as well. So, everything that we anticipated is occurring and then some."

Meeting Expectations

Because of careful planning and consistent execution, the laboratory at Ingalls Memorial Hospital expects to harvest annual savings in the range of 20% from its second-generation laboratory automation project. This demonstrates how other well-managed hospital and health system laboratories can also realize significant cost savings and quality improvement when they retire aging automation equipment and install next-generation automation solutions.

Moreover, the successful automation project at the Ingalls laboratory reinforces the importance of the continuous improvement mindset in the operation and management of clinical laboratories and pathology groups. A key element in the success of this new automation project was the use of Lean, Six Sigma, and similar process improvement methods. These techniques do make major and ongoing contributions to a lab's success. **TDR**

Contact Marilyn Nelson at 708-915-5771 or mnelson@ingalls.org.

Surprises in KLAS Rating of Anatomic Path Systems

In its newest ratings, released last month, Psyche's WindoPath was listed in first place

CEO SUMMARY: KLAS Research published its Top 20 Best in KLAS Awards in December and ranked Psyche WindoPath the top system in two categories. KLAS, which rates as many as 56 categories of healthcare software and professional services products in its annual report, does not provide much detail in how it conducts surveys of users, nor the number of users of each product who were surveyed. KLAS does say that it uses stringent methodology to ensure all research is accurate, honest, and impartial.

RELEASED LAST MONTH, the newest rankings of healthcare software and professional services products developed annually by **KLAS Research** placed WindoPath by **Psyche Systems Corporation** as the best-rated anatomic pathology information system.

In its report titled "Top 20 Best in KLAS Awards: Software & Professional Services," KLAS provided ratings for a wide range of healthcare software categories. Laboratory information systems (LIS) are rated in several of these categories.

In the category of "Anatomic Pathology," KLAS listed six anatomic pathology information systems. WindoPath by Psyche Systems was rated as first and **Sunquest Information Systems'** CoPath was rated as second.

KLAS, a company founded in 1996 and based in Orem, Utah, builds its ratings from surveys of healthcare professionals. *(See sidebar on page 17 for KLAS' explanation of the methodology it uses.)* In this regard, the company states its ratings are based on feedback from users of the various information products that KLAS rates.

KLAS provided THE DARK REPORT with an extract of the full report and asked that the details of the ratings for the anatomic pathology systems covered in the report not be published. KLAS generates money by selling its reports to healthcare providers and vendors. It also provides advisory services, performs custom research, and provides on-site consulting services.

Rating AP Info Systems

Across the anatomic pathology profession, it is believed that the two most widely used anatomic pathology information systems are **Cerner Corporation's** CoPath/Millennium Anatomic Pathology and **Elekta's** PowerPath Anatomic Pathology. Given the market shares held respectively by these two products, it was interesting that the KLAS ratings placed neither system in the top two places.

However, both systems were included in the list of six anatomic pathology information systems rated and ranked by KLAS. The other two systems included in the survey were **Meditech's** C/S

Anatomical Pathology and **SCC Soft Computer's** SoftPath.

In general, few in the anatomic pathology profession have much knowledge about KLAS and its rating service. Typically, when pathologists consider upgrading or purchasing a new anatomic pathology information system, they tend to rely on RFPs, interviews with vendors and reference checks with existing users. They may also consider the market share held by different path information products as they make a decision about which anatomic pathology information system to purchase.

Steps In The Buying Process

As part of the buying process, it is also helpful to know how many new customers each anatomic pathology vendor acquired during recent years. But that information is not easily available to most pathology group practices.

KLAS is a company which wants to provide more detailed information to healthcare providers preparing to upgrade or purchase software and information systems. In its most recent "Top 20 Best in KLAS Awards: Software & Professional Services" report, KLAS provides rankings in 41 categories of "software solutions" and 15 categories of "professional services."

Within the laboratory segment, KLAS ranks laboratory information systems in two primary categories, with eight sub-categories. There are three sub-categories for anatomic pathology.

Data Used For Rankings

It is not easy to understand the precise data inputs used by KLAS to develop its rankings. For example, was the number one ranking for Psyche's WindoPath based on surveys conducted with only pathology labs that acquired a new or upgraded pathology system during the 12 months prior to the survey's release last month?

If so, that would place a different interpretation on the survey's findings than if a statistically significant number of existing, long-time customers for each of the six pathology systems were included in the survey.

On the following page, one of the pathology profession's leading experts on clinical laboratory and pathology informatics discussess the challenges involved in evaluating and ranking the capabilities and performance of different LIS products and anatomic pathology information systems.

Finally, any client or regular reader of THE DARK REPORT with experience using a rating service like KLAS is invited to contact us and share their experience. TDR

(Go to sidebar on the following page.)

Contact Bruce Friedman, M.D., at 734-926-8365 or friedman@labinfotech.com.

How KLAS Develops Its Software Rankings

TO BUILD ITS RANKINGS of different healthcare software products, KLAS relies on interviews and direct feedback from provider organizations. In its report, "Top 20 Best in KLAS Awards: Software & Professional Services," it described the data collection process as follows:

KLAS utilizes a three-step process to collect candid performance data. First, KLAS collects a series of direct product evaluations completed by healthcare provider organizations.

Second, KLAS performs in-depth, confidential interviews with the IT executives and department directors completing the questionnaire to gather valuable insight into specific strengths, weaknesses and future expectations for the product.

Third, the gathered data is subjected immediately to an internal audit to verify completeness and accuracy, and to make sure the anonymity of the provider organization is maintained. During the audit, each data set is reviewed by a KLAS executive and at least two other people.

Lab Informatics Expert Explains Why Ranking Laboratory Info Software Can Be Problematic

THIRD-PARTY SERVICES TO RANK HEALTHCARE SOFTWARE PRODUCTS face many challenges and typically produce assessments that are not likely to be helpful to the typical buyer of laboratory information system (LIS) software.

That's the assertion of Bruce A. Friedman, M.D., Active Emeritus Professor of Pathology at the **University of Michigan Medical School** and President, **Pathology Education Consortium**. For almost three decades, Friedman has been among the leading experts in laboratory informatics. His well-read blog at *www.labsoftnews.com* regularly tackles issues involving laboratory software and new information technologies.

"The reason I say the rankings are meaningless is because laboratory information systems are unbelievably complex systems," explained Friedman. "You have to evaluate gradations by price, functionality, the target market, and a number of other factors, including size and complexity of the labs it supports.

➤ Months To Rate An LIS

Further, a thorough and proper evaluation of a laboratory information system takes weeks and months," he said. "This process is familiar to anyone who has had the responsibility of evaluating LIS products when his or her laboratory prepares to either upgrade or purchase a new LIS.

"The first challenge for a software rating system is that few laboratories are identical in their test menu, specimen volume, instrumentation, staffing, and use of information technology," noted Friedman. "It is why clinical laboratories and anatomic pathology groups use a request for proposal (RFP) process that generally requires several months or more to conduct.

"Such an RFP for a clinical lab or pathology system will ask the vendor to address up to 150 specific items," he stated. "Take the function of lab ordering. The RFP will ask each vendor questions such as: Can your software do A, B, or C, and can it accomplish D or E? The vendor will respond with a 'yes,' 'no,' or 'in development' relative to each of these functions.

"Then the lab crunches these numbers to come up with some kind of rated average as to how the capabilities of each vendor's software matches the specifications of the laboratory," he explained. "Not only is the laboratory truly evaluating each vendor's system with regard to its own operations, but, it is also evaluating the vendor itself and its financial stability.

"As part of this evaluation process, the lab wants to know the extent to which other people recognize these vendors as being reputable and their system reliable," he added. "It is a complex process but it is transparent. When requested, labs will often send you a copy of their RFP.

"Plus, the responses of the vendors derived from the RFP can be added as an appendix to the contract so that the vendors are then held to their responses legally," he explained. "Frankly, that kind of a process is the only one I would trust."

Friedman noted that a ranking service also has the challenge of evaluating a new product versus long-established LIS products. "**Epic's** LIS product is called Beaker. It is in use in maybe 10 hospitals and is in its earliest stages of development," he noted.

"A best-of-breed LIS is one that has been tested in the market for a number of years, can go head-to-head with any LIS and perform in a superior fashion," he explained. "Now, should a new LIS like Beaker, with a handful of sites, be listed as a top LIS comparable with a system from a **Sunquest**, an **SCC** or a **Cerner**, all of which have been on the market for at least 10 years and all of which have 200 to 500 installations, depending on how you count them?"

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Do you know about GRIPE? It's the **Group for Research in Pathology Education** and it just concluded its winter meeting last week at **Marshall University** in Huntington, West Virginia. The organization has approximately 120 subscribers and, although most are located in the United States, it does have subscribers in countries ranging from Grenada and Ireland to New Guinea and India. GRIPE's mission is to "advance the quality of pathology education through scholarly research" and related activities. For more information about GRIPE, visit the organization's URL: *http://peir.path.uab.edu/griper/*.

BRITAIN'S NATIONAL HEALTH SERVICE TO RAMP UP HPV TEST PROGRAM

It is a move that the United Kingdom's **National Health Service** (NHS) believes will both save money and improve patient outcomes. In England, programs to use HPV testing in cervical cancer screening conducted by general practitioners (GP) will be ramped up during 2011. As reported in the web service **PulseToday.co.uk**, currently in England, only two hospital laboratories—in Bristol and Manchester—use HPV tests as part of cervical cancer screening services.

ADD TO: HPV Testing

In the United Kingdom at this time, Scotland uses HPV tests only in the follow-up to treatment. Both Northern Ireland and Wales are conducting studies of HPV testing. An NHS spokesman stated that one pilot project involving HPV testing at a sentinel site in northwest London led to an 85% reduction in the number of women requiring consecutive post-treatment cytological surveillance.

TRANSITIONS

• **Caris Life Sciences, Inc.**, of Irving, Texas, announced that Amy Jensen Cunniffe would serve in the newly-created position of Senior Vice President for Government Affairs. Cunniffe will establish a Caris office in Washington, DC. Cunniffe most recently served at **GE Healthcare** in the role of Leader for the Government Relations Team. Caris' new office inside the beltway is a sign that the lab testing company expects much government activity in the regulation of healthcare, including molecular and genetic testing.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 7, 2011.

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*Preview–**Rina Wolf**, Xifin, Inc. on...*

Medicare's New Attack on Molecular Test Coverage: What Every Lab Needs To Know

There's plenty afoot in the world of coding, billing, and reimbursement for molecular testing. Start with Medicare carrier Palmetto's memo on molecular diagnostic tests. Next, add the work underway by the AMA's CPT Editorial Panel to reform and update codes for molecular diagnostic tests. Here's essential information to guide you to all the coming changes and help you prepare for new, stricter coding and billing guidelines. If your lab bills for molecular tests, then this is a "must attend" session for you!

Check for program details and to register!
visit www.executivewarcollege.com

- ***Surprising Changes Identified in THE DARK REPORT'S Biannual List of Anatomic Pathology Market Trends.***
- ***Understanding the Resurgence of Hospital Lab Outreach and Its Role in Fostering Increased Integration of Clinical Care.***
- ***Coming Soon to a Pathology Group Near You! Intergenerational Struggles involving Up-and-Coming Gen Xers and Soon-to-Retire Baby Boomers.***

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