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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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Across the Pond, Lots of Changes in Lab Testing

IN BOTH THE UNITED KINGDOM AND EUROPE, plenty of change is unfolding in clinical laboratory and anatomic pathology testing. Our intrepid Editor-in-Chief, Robert L. Michel, spent last week in England attending our annual Frontiers in Laboratory Medicine conference, now in its eleventh year.

He came back with interesting information on developments in several European nations involving laboratory medicine. Within the United Kingdom, a quality assurance review of pathology was just completed by a National Health Service team and made public. It recommends a number of important improvements to medical laboratory quality assurance, including better performance metrics for each laboratory that can be viewed by the public as they are collected and updated.

Additionally, there is continued progress on achieving regional consolidation and standardization of regional laboratories within the United Kingdom. At the same time, a process called "commissioning" requires that hospital-based laboratories now submit bids to provide lab testing for the general practice clinics and primary care trusts. This is introducing a bit of competition into the mix and creating new financial challenges for the clinical biochemists and pathologists who lead these laboratory organizations.

In Ireland, an ongoing fight over adequate budgets for the Irish Health Service has meant that long-standing plans for revamping medical laboratory testing across the nation continue to stay on hold. News headlines are full of the spats between the Irish Parliament and the Health Service Executive over the money available for improving patient access and the quality of health services.

Meanwhile, over in Denmark, that nation is embarked on an ambitious reorganization of hospitals—and hospital laboratory services. As reported at FiLM by Per E. Jørgensen, M.D., Medical Director at **Glostrup University Hospital** in Denmark, the move is "to fewer, but bigger" hospitals. Currently there are 46 hospitals in this nation of 5.6 million people. By 2020, it is proposed to reduce that number to 20 acute care hospitals, supported by a few specialty hospitals. In tandem, the medical laboratories of these hospitals will be consolidated.

For me, these are all reminders that our country's health system is not unique in its own ongoing reforms. Healthcare everywhere is undergoing transformation. Might we actually have it better than we think here in the USA? TDR

Quality Assurance Regs to Tighten for UK Labs

NHS pathology review recommends several important changes to lab quality requirements

CEO SUMMARY: In the United Kingdom, a window of opportunity has opened for improving the quality assurance activities of pathology and histopathology laboratories. Last week, at the Frontiers in Laboratory Medicine conference, the newly-published "Pathology Quality Assurance Review" was the focus of several keynote sessions. One recommendation is to develop key assurance indicators (KAIs) that each lab would report to the National Health Service and the public.

THERE WILL BE A MORE RIGOROUS SYSTEM OF QUALITY ASSURANCE for medical laboratories and histopathology laboratories in the United Kingdom (UK), based on the findings and recommendations of an independent pathology review that was made public last week.

In the United Kingdom, there is a different type of nationwide scheme for medical laboratory regulation, compared to what exists in the United States. Expectations are that this pathology review will initiate the development and promulgation of tighter national quality assurance standards for pathology laboratories in the UK.

The United Kingdom thus has the opportunity to create a state-of-the-art scheme for quality assurance and laboratory accreditation and become a global leader in this regard. That is, if the system it eventually adopts is properly designed and incorporates the latest methods in continuous improvement, Six Sigma, and quality management systems.

In its press release about the review, the **National Health Service** (NHS) stated that the report, titled "Pathology Quality Assurance Review," was recommending the "need for transparency, better safety checks on testing, consistency and standardization of processes and procedures" in how laboratories in the United Kingdom perform clinical lab testing.

It was Sir Bruce Keogh, Medical Director of NHS England, who commissioned the review in December 2012. Earlier that year, it was disclosed that, at the **Sherwood Forest Hospitals NHS Foundation Trust**, between 2004 and 2010, as many as 120 breast cancer

patients may have had inaccurate results from post-surgical testing of their tissues for estrogen receptors.

The review was led by Dr. Ian Barnes, who was the National Clinical Director for Pathology in 2012. Last Tuesday, at the 11th Annual Frontiers in Laboratory Medicine (FiLM) conference in Birmingham, England, Barnes and Peter Huntley, Workstream Lead for the pathology review, discussed the conclusions in the report, along with its recommendations.

FiLM is co-produced annually by the **Association for Clinical Biochemistry** and THE DARK REPORT. Its Editor, Robert L. Michel, was in attendance. This intelligence briefing is based on the notes taken by Michel during the presentation made by Barnes and Huntley.

The pathology review team determined that the current system for quality assurance in the UK "relies almost entirely on professionalism and goodwill." It is "focused on minimum acceptable standards," and is not "designed to provide public assurance to patients, nor to assist Boards and commissioners in fulfilling their statutory duties."

No Serious System Issues

One bit of good news from the pathology quality assurance review was that serious systemic problems in pathology testing were not found, with the caveat that the ability to accurately and precisely determine the quality of lab testing activities is falling behind the pace of new technology advances in diagnostic medicine.

In fact, the two speakers noted that the United Kingdom has been "at the forefront of quality assurance in pathology for the past 50 years, leading the way on external quality assurance. The UK was—along with Holland—the first European country to introduce a laboratory accreditation scheme for pathology."

Barnes and Huntley next identified why changes and improvements in quality assurance are necessary. They noted that:

- The current system of quality assurance in medical laboratories is fit for what it was originally designed to do, but, importantly, the current state is not fit for the future.
- The current system does not meet emerging requirements for transparency and well-evidenced quality assurance.
- The current quality assurance framework lacks key assurance indicators (KAI) to evidence quality and safety of pathology services.

'Too Much Variation'

Just as in the United States, experts in the United Kingdom have called attention to the weaknesses in the existing system of quality assurance and quality control when viewed across the entire profession of laboratory medicine. In the words of Barnes and Huntley, in the UK, there is "too much variation in the pathology testing service, a lack of harmonization and standards [across different laboratories], which is unacceptable to patients and users."

In the sidebar on page 5, the key recommendations of the Pathology Quality Assurance Review are listed. A number of the recommendations represent significant change to the existing system of quality assurance found in pathology and histopathology laboratories across the United Kingdom.

For example, it is recommended that key assurance indicators be developed and be published regularly. The goal is to allow the trusts, the commissioners (who "buy" lab testing services for their trusts), and patients to see the performance of individual pathology laboratories throughout the nation.

Quality Assurance Training

Another major change will be to upgrade the training of individuals responsible for quality assurance in their laboratories. At the same time, these individuals will need to undergo regular testing of their competency in this field.

Another recommendation with the potential to effect significant change involves better compliance by labs in reporting errors and incidents that might have caused—or did cause—patient harm. In this regard, the United Kingdom and the United States have one thing in common, which is that the true number of errors or incidents in labs with the potential to cause patient harm are unknown to government regulators. Further, many of those incidents which do reach the attention of regulators are not published, denying consumers access to that information.

As part of the review, Barnes and Huntley noted that pathology services in the United Kingdom employ about 33,000 people who work in 150 lab organizations. These labs perform approximately 200 million requests annually.

Within the UK, an organization called the **United Kingdom Accreditation Service** (UKAS) is responsible for two main accreditation processes in laboratory medicine. Laboratory organizations must accredit to the standards of ISO 15189. External Quality Assessment sources must accredit to ISO 17043–Conformity Assessment—General Requirements for Proficiency Testing.

Review Has Broad Support

Following Barnes' presentation, representatives from several important lab organizations each spoke of their support for the findings and recommendations of the Pathology Quality Assurance Review.

Included were individuals representing the **Royal College of Pathologists**, the Association for Clinical Biochemistry, the **Institute of Biomedical Science**, and the **British In Vitro Diagnostics Association**.

At this moment in time, the pathology review has the full attention of the NHS leadership and there is forward momentum. However, a change in government or unforeseen budget issues could cause this pathology reform effort to be sidelined before it is fully implemented. TDR

Recommendations From UK Pathology Quality Review

BELOW ARE LISTED THE MAJOR RECOMMENDATIONS of the "Pathology Quality Assessment Review" done for the National Health Service in the United Kingdom and published last week. *(For entire report: http://goo.gl/GGsN6i)*

- Systematically train pathology staff in skills of quality management systems and quality improvement methodology.
- Expand membership role and function of Joint Working Group for Quality Assessment in Pathology (JWGQA) of the Royal College of Pathology, and work with the United Kingdom Accreditation Service (UKAS) to implement changes in the accreditation process and publication of performance data [of participating laboratories].
- Assessment of individual's performance in external quality assurance (EQA) schemes.
- integrate quality and governance systems of pathology providers with that of the trusts. To include regular publication of quality performance and key assurance indicators (KAIs). Lab providers to refer samples for testing to third-party services.
- Improved adherence to existing guidance on the standardization and transparent reporting of errors from pathology services, including reporting of all incidents that could have, or did lead to patient harm.
- Improved pathology informatics to remain a priority. Professional bodies, IVD manufacturers, and others should work to minimize the differences between analytical processes, requesting, and reporting.
- Update accreditation of pathology services to clearly show which laboratories meet minimum requirements, and which are excelling to provide first-rate service quality.

New Blue Card Policies Cause Labs to Go Unpaid

Out-of-state labs were once in-network, but are now considered to be out-of-network

CEO SUMMARY: Widespread frustration continues within the independent clinical laboratory community about the new Blue Card rules that took effect in October 2012. That was when the Blue Cross Blue Shield Association revised its Blue Card program so that labs must bill the local plan in the service area where the specimen was obtained/collected. Further, most local Blue Cross plans are sending reimbursement checks directly to patients, leaving it to labs to find these patients and collect payment from them.

FOR 16 MONTHS, many independent clinical labs have struggled to understand and get paid under the revised procedures the **Blue Cross Blue Shield Association** instituted in October 2012, for its Blue Card program.

Labs report that they have attempted one or more of the following actions to address this situation: 1) enroll or attempt to enroll with the out-of-state local plans as a participating provider; 2) add additional staff to their billing and collections departments in an attempt to adjudicate claims; 3) add additional staff to collect from patients issued reimbursement checks directly from the local plans; and, 4) analyze data to determine whether it's better to be in-network with out-of-state Blues plans or remain out of network.

Many independent labs have lost specimen volume and/or testing revenue as a consequence of the new Blue Card policy. "I know of specific labs that have lost approximately 30% of total annual revenue," stated Charles C. Dunham IV, an attorney with **Bond Schoeneck & King** in Albany, New York.

Effective October 2012, the Blue Cross Blue Shield Association (BCBSA) implemented the major change to its Blue Card program it had announced earlier. In cases where a patient specimen was obtained/collected out-of-state, independent clinical labs would no longer be able to submit claims for lab services to the local plan in the service area where the test was performed, but rather would submit to the local plan where the specimen was obtained/collected.

As such, any lab testing services done at an out-of-state lab would be considered out-of-network for those Blue Card services and would be reimbursed at out-of-network rates, unless the lab was enrolled as an in-network lab with that specific local plan. *(See TDR, July 16, 2012.)*

Problems For Labs

This rule change has caused significant problems for labs throughout the United States. Essentially, it changed the provider enrollment status of any lab that provides lab testing services to a patient enrolled under a Blue Card plan where the specimen that is obtained or collected outside

Local Blue Cross Plans Respond with Reasons Why They Deny Requests of Labs to Join Networks

WHAT HAVE SOME BLUE CROSS LOCAL PLANS stated to labs when explaining the reason for denying the enrollment application?

"When labs submit an enrollment application to local plans to be considered in-network, they are likely to hear these reasons from the various local plans," observed Charles Dunham IV, an attorney with Bond Schoeneck & King.

"First, some local plans will say they have exclusive contracts with **Quest Diagnostics Incorporated** or with **Laboratory Corporation of America**," he stated. "They will assert that these exclusive contracts do not allow other labs to enroll as in-network providers.

"The second reason is the brick and mortar issue," Dunham said. "When a lab does not have a physical presence in the state, the local plans are not interested in contracting with out-of-state labs unless there is some lab testing being done within the state. However, most independent labs don't have facilities in multiple states—and didn't have them when providing lab testing to Blues beneficiaries before the new Blue Card policy was implemented.

"The third reason is based on the desire of the local plans to reduce overhead costs related to processing claims from multiple labs," stated Dunham. "These local plans apparently believe smaller networks are easier from an administrative standpoint.

"It could be argued that having smaller networks helps keep their premiums down and low premiums are important to customers," concluded Dunaham. "If their costs rise, they may need to increase premiums or reduce benefits to enrollees, neither of which they want to do."

of the state in which the lab is performing the testing service.

This significant change to the Blue Card rules has created problems for many lab organizations and for patient enrollees using their Blue Card benefit. Since the new Blue Card policy took effect, Dunham said that labs are facing at least three primary issues when seeking payment for the Blue Card claims.

"The first issue is provider enrollment, which means that labs may want to consider strategic contracting," said Dunham. "If your lab is out-of-network, then you may want to make two key determinations. First, how much lab testing would your lab get if it became an in-network lab for that Local Plan? Second, what are the in-network rates and how do they compare to the out-of-network rates? Labs that want to be in-network must accept the contracts and the fee schedules offered by the local plan.

"It is essential that your lab team understand the price and terms being offered to you as an in-network provider by each and every local plan your lab is considering," he stated. "Analyze what you would be paid on the in-network fee schedule versus what you would get paid as an out-of-network lab. Also, consider what percentage of claims are being denied to your lab as a non-participating provider.

Understand Price And Terms

"Upon completing this analysis, I've seen some labs decide that it is just not worth becoming an in-network provider," Dunham added. "Sometimes a lab will do better financially by just staying out-of-network.

"The second issue is claims processing/adjudication and the need to be persistent," he said. "This means working every claim diligently. Doing so requires ongoing conversations between the lab's billing staff

and the various local plans while resubmitting or manually submitting claims when the plans ask for additional information. In my experience, labs that have been persistent in this regard have processed more claims through the local plans than labs that have not been persistent."

Collecting From Patients

Dunham said that the third issue involves collecting directly from patients. "What has surfaced as a problem is that most local plans are paying patients directly for out-of-network services," stated Dunham. "This makes it even tougher for labs to get paid for these claims.

"Interestingly, the national policy of the BCBS Association is that payment for out-of-network services should be made directly to the patient because the contract is with the patient." explained Dunham. "Then, the patient is supposed to return the payment to the provider. But patients don't always pay the labs or understand what to do with the payment. Therefore, labs must track down these patients.

"One way that a lab can get the local plan to pay it directly and not send the payment to the patients is to use what's called an assignment of benefits form," he advised. "However, few states require plans to honor this assignment and pay providers directly if the providers have patients assign benefit payments to them.

Assignment Of Benefits

"For this to work, a lab needs to get each individual patient to sign an assignment of benefits form, usually at the time of service," continued Dunham. "This is often difficult because the lab typically never sees the patient.

"In most states, health plans are not required to pay the lab, even with an executed assignment of benefits form, and each local plan can decide if it will pay the out-of-network provider or the patient," he said. "When plans pay the patients, the patients are then supposed to pay the lab.

"Labs should try to collect from all patients early and often if they hope to be successful in collecting these amounts," noted Dunham. "Getting information on patients is difficult because—as an out-of-network provider—the lab that performed the test may not always be granted access by a local plan to view this patient's EOB and payment information online.

"In-network providers can go online to view almost all the information they need to check a claim's status, the adjudication amount, and how to reach the patient by phone and mail," he commented. "Unfortunately, if the labs don't have access to the patients' information online, they have to call the local plans and get someone there to track down each and every claim.

Collection Done Manually

"Too often, this form of collection was—and is—done manually, meaning the plan won't transmit either an electronic explanation of benefits or an electronic payment," observed Dunham. "That is why labs have needed to hire additional staff: Someone at the lab has to do this leg work to ensure that these lab test claims are paid."

Another tactic that labs can try may be easier. "It is always worth simply making application to become an in-network provider with a local plan," said Dunham. "Just going through the application process with a local plan is a positive development because—even if the plan rejects your lab—there could be a benefit to submitting an enrollment application when it comes to claims adjudication.

"At a minimum, the local plans will get to know your lab and that may make it easier to get an internal billing identification number," he continued. "It's not the same as being in-network, but it may help facilitate the claims process and help with obtaining payment status information." TDR

—Joseph Burns

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Once Again, Revenue Declines at Quest Diagnostics Incorporated

Fourth quarter and full-year 2013 earnings report provide evidence of weakening market for lab testing

FIRST TO REPORT its fourth quarter and full year earnings for 2013 was **Quest Diagnostics Incorporated**. It released its earnings report last Thursday.

For fourth quarter 2013, Quest Diagnostics generated revenue of $1.76 billion, compared to $1.77 billion in Q4-2012. This was a decline of 1% and in line with industry expectations.

Specimen volume was up 2.3% for fourth quarter, compared to same quarter in 2012. Revenue per requisition was 3% less than same quarter last year, of which 1% was attributed to a toxicology company acquisition and 2% due to ongoing reimbursement pressure.

For the full year, Quest Diagnostics reported revenue of $7.14 billion, compared to $7.38 billion in 2012. This was a decline of 3.2%. The company did not provide numbers on its full-year specimen volume or change in revenue per requisition.

Shrinking Annual Revenue

Anticipating 2014, executives at Quest Diagnostics told Wall Street analysts to expect the company's revenue to end up between flat and negative 2%. This predicts a trend of disappointing growth consistent with a trend that goes back several years.

For example, the high-water mark for annual revenue at Quest Diagnostics was in 2009, when it generated $7.46 billion. Thus, over the past four years, it has not been able to reach or exceed the revenue total that it posted in 2009.

This is one reason why Quest Diagnostics was probably willing to bid more than other potential buyers to acquire **Solstas Laboratory Partners** of Greensboro, North Carolina. *(See page 19.)* That deal was announced last month and may bring up to $350 million in annual revenue to the nation's largest commercial lab company.

Hospital Lab Agreements

Meanwhile, executives at Quest Diagnostics are hopeful that they can expand their company's presence in hospital laboratory management and operations. During the fourth quarter conference call, it was disclosed that the company had "reached agreement with three hospital systems on lab professional services arrangements."

Neither the nature of the arrangements nor the identity of the hospitals was provided. That may be a sign that these deals involve smaller community hospitals, some of which may be in financial trouble. Most of the hospital lab outreach sales announced in the past 48 months have been by hospitals or health systems that were under financial pressure and wanted to raise capital by selling their lab outreach businesses.

Finally, on a useful note for other laboratories, Quest Diagnostics reported a modest increase in patient bad debt. It said that most of this was due to increased co-pays and deductibles required of patients, and not from uninsured patients. TDR

CEO Summary: Henry Ford Health System's laboratory organization has become first in the nation to have all its laboratory sites "standardized under one source of leadership" and accredited to the standards of ISO 15189: Medical Laboratories. The journey to achieve this current state has taken almost 10 years and started with the development of a Lean culture throughout the health system's labs, followed by accreditation to ISO 15189 during 2013. Now the lab team is aligned in how it implements changes.

Henry Ford Health is largest system to have all labs working with ISO QMS

Lean Used to Lay Groundwork for Lab's 15189 Accreditation

IT'S AN IMPORTANT MILESTONE for the laboratory medicine profession. For the first time, a major health system in the United States has earned accreditation of its constituent laboratory sites to the standards of ISO 15189: Medical Laboratories.

The honor belongs to **Henry Ford Health System** (HFHS), based in Detroit, Michigan. It fulfills a goal of Richard J. Zarbo, M.D., D.M.D, the Senior Vice President and Chair of Pathology and Lab Medicine at Henry Ford. During 2013, Henry Ford became the "only integrated delivery system, where all laboratories are standardized under one source of leadership," to gain this accreditation.

The achievement is notable, particularly at a time when laboratories across the nation are under financial stress, yet must perform more testing in the face of shrinking budgets and mandated higher standards of quality.

There is competitive advantage to be gained from a lab that has introduced a quality management system (QMS) such as ISO 15189 across its organization. During a presentation last fall on why the clinical laboratories at HFHS became accredited to ISO 15189, Zarbo quoted Henry Ford himself. The great industrialist once said, "The competitor to be feared is one who never bothers about you at all, but goes on making his own business better all the time."

"Our accreditation to CAP 15189 is a way for us to be the best we can be, while using that achievement to attract new business and retain customers," observed Zarbo during his presentation at *Lab Quality Confab* last fall in New Orleans.

In 2013, the clinical labs at all four lab sites at HFHS achieved accreditation to ISO 15189. Zarbo believes HFHS is the largest such health system to have its labs earn accreditation to ISO 15189 and is the only integrated delivery system in which all laboratories are standardized under one source of leadership to gain this accreditation, as he told *CAP Today* in an article in November.

"Accreditation to this respected quality management system (QMS) is necessary because the clinical lab business today is about the pursuit of survival," he added. "We had six acute care hospitals a couple of years ago. Now we are down to four. As well, within our health system we are consolidating not just the labs, but we are also consolidating hospitals."

Consequently, specimen volume is rising within the HFHS labs, even as head count declines and the health system administration asks the labs to do more with less.

Several years ago, when the lab team recognized how these trends were likely to play out, HFHS established a two-pronged strategy. First, it would introduce Lean techniques into the labs and establish a Lean culture that would support continuous improvement.

Second, using the knowledge the lab staff had mastered about process improvement and Lean methods, the second step was to implement the QMS of ISO 15189 throughout the lab services organization at Henry Ford Health System. Zarbo was convinced that the labs needed to do both in order to continuously reduce errors and boost efficiency in an environment of declining lab test revenues.

"Earning the ISO 15189 accreditation was a challenge for us, but it was made just a bit easier because we had already completed the task of introducing Lean into the operation," recalled Zarbo. "We had also integrated or consolidated our laboratories before we began the process of becoming accredited to CAP 15189.

"Everyone knew that this was a long-range strategy," he continued. "It began as far back as 2004, when we started introducing Lean into our main hospital laboratories. After all these years of introducing Lean into each of our lab's work processes, we had established competence in Lean and the laboratory staff was comfortable with the Lean culture within our organization.

"During that same time, we were also dealing with significant integration and consolidation activities in our health system," explained Zarbo. "For example, the number of hospitals dropped from six to four and we moved more laboratory testing into our core laboratory.

"It was a four-year timeline," noted Zarbo. "During the four years of 2009 through 2012, we progressed through Lean first at our community hospitals, then to integration and consolidation. Beginning in 2012,

we undertook the ISO 15189 journey at all sites now that we were standardized.

"It's important to understand that where we started was just like where many labs begin: in a state of entropy or chaos," emphasized Zarbo. "In other words, even after the introduction of Lean, there were still many opportunities for significant improvement. We saw ways to both reduce costs and improve the clinical value of our lab services.

"Fortunately, we had a couple of years to become proficient with Lean and its techniques," recalled Zarbo. "That allowed us to start integrating laboratories within our health system. Integration helped us to eliminate many silos that existed. The benefit was that all lab sites became fully participating parts of our system-wide Laboratory Quality Management System.

"Once that integration was achieved, we continued to use Lean to identify ISO gaps and we began preparing to introduce the ISO QMS by creating electronic document control systems." he continued. "We used that document control system to standardize 10,000 documents in a paperless system across the entire healthcare enterprise.

Adopting Best Practices

"In other words, we were installing some of the antecedents that we would need for accreditation to ISO 15189," stated Zarbo. "It was a way to begin educating all staff members about ISO accreditation in preparation for the first ISO gap inspection. That gap inspection took place in January 2013. The final accreditation inspection was performed in June of 2013.

"Notice that we went from the gap inspection in January to the accreditation itself in less than six months," stated Zarbo. "We could move quickly from gap inspection to accreditation because our implementation of Lean principles and their use in integrating and consolidating labs had established many of the operational requirements of the ISO QMS. In effect, throughout the prior four years, our Lean initiatives were conducted in such a way as to fully conform to ISO 15189 standards.

Role Of Long-Range Plans

"It's important to note how we used long-range planning to lay the groundwork for our CAP 15189 accreditation," he added. "All the improvements we made in our labs over the prior four years and even going back further to 2004—so 10 years really—came as a result of our long-range plans.

"We didn't just wake up one morning and say, 'We're going to tackle Lean today and get it done immediately,'" stated Zarbo. "And we certainly didn't do that with our ISO 15189 accreditation.

"I emphasize the multi-year span of our lab's journey because earning ISO accreditation requires preparation," he said. "Plus, it represents change to the working culture in the laboratory.

"It means implementing something new and asking people to do things that they ordinarily do not do," continued Zarbo. "To help our lab staff through the transition to Lean and the accreditation to ISO 15189, we followed the eight steps of change management described in the book written by John Kotter, titled 'On What Leaders Really Do.'"

"Further, during implementation, we recognized that in order to achieve higher levels of quality, it could be perceived that we were layering an additional job on top of the work that the staff was doing already," he continued. "Our goal was to introduce ISO while at the same time helping people understand that we were not truly adding a new job on top of their daily responsibilities.

"This could be done because we had already restructured the lab so that Lean had become a normal way of life," he added. "We envisioned that ISO 15189 would become a way of life as well. In that way, neither Lean nor ISO 15189 were viewed as additional jobs.

"What leaders do is drive change," he continued. "We worked with the lab staff on these changes so that Lean and ISO 15189 became a natural way to address daily work in the lab. That is critical to the success of a lab's ISO journey.

"However, the rewards are substantial and ongoing," said Zarbo, "because it is always people who do the work. In fact, the simple truth about a quality management system is that the QMS does not produce quality. Rather, the QMS is the foundation that enables the staff to produce quality work."

Sustaining change is always an issue for clinical labs and pathology groups. HFHS lab leaders anticipated this challenge and addressed it directly. "We have both horizontal and vertical management for quality," added Zarbo. "That means we needed a Quality Technical Team for the laboratories. This technical team is composed of physicians, pathologists, directors, quality assurance champions, managers, and supervisors.

Quality Technical Team

"The Quality Technical Team meets via a monthly standing conference call," he said. "About 50 people participate on the call. Some individuals work on the main campus, but most call in from remote locations."

HFHS utilizes these conference calls more frequently, as needed. "For example, during the first six months of 2013 when we were closing the ISO inspection gaps, we had these conference calls once a week." observed Zarbo. "That allowed us to work together as a team to close each gap.

"Remember, the ISO QMS gaps had to be closed in a standardized fashion at all sites," he explained. "It was essential that all 28 medical centers and the four acute care hospitals worked collaboratively to close these gaps in the same fashion.

"Certain members of the laboratory's leadership team were critical to this process," commented Zarbo. "One such leader was Aaron Lupovitch, M.D., our 84-year-old Emeritus Chair and Director of Regulatory Quality Initiatives in our Quality Systems Division. He toiled tirelessly for years helping us to integrate the CAP accreditation requirements for ISO 15189.

"Another key contributor was Gaurav Sharma, M.D., senior staff pathologist,

Goals for 32 Lab Sites at Henry Ford Health

HERE ARE THE GOALS the clinical laboratories set for themselves at the Henry Ford Health System:

- All specimens from any operating room within the Henry Ford Health System are to be transported, grossed, and processed within the day of surgery at the Core Anatomic Pathology Lab.
- There will be continuous flow processing for biopsies and large specimens using Lean processes with short cycle times.
- For biopsy reports, 80% will be done within two days.
- For large specimens, all reports will be done within three days.
- Production in the lab should strive for the ideal condition, meaning work processes are:

  ...defect free (a goal of zero defects meets customers' expectations).

  ...done on demand (meaning they are supplied when customers want the work done).

  ...done immediately so that there is no waiting.

  ...done one at a time (meaning there is single-piece flow and batch size equals one).

  ...done in a continuous flow (meaning no batches or queues).

  ...producing minimal waste in materials, labor, energy, and other resources.

  ...done safely for every employee.

Associate Director of Clinical Core Laboratories, and Director of Compliance and Regulatory Affairs," he continued. "But it was our Queen of Quality, Quality Manager Rita D'Angelo, who oversaw the entire project as the chief architect of our Lean culture from its inception. She devised the rapid path used by teams to address gaps and helped engage all 800 lab employees to win the ISO accreditation."

Why Pursue ISO?

The decision to implement Lean and earn accreditation to ISO 15189 was based on the desire to harvest certain benefits and achieve key outcomes. "The first and most important result was deviation management," noted Zarbo. "As a result of becoming accredited to the QMS of ISO 15189:2007, we now record all deviations and all non-conformances that occur everywhere.

"The workforce tabulates them daily as they occur and they're recorded according to a classification scheme," noted Zarbo. "These are tracked with our internal trackers that are accessed on a shared website.

"By developing methods to control non-conformities, our lab's corrective-preventive action system is now more robust compared to what it was previously," he added. "Today, we immediately document the steps we take to resolve problems. In addition, we can document the steps we take when a deviation requires a root cause analysis.

Managing Change Effectively

"By focusing on deviation management, we not only accept education and process change as a solution, but we also monitor the effectiveness of whatever process was changed to eliminate that deviation," stated Zarbo. "Another benefit is that we closely document our system of continuous improvement and the changes we make to protocols and lab operations. This centers upon our digital document control system and that is something we didn't have before. All posted documents and job aids are filed under document control and that mirrors everything that occurs in our 32 laboratory sites.

"There was also substantial improvement in the operational quality outcomes we achieved," stated Zarbo. "Operational quality outcomes are particularly important to our lab because we've consolidated everything into our main hospital core laboratories. That means our volume on the main campus has increased, even though, at the same time, we experienced a sharp decline in our number of full-time equivalent employees.

"Even accounting for the reduction in our lab staffing, we have continued to pursue high goals," commented Zarbo. "They are ambitious and we are starting to reach those levels.

"For example, we have a goal to complete all tests for the emergency room in less than 30 minutes," he said. "We recently began to meet that goal, and it is noteworthy that we've achieved this even as the number of core lab employees declined significantly.

Establishing Benchmarks

"In the area of outpatient test turnaround times, we established three distinct benchmarks," continued Zarbo. "First, we want to report 98% of test results by 6 a.m. the next morning, which is essential for outpatient settings.

"Second, for outpatient specimens received by 5 p.m., we want to complete 95% of testing by midnight," he said. "Third, for outpatient specimens received between 5 p.m. and 8 p.m., we want to report 90% of those test results by midnight. We are starting to achieve these goals.

"For biopsies, our goal is a two-day turnaround time for all biopsies from all sites, including outreach," continued Zarbo. "We are achieving this goal despite the loss of one pathologist and several histotechnologists.

'Daily Management' Is Important Tool Used to Sustain Change at Henry Ford Lab Division

SUSTAINING CHANGES IN THE LAB FOLLOWING IMPROVEMENT PROJECTS is always a challenge. One effective method to sustain change is the use of short "daily management" meetings, such as is currently done by the laboratory team at Henry Ford Health System. "Daily management" is credited with helping nurture the culture of continuous improvement.

"Everyone in the laboratory organization at Henry Ford Health System understands the concept of 'daily management,'" stated Richard Zarbo, M.D., D.M.D., Senior Vice President and Chair of Pathology and Lab Medicine at Henry Ford. "These are short, quick-hitting meetings that help people stay focused on their team's daily metrics and the progress they are making toward their goals."

Zarbo noted that "daily management" (DM) is the ultimate in true "visual management" in the workplace. He explained that each DM meeting includes the following:

- Selected critical metrics define daily performance.
- Information must be simple to collect and easy to understand.
- Data needs to tell you at a glance in three seconds whether you are "winning" or "losing" today.
- Is visible at a distance to all involved in the meeting.
- Is directed toward a group, not individuals.
- Shows the standard and your team's performance toward sustaining it.
- Involves all physicians, administrative managers, supervisors, and tech leaders in the management process.
- Focuses the team on just a few critical metrics for success each day.
- Is used to drive PDCA problem solving in a blameless environment.

"Each lab team conducting its DM meetings looks at the metrics that we call "Q-T-I-P-S," added Zarbo. "This stands for quality, time, inventory, productivity, and safety. Emphasizing Q-T-I-P-S at each DM meeting has created a common understanding of what drives our business. It also provides the framework for each team in the lab to apply the Lean and process improvement tools to their particular area of responsibility."

"This brings us to the most important outcome: cost reduction," said Zarbo. "Our lab has demonstrated continuous cost reduction. For example, year after year, the overall expense of the core lab has declined.

"At the same time, we have tracked the costs that are charged back to the community hospitals for doing work in the core lab," he continued. "These are fully loaded expenses such as blood, information technology, couriers, and pathologists and they have also declined steadily.

"The bottom line in this discussion is that Lean and accreditation to ISO 15189:2007 allow us to be more efficient," concluded Zarbo. "This means we produce more tests with fewer staff and we continue to do so with lower costs and fewer defects. As you can imagine for an urban hospital system, these are impressive results." **TDR**

—Joseph Burns

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Medicare OPPS Rule Has Pitfalls for Labs

➤CMS finally issues rules for packaging certain lab tests for OPPS outpatients

➤➤CEO SUMMARY: On January 1, the new Medicare rule for requiring bundled or packaged reimbursement for certain services covered by the hospital Outpatient Prospective Payment System (OPPS) became effective. Just four days earlier (on December 27), Medicare officials issued instructions on how to bill for these services. The new rules trigger serious compliance risks if providers—including labs—fail to meet these requirements.

SINCE THE START OF THE NEW YEAR, both clinical laboratories and hospitals must pay attention to Medicare's new "bundled payment" rules for certain outpatient procedures.

However, the federal **Centers for Medicare & Medicaid Services** (CMS) issued instructions on how to implement this new complicated billing procedure only on December 27. "That left labs and hospitals just four days before the new rules went into effect on January 1," stated Robert E. Mazer, a lawyer and Principal with **Ober Kaler**, in Baltimore, Maryland.

➤Medicare Bundled Pricing

At issue are the "bundled pricing" rules for certain procedures that took effect on January 1, 2014. The result is that hospitals spent January implementing the procedures necessary to get paid under the revised hospital outpatient prospective payment system (OPPS).

"Under the new rule, CMS adopted a policy that calls for 'packaging' certain clinical laboratory tests provided to hospital outpatients into the OPPS," stated Mazer. "Most clinical laboratory tests provided to hospital outpatients are included under the new packaging or bundling policy, although certain molecular pathology tests are excluded from packaging."

"The new payment policy this year applies only to services for Medicare beneficiaries who are hospital outpatients," wrote Mazer in a report issued by Ober Kaler. "Although CMS indicated that it has included the cost of laboratory tests in determining payments for hospital outpatient services, hospitals can expect a likely reduction in Medicare payments for clinical laboratory tests furnished to their outpatients."

In the report to Ober Kaler's clients about the new rules, Mazer wrote:

> *CMS' instructions further define those laboratory tests that would be exempt from the "packaging" requirement. Tests performed under the following three scenarios would not be "packaged," but instead would continue to be paid under the Medicare*

clinical laboratory fee schedule (CLFS):

1) The test is a "non-patient" laboratory test; 2) the patient does not receive any hospital outpatient services other than laboratory tests as part of the same "encounter;" or, 3) the patient does receive hospital outpatient services in addition to laboratory tests during the same "encounter," but the tests are "clinically unrelated" to the other hospital services, and the laboratory tests were ordered by a different practitioner than the practitioner who ordered the other services.

The instructions specify that the same "packaging" principles apply whether the hospital actually performed the laboratory tests or if they were provided "under arrangement," that is, the tests were performed by another laboratory that had agreed to accept payment from the hospital as full compensation for the test.

Clinical laboratory services for outreach non-patients (outreach services) are subject to the new billing procedure, Mazer said in an interview with THE DARK REPORT. "While the new packaging procedure applies to clinical laboratory tests for hospital outpatients only, hospitals need to make sure that they properly designate the testing as for a hospital outpatient or a non-hospital patient (outreach) to which the new principles would not apply," he explained.

Definition Of Non-Patient

"The instructions CMS issued note that a non-patient is an individual who is neither an inpatient nor an outpatient but whose specimen is provided to the hospital for testing and who is not physically at the hospital," he added.

"In addition to differentiating between hospital outpatient and non-patient tests," he continued, "hospitals will need to develop procedures to differentiate between clinical laboratory tests for hospital outpatients that should be packaged and those that should be billed under the CLFS. This includes determining whether particular laboratory tests were ordered for a purpose that was clinically unrelated to the primary procedure.

"CMS stated that laboratory tests would be 'packaged' when they were considered integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting," Mazer wrote. "A laboratory test that was 'packaged' would be paid for by Medicare only as part of OPPS. A laboratory test that was not 'packaged' would continue to be paid separately based on the Medicare clinical laboratory fee schedule (CLFS)."

Mazer said that in the 2014 OPPS final rule, CMS adopted a two-step approach to determine which laboratory tests would be packaged for OPPS payment. "Under

Two Examples for OPPS Billing of Clin Lab Tests

UNDER THE NEW packaging or bundling policy for the hospital outpatient prospective payment system (OPPS), the federal Centers for Medicare & Medicaid Services (CMS) provided two examples.

"According to CMS, if a Medicare beneficiary was scheduled for eye surgery by an ophthalmologist, but on the same date of service received unrelated laboratory tests that had been ordered by his or her cardiologist, those laboratory tests would not be packaged," wrote Robert E. Mazer, a lawyer and Principal with Ober Kaler, in Baltimore, Maryland. "As a result, the hospital would receive separate payment for those laboratory tests under the clinical laboratory fee schedule (CLFS).

"By contrast, if the ophthalmologist ordered laboratory tests as a part of preoperative testing and those tests were performed on the same date of service as the eye procedure," continued Mazer, "then payment for the laboratory tests would be packaged into the payment for the surgical procedure under OPPS."

the new payment policy, a laboratory test will be 'packaged' when 1) it is provided on the same date of service as the primary service; and, 2) it was ordered by the same practitioner who ordered the primary service," he said.

When To Package A Lab Test

"By contrast, a laboratory test will not be packaged if it is the only service provided to a Medicare beneficiary on the date of service," stated Mazer. "Additionally, a laboratory test that is performed on the same date of service as the primary service will not be packaged if it is unrelated to the primary service and is ordered by a practitioner who is different from the practitioner who ordered the primary service." he wrote. "Note that tests for non-patients would never be packaged." *(See sidebar on page 17 for two examples.)*

Mazer explained that when putting this arrangement in place, CMS called for using the type of bill (TOB) 13x and 14x. Previously, 13x was used for outpatient diagnostic testing services and 14x was used for laboratory tests performed on a laboratory specimen for a non-patient.

"Under the new payment policy, laboratory tests that are packaged into OPPS must be billed on a 13x claim with the primary service," he said. "A laboratory test that is not packaged should be billed on a 14x claim. According to CMS, it will be the hospital's responsibility to determine when to separately bill laboratory tests on the 14x."

As Mazer explained, every hospital needs to implement procedures that reflect the new payment policy. The hospital's procedures should cover outpatient tests performed by the hospital laboratory directly and laboratory tests referred to a reference lab.

Lab 'Under Arrangement'

Mazer also pointed out that "the instructions issued December 27 specify that tests provided for a hospital outpatient by another laboratory 'under arrangement' are subject to the new policies."

Labs are likely to have three other areas of concern. "One unknown involves clinical laboratory services performed by independent labs that provide reference tests for hospital outpatients," observed Mazer. "These reference labs may receive requests from hospitals for additional discounts on such tests—based on the reduced Medicare payments that hospitals will receive under OPPS.

"The second area of concern associated with the new OPPS rule is the possibility of fraud," warned Mazer. "Hospitals should be aware that Medicare contractors may actively look for improper arrangements that are intended to circumvent the new payment policy and to avoid the claims processing edits that will be put in place."

Third, hospitals and laboratories should be on the alert for glitches in the new Medicare edits that result in the improper denial of payment claims. "CMS recently acknowledged that an edit it put in place to prevent payment of the technical component (TC) of pathology services with the same date of service as an outpatient hospital service also incorrectly denied TC claims that had a place of service other than the hospital," noted Mazer.

Splitting The Fee Bundle

The most interesting question that arises from Medicare's new rule for packaging these OPPS services is how much of the bundled fee hospitals will be willing to pay for the laboratory tests. Other clinical services must be included in the package and all of these providers will want to maximize their share of the bundled fee.

Another important question relates to the financial impact this OPPS rule will have on both hospital labs and reference labs that provide lab testing services that are covered by the new rule. Labs will need some weeks or months for enough claims to be submitted and settled before that question can be answered. TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last month, it was announced that **Solstas Lab Partners** of Greensboro, North Carolina, had agreed to be sold to **Quest Diagnostics Incorporated**. The sales price is $570 million and financial analysts on Wall Street estimate that the annual revenue at Solstas Lab Partners is about $350 million. This would indicate that Quest Diagnostics paid a multiple of about 1.6 times annual revenue for Solstas.

ADD TO: *Quest's Lab Acquisitions*

It was about one year ago when Quest Diagnostics finalized its purchase of the laboratory outreach business of the **UMass Medical Center** in Worcester, Massachusetts. Four weeks ago, the *Worcester Telegram & Gazette* reported that UMass administration disclosed that it received a purchase price of $108 million from Quest Diagnostics for the outreach lab business. It is believed that the UMass lab outreach business was generating about $90 million in yearly revenue. If accurate, it would mean that Quest Diagnostics paid a multiple of 1.2 times net revenue on that purchase.

HC1.COM NAMED RED HERRING GLOBAL 100 WINNER

It was big news at **hc1.com** in Indianapolis, Indiana, this fall when the fast-growing company was named to the *Red Herring Global 100 Company* list. Since 1996, investors have looked at this list as an "an instrument for discovering and advocating the most promising private ventures from around the world." U.S. companies named to this list in the past have included **Google**, **YouTube**, and **eBay**. hc1.com entered the market in 2011 with its lab-specific customer relationship management (CRM) product, which is a cloud-based service. The *Indianapolis Business Journal* reported in December that hc1.com's service was being used in 500 healthcare facilities and currently pulls data from more than 200 million healthcare transactions annually.

TRANSITIONS

• Gene Cartwright was named as the new CEO for **Guided Therapeutics, Inc.**, of Norcross, Georgia. Previously, Cartwright held positions at **Omnyx, LLC**, **GE Healthcare**, and **Abbott Diagnostics**.

• Howard Doran was appointed to be the new CEO and President at **LipoScience Inc.**, of Raleigh, North Carolina. Doran has a lengthy career in the *in vitro* diagnostics industry. He has held executive positions with **Constitution Medical**, **Hologic, Inc.**, and **Cytyc Corporation**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 24, 2014.

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***Preview:* Michael Laposata, M.D., Ph.D. on:**

Vanderbilt's Diagnostic Management Teams Deliver More Value to Docs and Patients

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