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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Texas Doctors Dropping Out of Medicare

IN A MAJOR STORY LAST WEEK, the *Houston Chronicle* reported that the rate of Texas physicians who are dropping the Medicare program has increased 30-fold in 2010 compared to 2006. These findings indicate the level of "no confidence" that growing numbers of physicians have about the Medicare program.

The *Houston Chronicle* wrote that 50 physicians had opted out of Medicare in the first three months of 2010 and that more than 300 Texas physicians dropped the program in the previous two years. The *Chronicle* used data from **Trailblazer Health Enterprises**, the Medicare carrier for Texas, that included the number of physicians who had notified Trailblazer that they would no longer participate in the Medicare program. As recently as 2006, the *Chronicle* determined that only seven Texas doctors had opted out of providing for the Medicare program. The opt-out numbers were 70 in 2007, 151 in 2008, and 135 in 2009. Opt-out numbers between 1999 and 2002 were no more than three physicians opting out per year.

The **Texas Medical Association** (TMA) said that the *Chronicle's* surprising numbers "far exceeded their assumptions." In 2008, TMA had surveyed Texas physicians and learned that 42% of those doctors participating in the survey were no longer accepting new Medicare patients. The more disturbing finding was that, among primary-care doctors surveyed, the percentage of physicians no longer accepting Medicare patients was a stunning 62%!

Susan Bailey, M.D., President of the Texas Medical Association, told the *Chronicle* that "This new data shows the Medicare system is beginning to implode." She attributed the growing number of physicians opting out to years of inadequate Medicare reimbursement, combined with the scheduled 21% cut in physician reimbursement that has yet to be fully resolved by Congress.

For pathologists and laboratory administrators, these numbers are an ominous portent. It is an early indication that greater numbers of physicians are prepared to cease serving Medicare patients in coming years, should Congress fail to maintain adequate levels of reimbursement. Of course, that begs the bigger point: where can Congress get the money needed to fund physician reimbursement at more generous levels? Confronted by physicians willing to cease serving Medicare patients, could that motivate lawmakers to possibly shift some of the future funding for Part A lab testing services over to physician services? TDR

ISO 15189 Accreditation Earned by Spectra Labs

Adoption of ISO 15189 and its QMS directly improves lab test quality for Spectra's renal patients

CEO SUMMARY: Spectra Laboratories Inc., recently announced that it had earned accreditation to the ISO 15189:2007 standard, following an assessment by a team from the Association for Laboratory Accreditation (A2LA). Spectra is a high-volume laboratory that serves renal patients. It also provides clinical trial testing for pharmaceutical companies. Spectra officials stated that the laboratory wanted to adopt the quality management system (QMS) that is the foundation of ISO 15189.

EARLIER THIS MONTH, it was announced that **Spectra Laboratories Inc.**, in Rockleigh, New Jersey, had earned accreditation to ISO 15189:2007 Medical Laboratories.

With this accomplishment, Spectra Laboratories is the first U.S.-based clinical laboratory to earn this accreditation from the **American Association for Laboratory Accreditation** (A2LA) in Frederick, Maryland.

Spectra Laboratories is owned by **Fresenius Medical Care North America**. It is a high-volume lab with more than 500 employees at the Rockleigh site, handling approximately 109,000 accessions each week and performing almost 40 million tests annually. Established in 1982, Spectra Laboratories is the nation's largest provider of end-stage renal disease (ESRD) laboratory testing services.

Its two labs (one in Rockleigh and the other in Milpitas, California), provide laboratory testing for 168,000 renal patients in 2,300 free-standing or hospital-based dialysis facilities. Spectra also does clinical trials testing for pharmaceutical companies.

"Obtaining accreditation to ISO 15189 is significant for three reasons," stated Chinu Jani, General Manager and Vice President at Spectra's Rockleigh laboratory. "First, it directly improves how we serve our patients. Because our patients are on dialysis, managing this lab is very different than managing a lab working to diagnose illness in an ambulatory population.

"The patient population in our dialysis centers is very sick," he explained. "Every patient that we serve has multiple co-morbid conditions. To support high quality care, we have to aim for ultra precision with our analytes. A 0.1 or 0.2 unit change

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

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in albumin, for example, can make a big difference in how these patients are classified. In that way, this is not just a regular laboratory. The introduction of ISO 15189 into our laboratory provides the right framework and environment to assure the highest quality across every process and activity of our laboratory.

International Recognition

"The second reason was to earn an accreditation recognized by our corporate clients and internationally," explained Jani. "Our lab here in Rockleigh supports a clinical trial business for several pharmaceutical companies. Those companies recognize the value of our being accredited to ISO 15189.

"Further, we have a partner laboratory in Europe," he explained. "One requirement of our partner lab is to have the ISO accreditation. Now that Spectra Laboratories is accredited to ISO 15189, it means our laboratory here, our partner lab in Europe, and the companies with whom we work all meet the same global standards for medical laboratory testing. These standards are more rigorous and demanding in their execution than those to which the average commercial lab or hospital-based laboratory is accustomed.

"By saying this, I'm not taking anything away from commercial labs or hospital-based labs," he added. "I'm simply saying that the level of quality management and the documentation of quality management is much more rigorous in a lab accredited to ISO 15189 than it is in a lab that is not accredited to ISO 15189.

"The third reason why this accreditation is important to us relates to the basics of ISO 15189," observed Jani. "The true areas of emphasis are Quality Management Systems (QMS) and technical competency. This requires everyone on the staff in every department to have technical proficiency in every phase of what we do, meaning pre-analytical, analytical, and post-analytical.

"It also means that the QMS is the basis for every process that we do in our laboratory," he added. "The QMS maps out every process in the lab.

"When Spectra Laboratories started this journey in 2005, we reached out to every employee in this facility—and particularly to every one in the laboratory area—to ensure that each one could map out the processes and procedures that they do," he said. "The QMS of ISO 15189 calls for each staff member to be, not just competent in each procedure he/she performs, but also knowledgeable on how it impacts and fits into the whole process.

"This has a practical consequence in our laboratory," Jani stated. "Regardless of the project or activity—whether it's processing the normal workload of tests each day or adding more instrumentation to a particular department—everyone involved looks at the processes as he/she goes about their individual tasks, and the whole lab works like a well-oiled machine.

Compliance With Every Step

"When this is done for every process every day; when there is compliance with every step in every process, the inevitable consequence is a better laboratory which is more efficient and more productive," Jani said. "That translates to excellence in service to our clients and new heights of morale among the employees."

Betty Lim, Spectra Laboratories's Director of Quality Systems and Regulatory Affairs, agreed, saying, "The goal of this five-year project was not simply to pass the assessment process, earn acceditation to ISO 15189, and stop there. From the start, our goal was to adopt and apply ISO 15189 to build a strong QMS.

"Effective training and competency programs help us continuously improve and sustain the performance of our laboratory in every activity," she continued. "Getting the accreditation, i.e., getting the stamp of approval and recognition for what we have done, is not the end of the road. The journey continues.

ISO 15189 Accreditation Unlocks Many Benefits and Improved Processes At Spectra Laboratories

STAFF AT SPECTRA LABORATORIES INC., IS very clear on the outcomes from achieving accreditation to ISO 15189:2007.

"From its inception, ISO gave us the incentive at all levels to strive to be a top quality laboratory that produces the highest quality results and is continously improving," commented Maria Sarcona, Spectra's ISO Coordinator, Quality Systems.

"Using the 'Path of Workflow' for our processes and procedures is now the fundamental basis for organizing projects," she added. "The QMS of ISO 15189 emphasizes training personnel to use the step-action based procedures. It ensures that everyone follows standard operating procedures in the correct way and does not change processes at will. Having a good document management system helps sustain this compliance.

"Process mapping was a tremendous tool that aided us in focusing on standardization, paying attention to the smallest details, and ensuring validation," continued Sarcona. "On the quality systems side, it supports us in working toward correcting errors and—more importantly—preventing errors with the use of a structured program. It also helps us sustain these improvements while keeping the patient as the primary focus."

"There are least four major lessons we learned during this project," noted Lim. "The first lesson is to engage the entire laboratory staff from day one. Communication and involvement are essential.

"At the start of our effort to achieve ISO 15189 accreditation, we established our ISO Core Team" stated Lim. "This was, and still is, a ten-member committee. It includes a representative from each key department in our business. The representative or 'ISO Leader' is the liaison between the Core Team and the staff.

All Areas Represented

"These functional areas are represented: quality systems, laboratory operations, customer service, human resources, billing and accounting, materials management, and information technology," she said. "Because the ISO standards cover everything from pre-analytical to post-analytical, all departments involved in getting the results out the door are represented. The 'ISO Leaders' spread the word within each department."

"The second key lesson is the importance of encouraging the ongoing engagement of middle management and of all laboratorians, the rank and file," Jani agreed. "We think the best way is to consistently send the message that the laboratory is on a path to transform quality and take it to the next level."

"The third major lesson is to have the absolute support of senior management to make this work," explained Lim. "All leaders in the organization need to understand how ISO 15189 and the QMS underpin ongoing operations and contribute to continuous improvement in quality, in productivity, and in the integrity of the service provided.

"The fourth lesson is to start off with the necessary expertise to put your lab directly on the correct ISO path from day one," stated Lim. "After this program launched in February 2005, we decided to go outside for a consultant and we hired Lucia Berte, the founder of **Laboratories Made Better**, in Broomfield, Colorado."

"Lucia is a nationally known consultant with expertise in quality management systems," explained Jani. "Her guidance during the first two years of our implementation of the ISO standards and QMS gave the project structure and direction. Her services were invaluable. It was a smart investment for us.

Spectra Labs is First Clinical Lab to Earn ISO 15189 via American Association of Laboratory Accreditation

WHEN IT EARNED ACCREDITATION to the ISO 15189:2007 standard earlier this month, Spectra Laboratories Inc., became the first medical laboratory in the United States to use the American Association of Laboratory Accreditation (A2LA) for its ISO designation.

There are two reasons why Spectra Laboratories opted for A2LA for its ISO accreditation, and both are based on international activities involving laboratory testing. First, Spectra does some clinical trails testing on behalf of pharmaceutical companies which operate in multiple countries. Second, Spectra coordinates some of these testing activities with a partner laboratory in Europe.

By earning its ISO 15189 accreditation through A2LA, Spectra Laboratories gains recognition of its quality and its quality management systems in a number of countries across the globe. That is because Frederick, Maryland-based A2LA is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

"For Spectra Laboratories, this means that its test and calibration data will be accepted by all international accreditation bodies that are signatories to the ILAC mutual-recognition agreement and by 46 economies around the world," observed Ray Minnick, Accreditation Officer for A2LA. "This includes countries in Europe, Africa, Asia, Australia, New Zealand, and North, South, and Central America."

"Don't forget that, five years ago, there was no clinical lab in the United States that had implemented ISO 15189, let alone achieved accreditation," he added. "In that sense, we were totally on our own in learning how to apply the QMS in our lab."

"Once we established the basics of the QMS across our laboratory, we found it was important to stick with the process regardless of how long it takes," Lim said. "During the life of this project, several other priorities required attention.

➤Compliance With Every Step

"For example, we implemented a new laboratory information system (LIS) during this time," she said. "So, even though ISO 15189 was not always immediately in front of us, we did not stop working toward that goal. We kept moving forward step-by-step to embed ISO thinking in our day-to-day functions.

"Earlier this year, the ISO 15189 assessors came to the laboratory," said Lim. "Overall, that assessment went well and we responded quickly to address the deficiencies. Led by our ISO Core Team, the staff throughout the laboratory made the necessary improvements so that our final assessment was successful."

Several aspects of Spectra Laboratories' ISO 15189 accreditation are noteworthy. First, as a U.S.-based division of an international healthcare corporation, it had a motive to implement a quality management system that is internationally accepted. ISO 15189 and its quality management system (QMS), as accredited through A2LA, allowed it to meet that goal.

Second, as a clinical laboratory serving a patient population with significant comorbidities, it was seeking a way to further improve the analytical accuracy and quality of the lab testing services it performs. Spectra Laboratories decided that ISO 15189 was the option that would best deliver that outcome. This may be an early sign of how ISO 15189-accredited clinical laboratories could raise the competitive bar. TDR

Contact Chinu Jani at 201-767-7070 or Chinu.Jani@fmc-na.com; Betty Lim at Betty.Lim@fmc-na.com.

Genetic Testing Genie Is Now Out of the Bottle

Walgreens backs off on plan to sell consumers genetic test kits in 6,000 of its retail pharmacies

CEO SUMMARY: There's been an uneasy standoff between companies that want to sell genetic tests directly to consumers over the Internet and both state and federal regulators. But now it appears that the FDA is ready to take off the gloves and assert greater control over genetic testing. The agency moved swiftly to challenge six genetic testing companies that offer genetic testing directly to consumers. One consequence might be more regulation of laboratory-developed tests (LDTs).

FOR YEARS, pathologists and laboratory professionals have waited for the genetic testing genie to escape from the bottle. That may have happened last month when **Walgreens Company** announced that it would start selling genetic tests off the shelf directly to consumers, beginning May 14.

Walgreens had teamed up with **Pathway Genomics Corporation** of San Diego, California. Pathway packaged DNA saliva collection kits that Walgreens would stock on the retail shelves of its 6,000 pharmacies. Consumers would buy the kits and send their specimens to Pathway to be analyzed. The Pathway test panel is designed to produce "personal genetic health disposition results for more than 70 health conditions, including pharmacogenetics (prescription medication response), propensity for complex disease, and carrier status (pre-pregnancy health) information."

Public reaction to this news was immediate. Just days after its announcement, Walgreens backed down and stated that it would not sell the genetic tests after all. But the brouhaha didn't end there.

Within days, on May 10, the **Food and Drug Administration** (FDA) sent a letter to the CEO of Pathway Genomics. The FDA requested information on the Pathway Genomics Genetic Health Report and noted that it had no FDA clearance or approval number for that product.

To make sure that the genetic testing community got the message, on June 11, just four weeks later, the **Food and Drug Administration** (FDA) sent a strong sign of its displeasure by delivering letters to five companies that provide genome-sequencing tests to consumers. The companies were **deCode Genetics**, **Navigenics**, **23andMe**, **Knome**, and **Illumina**.

FDA Asserts Its Authority

In these letters, the FDA asserted its authority to regulate these types of genetic tests under the statutes covering medical devices intended for use in humans. All six companies that received letters from the FDA—as well as the entire genetic testing industry—were put on notice that federal regulators are now prepared to deal with the issue of how genetic tests should be regulated.

Meanwhile, the original decision by Walgreens to stock genetic tests on its shelves and sell directly to consumers set off a vigorous debate. On one side are those medical professionals who ardently advocate that consumers should only explore their personal genome under the guidance, direction, and counsel of trained experts.

These experts argue that medicine is such a complex science that consumers—when given unfettered access to sophisticated genetic information—are likely to make misinformed decisions which can too often result in serious harm, if not increased risk of death.

On the other side are the ultimate free marketers, who, with equal passion, point out that people have a natural right to any and all information about themselves and their family members. They believe individuals are fully capable of handling this information, just as they do in many other complex or sophisticated areas of modern life.

Of course, most pathologists and medical laboratory professionals fall somewhere in between the two extreme poles of these opposing viewpoints. They see a role for expert advice and some limits on how consumers might access and act upon their own unique genetic information.

➤Claims For Test Performance

One point is not disputed. When most of these genetic testing companies appeared in the market over the past three or four years, the claims they made to consumers were typically vague and non-specific. That is no longer the case. Among the letters written by the FDA to the six genetic testing companies, the FDA quotes specific claims that have been advertised by the company receiving that letter.

For example, in its letter to 23andMe, the FDA writes that "your website states that the 23andMe Personal Genome Service is intended to tell patients in advance how they will respond to certain medications including warfarin and clopidogrel." The FDA asks 23andMe to provide scientific data to support that claim.

It goes without saying that any enforcement decisions and new regulatory policies developed by the FDA have the potential to apply to genetic and molecular testing done by clinical laboratories, while also bringing laboratory-developed tests (LDTs) under tighter FDA scrutiny. TDR

A Look at Walgreens' Genetic Testing Kits

WALGREENS INTENDED TO PUT saliva collection kits on the shelves of its retail pharmacies. Consumers would purchase the kits for between $20 and $30, then send their specimen directly to Pathway Genomics Corporation.

Pathway Genomics was offering to do genetic sequencing of the specimen and report the "personal health disposition" of the customer for as many as 70 health conditions. The cost of the genetic testing was to range from $79 for a basic analysis of 10 genetic sequences to $249 for the complete genetic analysis offered under this program.

Pictured above is how Walgreens and Pathway Genomics intended to package the DNA saliva kit that would be stocked on the retail shelves of 6,000 Walgreens pharmacies.

Medicare Update

Pathologists Not Enrolled In PECOS By July 6 Risk Denial of Medicare Claims

JULY 6, 2010, IS THE NEW DEADLINE for pathologists to enroll in the Provider Enrollment, Chain and Ownership System (PECOS) or risk being denied payment for Medicare claims.

The federal **Centers for Medicare & Medicaid Services** (CMS) recently issued a statement that it will not pay physicians and their referring providers if they fail to enroll in PECOS. In response to this news, **Pathology Service Associates, LLC** (PSA), sent a notice to its client pathologists last week recommending that they act in a timely fashion to complete their enrollment in PECOS.

PSA said that the July 6 deadline is new. Before announcing the new deadline last week, CMS had set the PECOS enrollment date as January 3, 2011.

Payments in Question

"CMS has refused to clarify whether or not they would continue to pay claims for physicians if both the physician and referring provider are not enrolled in PECOS by July 6, 2010," PSA said. "Therefore, PSA will continue to monitor the status of PSA client enrollment with CMS and encourages our clients to continue contacting their referring physicians regarding enrollment."

Significantly, pathologists and all physicians should recognize that enrollment in PECOS is a separate process from enrolling in traditional Medicare. Although they are likely in the Medicare system, PSA believes many physicians are not yet enrolled in PECOS.

PSA's own statistics bear this out. It reports that only 55% of its affiliated pathologists are currently enrolled in PECOS. It says the number is that high, in part because PSA has assisted its affiliated pathologists in submitting to Medicare the required PECOS enrollment forms.

"As of June 1, 57% of these enrollments have been processed by CMS," PSA said. The carriers that process the enrollment forms, however, have informed PSA that there is a backlog in enrollment packages over the past few months. This is causing a delay in the processing of some pathologists' enrollment forms and pushed them back from 60 days to 90 days. "PSA will continue to keep our clients updated on their enrollment status," PSA said.

The surprise that awaits many pathologists is the fact that they need to ensure that all their referring physicians are also enrolled in PECOS. Recognizing this fact, PSA advised that "Due to this uncertain deadline and backlog in enrollment processing, PSA encourages our clients to contact their referring physicians immediately regarding enrollment. At present, claims for PSA billing clients are being processed normally but we have begun receiving warning messages from some Medicare carriers indicating that many of our client's referring physicians are not enrolled in PECOS or otherwise not found in the carrier's claim systems."

According to this new Medicare rule, physicians who order and refer durable medical equipment, prosthetics, orthotics and supplies, or home health services are required to be enrolled with Medicare through PECOS by July 1. But CMS also is requiring that doctors who order or refer imaging, laboratory, and specialist services must be enrolled by July 6, according to *AM News*. TDR

Contact Leigh Polk at 800-832-5270 x 2941 or lpolk@psapath.com.

CEO Summary: One of pathology's greatest challenges is adequate reimbursement for hospital Part A Pathology Services. Over the past two decades, ever more hospitals took steps to reduce or eliminate payment to pathologists for these services. Now several innovative pathology groups are using a performance-based strategy to negotiate win-win Part A Pathology Service contracts with their hospitals and health systems. Properly structured, these Part A agreements do increase reimbursement to pathologists.

Creating a Win-Win Outcome for Pathologists and the Hospital

Using Performance-Based Part A Hospital Path Contracts

ONE OF THE PATHOLOGY PROFESSION'S most pernicious unresolved issues is inadequate payment by hospitals and health systems for Part A Pathology Professional Services.

"Almost every pathologist knows what it feels like to have the administrators of the hospital or the health system sit down at Part A contract renewal time and insist that the hospital should pay less—or even nothing—for Part A pathology services!" declared Robert H. Tessier, Senior Reimbursement Consultant for **HBP Financial Services Group, Ltd.**, in Woodbridge, Connecticut.

Tessier believes that the time has come for pathologists to turn the tables on hospital administrators during pathology Part A contract renewal negotiations. "There's a cluster of pathology groups that made a commitment to reverse this situation. These pathologists decided that they could deal from a position of strength.

"In recent years, these pathology groups have established a value proposition that was recognized by the hospital administrators and resulted in equitable levels of reimbursement for Part A Pathology Professional Services," said Tessier. "We have developed a strategy for pathology Part A contract renewals which is proving consistently successful. But this strategy is not for the faint-of-heart. It requires a determination and diligence. Anything less and the outcome tends to be that the hospital prevails in its position that the pathologists should be paid less for Part A services when the contract renews."

Tessier was sharing these experiences during a recent audio conference produced by THE DARK REPORT and titled: "Negotiating Pathology Part A Reimbursement with Hospitals: Why the Performance-Based Approach Opens the Door to Increased Value."

What Tessier and several innovative pathology groups in New England have done is to create a pathology Part A strategy anchored around a performance-based approach. One contract renewal cycle at a time, these collaborators are demonstrating that hospital administrators will adequately reimburse for Part A Pathology Professional Services, if the basis of the added reimbursement is an increase in value that the hospital can measure.

"Performance-based pathology Part A contracts are the future," stated Tessier. "Hospital administrators understand the concept of paying more for added value. For example, they see payers offering them pay-for-performance incentives, generally linked to objectively-measured improvements in patient outcomes.

"What we've done with our performance-based strategy is go to hospital administrators and lay out the compelling reasons why it is in their best interest to pay more for Part A clinical pathology services—in return for the pathologists achieving mutually-agreed targets that are valuable to the hospital," offered Tessier.

For pathologists interested in turning the tables on hospital administrators during pathology Part A contract renewal talks, Tessier recommends a three-step process. "Step one is to collect relevant data. Step two is to educate the administrators and align goals. Step three is to work with the hospital or health system finance department to analyze and quantify the results.

Performance-Based Services

"This is a simple business strategy, but it requires the right level of detail to succeed," he said. "To make performance-based pathology Part A reimbursement work for both parties, hospital-based pathologists need data in order to tell a persuasive story about the value they add to the hospital.

"Upon demonstrating this value, they can work with hospital administrators to set performance-based goals for the coming year and years," continued Tessier. "Then, as these goals are achieved, increased pathology Part A reimbursement results—and the hospital administrators are willing to pay these additional sums to pathologists in exchange for that additional value.

"Most pathologists have a great story to tell about the work they do," he stated. "Performance-based negotiations create the

opportunity for pathologists to formally discuss results with administration, on a basis that provides a reward for those who can demonstrate accomplishments.

"This requires developing consistent goals and objectives between the hospital and the pathologists, along with formulas that reward specific benchmarks," stated Tessier. "It also requires developing a methodology that evolves as circumstances change—even as the methodology ensures that both the hospital and the pathologists will mutually benefit from improved results.

A Need to Collect Data

"To make this work, pathologists need to look at data the same way that the hospital finance department looks at data," he explained. "This includes such elements as cost-to-charge ratios, the direct cost and indirect cost allocation, and the difference between revenue (or charges) and income (or cash).

"Pathologists also need to carefully review all existing third-party contracts for anatomic pathology (AP) services and clinical pathology (CP) services and note the current actual payments under these contracts," he added. "It is important to reconcile billing for AP technical services versus the AP professional services.

"Another highly valuable action item is to conduct a market study for the amounts of Part A compensation that is paid by hospitals in the surrounding region," Tessier advised. "This information should be gathered from two sources.

"First, contact pathologists at local hospitals and get information about their pathology Part A contracts," he said. "Make sure to identify the payment amount and any specific services and targets covered by these Part A contracts. Often pathology groups will provide this information in exchange for receiving a copy of your completed Part A reimbursement survey for the region.

"Second, mine the public reports which have information about pathology Part A payments made by hospitals in the same state," Tessier noted. "Use the Freedom of Information Act (FOIA) and request Part A data that hospitals have filed in their Medicare Cost Report, Schedule A-8-2.

What Other Hospitals Pay

"In particular, capture the number of full-time pathologists and the number of PAs [pathology assistants] on staff who are employed by the hospital or by the pathologists; the number and type of personnel being supervised; and the number of lab tests by lab section," he recommended. "Also capture the number of direct patient care accessions for surgical, clinical, non-gynecology, and gynecology-cytology.

"In addition, it's important to collect data on the gross revenue for inpatient, outpatients, and referrals," continued Tessier. "For autopsies, include the total paid for autopsy volume under Part A or as a separate fee per autopsy.

Develop An Hourly Rate

"Consider using the published Medicare reasonable compensation equivalent (RCE) calculation for pathology and adjust it for inflation, CME, and actual malpractice cost," he said. "Multiply this hourly rate by the time pathologists spend on Part A pathology services.

"Present administration with detailed time studies, customized to each hospital, during contract negotiations," noted Tessier. "Make sure they are accurate, based on defendable data, and well understood by the hospital administrators.

"In our negotiations, the RCE is a reasonable amount of money per hour which we use. (*See the table, Educating Your Administration—RCE, on page 13.)* These numbers provide a basis for a per-hour rate to use in determining reimbursement for Part A pathology services. This rate is likely to be in the range of $129 to $136 per hour, depending on the region," said Tessier.

Educating Hospital Administration about the Value of Part A Pathology Services

Reasonable Compensation Equivalent (RCE) Calculation
Speciality: Pathology

	Non-Metro Areas	Metro Areas less than 1 million	Metro Areas greater than 1 million
Medicare Published RCE Limit 2004	$208,000	$219,500	$215,700
Plus: Inflation at 3% per year			
Assume RCE Limit for year 2010	$248,363	$262,094	$257,557
CME (estimate)	$ 5,000	$ 5,000	$ 5,000
Malpractice Actual (estimate)	$ 16,000	$ 16,000	$ 16,000
Total	**$269,363**	**$283,094**	**$278,557**
Annual Hours	2,080	2,080	2,080
RCE per Hour for Pathology	$ 129.50	$ 136.10	$ 133.92

In the example above, Robert H. Tessier, Senior Reimbursement Consultant for HBP Financial Services Group, Ltd., demonstrates how he develops an hourly cost for Part A Pathology Service contracts using Medicare published data for Reasonable Compensation Equivalent (RCE) in pathology.

"Once the data is ready, it should be used to educate administrators about the Part A value," he noted. "We do that for our pathology clients by preparing a detailed fact book.

"This fact book is not the annual pathology department report," he continued. "Instead, it is a supplement that would quantify all of the pathologists' accomplishments for the year. This report should outline any programmatic expansion that occurred and explain the specific involvement of the pathologists in each of these endeavors.

"This fact book should be the basis of a formal meeting of at least 90 minutes with the hospital administrators," noted Tessier. "Use this time to establish the pathology group's goals and objectives for the next hospital fiscal year, which should be the same fiscal period that finance and administration uses when making presentations to the board of directors.

"To prepare for this meeting, the pathologists should determine the goals that administration and finance aim to hit, then ask themselves, 'What creative ideas can the pathologists present?' Where can the pathologists be proactive? What is the best use of physician talent and department managers and staff?'" said Tessier.

Set Specific Financial Goals

"At a minimum, the pathology group must provide high quality and cost effective services with quality assurance provisions," emphasized Tessier. "Then, you will want to suggest specific financial goals. These goals might include: 1) partnering with the hospital to ensure that laboratory benchmarks continue to improve; 2) that unit costs in the lab are reduced through economies of scale; 3) that best prices for equipment and supplies are negotiated; or, 4) that high patient satisfaction scores are achieved by the laboratory, as compared to national benchmarks from **Press-Ganey Associates**, for example.

"Another performance measure can be to ensure that the hospital has the most highly-respected laboratory in the region by surveying the medical staff routinely and then seeking to achieve the highest levels of satisfaction," he continued. "This tasks the pathologists with the responsibility to ensure that the laboratory is a positive and highly-productive work environment. This can be measured by tracking the number of employees on the waiting list who wish to apply for job openings in the lab.

Getting Attention

"One of the best ways to get the full attention of hospital administrators is to focus on outreach for both AP and CP services," advised Tessier. "Recognize that income from clinical laboratory testing has the greatest impact on the hospital.

"One formula I like to use to determine the financial benefit to the hospital from outreach laboratory testing is to take the net revenue from increased CP outreach testing and subtract the direct costs of that testing," he said. "Include a percent of this figure from increased CP outreach income into the Part A incentive plan.

"When quantifying outreach, it is highly beneficial to the success of the Part A contract negotiations that the pathology group works with the hospital's finance staff to determine the relationship between revenue (charges) and real income for AP and CP services," noted Tessier. "For example: AP may equal about 30% of total laboratory revenue and the referred technical component per case will be about $35 to $45. The CP component will equal less than 25% of revenue.

"These numbers are important to quantify because they will show the actual effect of adding new outreach lab testing business," he added. "And, remember that the finance department will want the real income that can be expected—not the inflated 'gross charges billed.'

"To expand and increase testing volume from the hospital's laboratory outreach program, the pathology group can offer to develop and direct the sales effort for AP and CP services," he continued. "If there are outreach sales reps, give them training, guidance, and collateral marketing support. If there are currently no outreach sales reps, consider hiring a sales rep as an employee with a strong bonus program consistent with that of competing commercial labs.

"Finally, it's important to demonstrate what the pathology department will do with any increased income it receives by discussing the importance of dividend reinvestment with the hospital administrators," suggested Tessier. "Dividend reinvestment is critical because administrators and finance professionals often complain that all hospital-based physicians (including pathologists) have exclusive arrangements that earn income but they don't give anything back to their departments or to the hospital.

"Be aware that even modest contributions are respected by both the hospital administrators and the finance professionals," he continued. "Their support can come in the form of expertise as well as financial support.

"Consider a significant contribution to the development of improved laboratory operations," Tessier recommended. "Ideally, this support can be a tax-exempt charitable contribution to a department fund from each of the pathologists."

Effective Contract Strategy

Performance-based Part A Pathology Service agreements provide pathology groups in any region with an effective way to deliver added value to their parent institution. But to be successful, pathologists must do their homework to gather accurate data before commencing negotiations. **TDR**

Contact Robert Tessier at 203-397-8000 or Rtessier@hbpworld.com; Saraswathi Nair, M.D, at Saraswathi.Nair@Norwalkhealth.org or 203-852-2652.

Boosting Part A Pathology Reimbursement Means Being a Visible Part of the Hospital's Clinical Team

ONE PATHOLOGY GROUP which has benefited from the "performance-based" Part A pathology strategy is at **Norwalk Hospital** in Norwalk, Connecticut.

"In any contract negotiation, it is important to keep the customer in mind," explained Saraswathi Nair, M.D., Chair, Department of Pathology & Laboratory Medicine at Norwalk Hospital. "We have several years experience with using performance-based benchmarks in our Part A Pathology Service contract with the hospital and we think this approach is win-win for both the hospital and the pathologists.

"When pathologists are in Part A contract negotiations, you will find that the negotiations can certainly break down quickly for any or all of these three reasons: 1) if your clinical colleagues in the hospital view the pathology group as being obstructionist; or, 2) the pathology group is viewed as not a part of the team; or, 3) the pathology group does not provide the kind of clinical services that the hospital expects the group to provide.

Support Of Clinical Team

"These are essential points to keep in mind," said Nair. "If your pathology group does not have the support of the clinical team, the Part A negotiations with the hospital administrators will not be successful.

"At the same time, it is the hospital administrators (meaning the CEO and the CFO) who will be looking at the proposed contract," she stated. "That is why, for the particular purpose of these negotiations, I define the customer to include the hospital and the clinical team, in addition to the patient. After all, the pathologist serves all of these customers.

"In addition, it should be emphasized that the pathologist needs to be a highly visible member of the hospital team," she said. "When clinical integration takes place and the pathologists are seen as a contributing part of the hospital team, then the administration will recognize the pathology group as a department that is considered a full partner in the hospital's growth opportunities. That is a key to a successful Part A contract.

"Next, I can't stress enough the importance of doing all the homework necessary for the Part A contract negotiation process *before* the discussion begins," added Nair. "This negotiating activity has to start with the financial officer and the financial team at your institution, for a simple reason.

"The cornerstone of your pathology group's list of benefits and contributions are data and numbers that have been developed in concert with the hospital's financial staff," noted Nair. "It is their validation of the beneficial contribution to income and operational cost savings that back up your pathology group's statements during Part A negotiations.

"These numbers are also the basis for developing the performance measures that will be used to trigger additional Part A pathology payments as the pathology group achieves these standards."

As a result of these efforts, the pathologists at Norwalk Hospital made a number of improvements, including starting an outreach program and hiring and paying for a dedicated outreach client service sales representative, Nair said. The sales rep earns $78,000 in salary and benefits and the hospital pays 75% of these costs.

Nair said that AP business has increased by 4% to 5% over previous levels, despite increased competition from commercial labs. Clinical lab outreach testing volume has increased 12% to 14% per year.

Lab Mergers

Halfpenny Technologies Buys Laboratory Management Services

Acquisition gives Halfpenny added capabilities to provide lab test data to HIEs and payers

TO BROADEN ITS CAPABILITIES in handling laboratory test data, **Halfpenny Technologies, Inc.**, announced the acquisition of **Laboratory Management Services** (LMS) of Hauppauge, New York, earlier this month.

Halfpenny seems to be particularly interested in the informatics solutions developed by LMS to make it easier for clinical laboratories and pathology groups to report laboratory test data to health insurance plans.

Halfpenny CEO Jerry Baker noted that the LMS acquisition would allow his company to "offer a complete range of laboratory-focused, technology-enabled clinical data and reporting business tools."

In recent years, Halfpenny has taken its expertise in electronic laboratory test ordering and results reporting between doctors' offices and laboratories and expanded into other areas of health informatics integration. It spotted opportunities to support the numerous health information exchanges (HIEs) under development in many regions across the country, for example.

Linking Local Labs & Payers

Laboratory Management Services has several innovative products aimed at making it easier for local laboratories to participate in management care networks. In the role of network administrator, LMS can help both local labs and health plans create lab testing networks that utilize an "any qualified provider" model with pricing based upon the health plan's standard fee schedules for clinical lab services.

In support of the managed care network LMS provides local laboratories with a way to handle lab credentialing, data reporting to the health plan, quality management, and similar activities in its role as network administrator and as a single point of contact with participating health insurance plans.

Managed Care Companies

In the past 24 months, managed care companies have begun to ask clinical laboratories to electronically provide laboratory test results in a form that meets the needs of the payers and also allows them to populate the electronic health records (EHRs) of their beneficiaries. However, moving such data in the right format between laboratory and managed care plan can be a challenge.

Mike Snyder, President of LMS, stated that most health insurance plans "are unaware of the hurdles that laboratories face with respect to sharing clinical data." The opportunity for the two companies is to combine "LMS's management tools with Halfpenny's specialized interface engine" enabling Halfpenny to "securely and cost-effectively facilitate data exchange between health plans and clinical laboratories." TDR

Lab Briefs

CLARIENT INKS PACT WITH GENERATION HEALTH FOR GENETIC TESTING

PAYER PRE-AUTHORIZATION OF GENETIC TESTS is the reason for the newly-announced contract between **Clarient, Inc.**, and **Generation Health, Inc.**, of Upper Saddle River, New Jersey.

Announced on June 10, the agreement positions Clarient to be the preferred provider of genetic tests for Generation Health. Generation Health was founded in 2008 to be a genetic testing benefit management company.

It has adopted the pharmacy benefit management (PBM) business model to genetic testing. In fact, Generation Health was founded by its President and CEO, Richard K. Schatzberg, who spent 20 years at **Medco Health Solutions**, one of the nation's largest PBMs.

Under the new agreement, effective July 2010, Clarient will collaborate with Generation Health (GH) "to facilitate the diagnostic testing for gene mutations in patients who suffer from certain oncology indications. In January 2011, plans are to expand the program, offering managed diagnostic testing to all GH clients."

As more managed care plans take steps to pre-authorize expensive genetic and molecular diagnostic tests, it will become harder for local clinical labs and pathology groups to provide such testing. It is widely-expected that these companies will limit testing only to laboratories contracted by payers or GBMs to do this work.

Pathologists and laboratory directors should be aware of these developments. THE DARK REPORT has predicted that payer pre-authorization of genetic testing will be a fast-moving trend. In fact, there is already a term to describe this new classs of health company. It is "genetic benefit manager" (GBM).

The growing line-up of players in the GBM field illustrates the swift uptake of this trend. Already this year, **DNA Direct** was acquired by Medco to handle pre-authorization of genetic tests for its customers. Earlier this spring, **McKesson Corporation** launched its Advanced Diagnostics Management (ADM) business unit to managed genetic test pre-authorization for payers. **CVS Caremark** is a part owner of Generation Health.

It is not a coincidence that so many billion-dollar corporations want to be in the "genetic benefit manager" business. It will be one of the faster-growing sectors of healthcare.

GENMARK'S IPO MAKES IT NEWEST PUBLICLY-TRADED IVD FIRM

ON MAY 28, the shares of **GenMark Diagnostics, Inc.** began trading on the NASDAQ exchange under the symbol GNMK. It thus became the newest molecular *in vitro* diagnostics (IVD) manufacturer to have its shares trade in the public markets.

But GenMark Diagnostics is actually the new public face for **Osmetech, PLC**, based on London, England. Upon completion of the initial public offering (IPO), which raised $28 million, Osmetech's assets were placed into GenMark Diagnostics, which is based in Pasadena, California.

GenMark intends to develop its proprietary eSensor detection technology, sold as the GenMark XT-8 System. It supports multiplex detection of DNA and RNA targets. GenMark is moving forward with plans to clear three diagnostic test kits with the FDA. The tests—a Cystic Fibrosis Genotyping Test, a Thrombofilia Risk Test and a Warfarin Sensitivity Test—will be designed to run on the XT-8 system.

Osmetech has struggled to develop this technology and bring it to market. In GenMark stock filing, it noted that "losses attributable to continuing operations were approximately $4.8 million for the three months ending March 31, 2010 and for the years ending December 31, 2009, 2008 and 2007 [losses] were approximately $20.0 million, $28.4 million and $23.9 million, respectively."

BIG FRENCH LAB FIRM ACQUIRED BY INVESTORS

PATHOLOGISTS interested in the globalization of laboratory testing may be interested in the details of the recently announced sale of **Laboratoire Cerba**, based in Paris, France. Laboratoire Cerba is considered to be France's largest commercial laboratory company and does business in several countries.

The French private equity firm **PAI Partners** announced that it would pay €500 million (US$600 million). The *Financial Times* reported that "PAI plans to take advantage of a change in French regulation that allows Cerba to acquire smaller rivals in the routine clinical pathology and clinical trials markets, which remain highly fragmented in France."

Cerba has said that its consolidated revenue in 2010 is projected to be €250 million (US$309 million), of which 35% will come from international sales. It has 34 locations in Europe, South Africa, Australia, China, and the United States. There are 1,300 employees, including 85 clinical pathologists. Laboratoire Cerba performs 85,000 tests per day.

CALIFORNIA FINES UCLA MED CENTER $95,000 FOR MULTIPLE PATIENT PRIVACY BREACHES IN 2009

ON JUNE 10, IT WAS ANNOUNCED that the State of California had fined **UCLA Medical Center** a total of $95,000 for violations of patient privacy laws. Press coverage of the fine identifies workers in the pathology department as the lawbreakers.

When these patient privacy violations happened in 2009, it was widely reported by the media that patient records of two celebrity patients had been viewed by personnel at the **UCLA Medical Center** in Los Angeles, California, in violation of the hospital's regulations and state law.

Although neither the state nor UCLA Medical Center have identified the patients, media outlets reported that the records of pop singer Michael Jackson and actress Farrah Fawcett, who both died at the medical center, were accessed by unauthorized personnel.

Officials at the UCLA Medical Center discovered the unauthorized access to those patient records within days of the incidents. The violations were promptly reported to state officials.

A report on the case indicates that a "medical school employee and an employee in the Department of Pathology and Medical Support Services were found to have accessed the patient's records two days before. The medical school employee had even printed labels for laboratory tests that had been performed on the patient."

Days later, hospital officials determined that a second breach of the same patient's records had occurred, involving two contract workers with the hospital's pathology billing service. When confronted with the privacy breaches, these two individuals are reported to have "admitted inappropriate access, they were curious."

The details about the involvement of individuals working within UCLA's clinical laboratory and pathology department were not known until the release of this report. However, this new information about the breach of privacy for celebrity patients is a reminder to all clinical laboratory managers and pathologists of the need for ongoing diligence in protecting the privacy of all patients at all times. This is particularly true because passage of the HITECH Act has created new patient privacy compliance requirements for healthcare providers. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Early in June, exactly 96 customers of **23andMe, Inc.**, were notified that they had received the wrong genetic test results. It was particularly bad timing, since the company had just been sent a letter from the FDA asserting its authority to regulate genetic testing. Bloggers reported that, on its web site and accessible only to customers with a PIN, 23andMe explained that its contract testing laboratory had committed human error. A single 96-well plate with samples had been incorrectly placed. Bloggers also reported that the mistake happened at **Laboratory Corporation of America**, which does genetic testing on contract for 23andMe.

MORE ON: *23andMe*

Among some of the 96 individuals who got the wrong genetic test results, there was considerable consternation. In fact, it was the customers who discovered the mistakes and brought them to the attention of officials at 23andMe. One mother who posted on the web described her distress that the results, as reported by 23andMe, showed her daughter as a match for the family, but that her son was not a match for either herself or her husband. Critics pointed out that, prior to this problem, 23andMe appeared not to have put even basic error-checking procedures in place. These events are a reminder to the clinical laboratory testing profession that the media is increasingly swift to pick up and report errors associated with laboratory testing.

RED CROSS FINED $16 MILLION BY FDA FOR BLOOD ISSUES

Last week, the **Food and Drug Administration** levied a $16 million fine on the **American Red Cross**. Most of the issues focused on violations in the screening of donated blood for the years 2008 and 2009. A fine of $10 million was assessed for mismanagement of blood products, including red blood cells, plasma, and platelets. The balance of the fine—$6 million—was for faulty manufacturing processes. About 43% of the blood supply in the United States is supplied by the American Red Cross.

GEN-PROBE INVESTS $50 MIL IN PACBIO

Gen-Probe, Inc., made a $50 million strategic investment in **Pacific Biosciences, Inc.**, of Menlo Park, California. Pacific Biosciences is developing technology to perform whole human genome sequencing. The two companies will collaborate to develop new clinical diagnostic systems. This transaction shows how established molecular IVD companies are exploring ways to use rapid gene sequencing technologies.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 12, 2010.