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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

Era of Digitized Pathology Systems Approaches

SURGICAL PATHOLOGISTS SHOULD GET READY! I predict that they will soon have the opportunity to purchase and use fully digital, automated pathology systems that can perform primary diagnosis. When that happens, it will mark the final cycle of the era when the principal method of diagnosing tissue was that of eyeballs fixed to microscopes, scanning cells as glass slides are pushed around the stage.

The introduction of digital pathology systems capable of primary diagnosis will likely be the single most disruptive event to anatomic pathology in the past two decades. That's because automation of the primary diagnosis of tissue will upend current work flow and clinical practices in surgical pathology.

I make this prediction, based on two market developments in anatomic pathology. One development is the success of **Aperio Technologies, Inc.,** in placing fully digital pathology systems in as many as 375 laboratories in 25 countries. This company is finding a ready market for its digital solutions that support existing pathology work flow and clinical practices.

The second market development is the long-awaited entry of **General Electric** into laboratory medicine. As you will read on pages 9-11, **GE Healthcare** is partnering with some of the best minds in digital pathology at the **University of Pittsburgh Medical Center** (UPMC) to create **Omnyx, LLC**. The aim is to develop digital pathology systems that can integrate the transmission and use of digitized pathology images across the care continuum, support improved workflow, and contribute to increased clinical quality—as well as automate primary diagnosis. The two partners estimate that the market for digitized pathology systems will be about $2 billion per year.

I suspect GE is making this move now because it believes it has digital and other technologies that can be transformational to anatomic pathology. It wants to leverage its experience at digitizing radiology and evolving radiologists into a fully digital work flow by doing the same in anatomic pathology. In the 1990s, such companies as **NeoPath, Inc.,** and **Neuromedical Systems, Inc.,** privately showed THE DARK REPORT how digital cytology systems and software algorithms could do accurate, automated primary diagnosis on a variety of tissue types. Now the question is: are surgical pathologists ready to accept digital pathology systems that can move them away from microscopes and in front of computer screens? GE's entry into this marketplace is evidence that it believes the answer is: "Yes!" TDR

NPI Rules Slow Payments To Pathology Groups, Labs

Private payers and Medicare carriers kick out high volume of claims for incorrect NPI compliance

CEO SUMMARY: New rules requiring use of National Provider Identification (NPI) numbers took effect on May 23. Since then, Medicare carriers and payers nationwide have rejected claims from pathologists and other providers that do not comply with the new NPI rules. A missing NPI on just one claim will result in the front-end rejection of the entire submission file to Medicare. Cash flow to some pathology groups and other physicians has dropped. It may be another month or more before normal cash flow is restored.

CASH SHORTAGES FROM UNREIMBURSED MEDICAL CLAIMS were so severe last week that some pathology groups were struggling to meet payroll, according to claims processors. Medicare and private payers have rejected claims at a sharply increased rate since May 23.

To provide pathologists and laboratory directors with an assessment of this unreported, but serious problem to provider cash flow, THE DARK REPORT contacted three national companies that provide billing and collection services to clinical laboratories and pathology group practices. These experts confirmed that a cash flow disruption is under way and is affecting providers throughout the nation.

"Most payers and Medicare carriers were unprepared for the number of problems and the volume of claims that were affected by the May 23 implementation date for the new NPI rules," said Pam Evans, Regional Director of Operations for **Pathology Service Associates, LLC**, (PSA) a company in Florence, South Carolina, that provides revenue cycle and business management services for more than 78 pathology groups in 28 states. "Nationally, payers affected by NPI-related problems include those for Medicare, Medicaid, and the Blues plans, among others. We hope that claims processors will correct most of the problems by this time next month. That would enable normal cash flow patterns to be restored.

"On Tuesday, May 27, we recognized the mass chaos from the NPI implementation," noted Evans. "From what we can tell, as of May 23, payments stopped for NPI-related rejections and will not resume until the problem is resolved. By the end of the first

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

week in June, we started seeing some physician practices struggle to meet payroll.

"For many practices, Medicare is 30% to 40% of their business or greater," added Evans. "If Medicare stops paying, that means less income and it could be 30 to 60 days—possibly longer—before the flow of reimbursement from Medicare claims is restored."

This problem was not a surprise. "Many payers allowed early testing of claims formats, whereby some NPI-related issues were identified before the May 23 deadline," she explained. "We are working through those with success. However, other payers were unable to test before the implementation date. The volume of problems confronting these payers is more than they can handle expediently.

"A distinction should be made regarding the types of NPI issues that are occurring," Evans continued. "Most providers have their NPI numbers, as there was a big push last year to obtain NPIs for providers, as well as for referring physicians. A few providers who were ill-prepared may still have problems in these areas. The main issues we see relate to the electronic formats by which claims are submitted and how different payers receive and process information.

"Each payer has a different set of requirements," she added. "Many payers were hard-pressed to provide detailed information on how claims should be submitted to them. As a consequence, payers must now provide guidance to providers on how to format claims to accommodate their systems and their processing guidelines."

Rejecting 24% Of Claims

Emdeon Business Services of Nashville, Tennessee, a Medicare claims processor, reported that 24% of claims it handled (representing about $26 million in reimbursement) had been rejected since May 23, the effective date for the new NPI requirement. Normally about 6% of claims (or about $10.6 million) would be rejected.

In its report, Emdeon suggests that pathology may have a bigger problem with rejected claims than other physician specialities. To determine the extent to which providers' submissions complied with NPI standards before the deadline of May 23, Emdeon analyzed professional claims it received for one week in April. It found that the use of NPI was drastically lower when secondary providers were involved on a bill from a primary provider, such as is common when laboratories submit bills for work done for referring physicians.

In its analysis, Emdeon also determined that, if all payers strictly adhered to the new NPI rules, 69.3% of all submitted claims nationally would be rejected, causing significant cash flow issues for providers. Emdeon noted that 69.3% of claims nationally would represent almost $2.5 billion in reimbursement to providers.

Resolving Issues With Claims

"Once a claim is rejected, pathologists and lab directors need to identify and resolve the problem as quickly as possible. They need to work with their payers and Medicare carriers to resubmit any rejected claims," recommended Evans. "But resolving problems related to NPI rejections can take up to 60 days. Only after the NPI problem has been resolved can the claim be resubmitted. Then the usual processing timeline follows before payment is actually made to providers."

"The timeline to fix these problems varies from payer to payer for a number of reasons," said Tanya Canup, PSA Implementation Coordinator. "It depends on what is wrong with each individual claim and what the payer requires to resolve the problem.

"Some pathologists and other physicians may still need to apply for additional NPIs, complete appropriate paperwork, then submit it to the payer," observed Canup. "As payers get these forms, it takes them some time to update their systems. **Palmetto GBA** has processed updates in as

Pathology Groups and Laboratories Frustrated As Private and Government Payers Reject Claims

NOT ONLY IS THERE CHAOS in how different payers and Medicare carriers are rejecting claims since the new NPI rules took effect on May 23, but there is lack of uniformity in how payers advise providers about the process to resolve problems with the rejected claims.

"Each carrier gives us different advice about how to resolve the problem," declared Pam Evans, Regional Director of Operations for Pathology Service Associates, LLC (PSA) of Florence, South Carolina. "There is no standard resolution for this problem. Even though all the carriers serve CMS, each operates independently.

"Pathology poses additional challenges for some payers," added Evans. "Some hospital-base pathology practices might file relatively simple claims, since they have one NPI number and one legacy number. In most cases, claims from those practices are handled acceptably.

"But if the situation is more complicated, a large proportion of claims can be rejected," she said. Take the example of a pathology 'super group' that has one NPI number and three legacy numbers. If multiple provider types are involved—meaning a physician group and independent lab under one taxpayer identification number, then problems may occur. We see carriers that don't know how to handle these claims."

"It seems the operational details of changing from legacy numbers to NPI were not considered fully, particularly for the pathology segment," stated Tanya Canup, Implementation Coordinator for PSA. "That's partly because pathology is so complicated. Some pathology groups are based exclusively in hospitals. Some pathology groups own and operate independent laboratories and some pathology groups do both.

"CMS and the carriers did not provide adequate guidance during the NPI application stage to prevent some of the problems we now encounter," added Canup. "In their defense, they may not have known what problems they would encounter after May 23. That meant many Medicare carriers didn't know what to do when these claims hit the door."

"Prior to May 23, we spent a lot of time testing claims, but as long as these claims also included legacy numbers, carriers could identify who should be paid," interjected Evans. "That changed on May 23, when legacy numbers were no longer included on claims. Payers then saw many gray situations but didn't know how to process those claims. Plus, some carriers told us simply, 'if there is any question about where the money should go, it won't go anywhere'."

little as two days while some carriers are taking up to 60 days. Only after that process is completed, can the provider resubmit the claims. For physicians, that is a long time to wait for reimbursement."

"While it is still too early since May 23rd to analyze all data related to the implementation of the NPI rule, some issues and trends have appeared," said Tim Allaway, Vice President of Payer Services of **RelayHealth**, a medical billing service provide for clinical laboratories and a division of **McKesson**. "There was a definite increase in the percentage of claims received from providers that are rejected at the clearinghouse before being sent to payers. While the increase is not huge, it is significant.

"There was also an increase in the percentage of claims being pended or rejected when they get to the payer," Allaway added. "This is especially true for the Medicare and Medicaid claims. As with other standards in the industry, implementation of the NPI has varied greatly across the payer community.

"Clinical laboratories have encountered three major issues," Allaway said. "First, providers may not have registered their NPIs with payers before May 23, thus causing their NPIs not to be included in the payer's crosswalk system. This causes claim rejec-

tions as payers attempt to map NPIs to legacy provider information.

"Second, providers may not be sending NPIs for all segments where a provider must be identified (billing, rendering, service facility, and referring)," he continued. "Third, providers may be sending NPIs, but not the correct NPI in the correct loop/segment. For example, they may be sending a type 2 (group) NPI in a rendering provider segment. Or, they may be sending a type 1 (individual) NPI in a billing or service facility segment when they are registered as a group.

"At the same time, we can see four major issues that originate with the payers themselves," he said. "First, some payers did not fully test their NPI-only logic before implementing the system on May 23. Problems have been experienced with front end editors, translators, and second level edits. Interestingly, Medicare seems to have the highest level of rejected claims. Yet Medicare has required NPI on claims since January 2008 and has encouraged providers to test NPI-only claims submissions for several months prior to the May 23 effective date.

Legacy Numbers Used Too

"Second, some payers still require legacy provider identifiers," added Alloway. "While the law says all covered health plans must use NPI-only to identify providers, some payers remain unable to accept NPI-only claims. A good example is the New York Medicaid system. Third, some Blues, such as those in Oklahoma and Texas, are generating non-compliant files. Fourth, some payers have improper edits in place that continue to require legacy identifiers in some provider loops and segments. **CareFirst** in Delaware, is one example. As of June 12, that plan had no estimate as to when it would resolve this situation.

"On top of these four sources of payer-originated problems, we know of one payer that rejected all claims for a period of time after May 23," Allaway continued. "As a result, providers were required to resubmit all claims. One Medicaid plan incorrectly rejected valid claims by requiring a one-digit payee code. As of June 12, this code resulted in the rejection of almost 7,000 claims valued at more $15 million in provider payments—and no solution was available as of late last week!"

Eddie Miller, Vice President of Pathology Operations for McKesson, commented: "In monitoring the more than 250 pathology and lab clients we service nationwide, we see a measurable softening of our cash run rates. When we call payers, we discover that a large number of claims are pending in their systems."

Use of NPI Mandated Under HIPAA Statute

BLAME THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) of 1996 for all the turmoil surrounding claims rejected since May 23 for not meeting the new rules for use of National Provider Identifier (NPI) numbers.

HIPAA mandated that all physicians and provider organizations use National Provider Identifier (NPI) numbers on claims. The deadline for large health plans and provider organizations to implement NPI was May 23, 2007, but the federal Department of Health and Human Services (HHS) delayed implementation of NPI for individual physicians and small health plans until May 23 of this year.

On its Web site, HHS says NPI is required for all HIPAA standard transactions, meaning that for all primary and secondary provider fields, only the NPI will be accepted and only the NPI should be sent on all HIPAA electronic transactions (837I, 837P, NCPDP, DDE, 276/277, 270/271 and 835), paper claims (UB-04 and CMS-1500), and SPR remittance advice. Using Medicare legacy identifiers in any primary or secondary provider fields will result in the rejection of the transaction, HHS said. More information is available on CMS' Web site: *http://www.cms.hhs.gov/NationalProvIdentstand/*.

"New NPI rules required labs to adjust quickly," Miller added. "All of this went into effect on May 23, meaning we are still a few days too early to say that cash flow will be impacted for all pathology groups in the country. But we know that there will be a cash flow effect because we called some of the big carriers to check the status of claims.

"Each time we check with various payers and carriers, we are told that the claims are pending," he explained. "Normally those claims would have already been paid. In other words, if a carrier typically pays in 14 days and we call on day seven to check the status of a claim and it's pending in the systemp—it means that provider is not going to get paid in the normal time."

Review Front-End Reports

Lâle White, Founder and Executive Chairman of **XIFIN, Inc.**, a company in San Diego that specializes in lab accounts receivable and financial management, agreed that front-end reports are a lab's first indication of a problem. "Your lab's front-end reports are like the canary in the coal mine," she said. "Your first information about rejection of a claim or a submission file is that front-end report. If just one claim within the file is missing an NPI, Medicare will reject the entire submission file on the front end. Medicare advises that it is important to pull out these claims before resubmitting the file in order to eliminate payment delays on clean claims.

"Our clients have worked on the NPI issue for a long time," continued White. "As a result, the only place where our clinical laboratory clients are experiencing trouble with submitted claims is when they have been unable to get NPIs from their ordering physician-clients.

"On the other hand, I hear stories about laboratories experiencing financial devastation in cases where the payer has not handled the NPI implementation well," added White. "For example, **Nordian Administrative Services, LLC**, in Lawrence, Kansas, requires a separate EDI registration of the provider's facility NPI number to process electronic claims. If this was not done before May 23, Noridian rejected all submissions after May 23. Noridian informed providers that there will be delay of four to five weeks in processing these registrations, which must be done before any electronic claims will be accepted.

"First and foremost, labs should monitor their front-end acknowledgement reports to make sure their claims are being accepted for adjudication," White explained. "If a laboratory reviews its front-end rejections from Medicare, then it will know if it is going to have a cash flow problem. Most labs and other providers don't give their front-end rejections the same attention as back-end denials. But that is likely to change if the flow of reimbursement money dries up.

"Next, labs should watch for denials on the back end, which is commonly done by most lab billing departments," White added. "Labs usually have a procedure to review denials, because they come with explanation of benefits (EOBs) forms from the payer. The problem with the claim can then be fixed, allowing it to be resubmitted.

Be Proactive On Rejections

Despite all the advance warning about the deadline for use of National Provider Identification numbers, it is apparent that Medicare carriers, Medicaid carriers, and private payers did not succeed in preparing providers for an orderly transition. Since the May 23 implementation date for use of NPI, many pathology groups and laboratories have experienced a serious reduction in cash flow due to rejected claims. Billing experts may be optimistic in their predictions that cash flow to providers is likely to return to normal during July. TDR

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GE, UPMC Create Company For Digital Path Imaging

➤Joint venture estimates market potential is $2 billion for fully-digitized pathology systems

➤➤CEO SUMMARY: It's a new joint venture with the potential to transform surgical pathology. General Electric Healthcare has extensive experience at supporting physicians' work flow with digitized imaging systems, plus ample experience with molecular biomarkers. The University of Pittsburgh Medical Center's pathology department is a world leader in whole-slide imaging and digitized pathology systems. Together, the two partners hope to gain FDA approval for a fully digitized pathology system in about two years.

RECOGNIZING THE OPPORTUNITY to replace glass slides and microscopes that clinical labs have used for more than a century, on June 5, **GE Healthcare** and the **University of Pittsburgh Medical Center** (UPMC) announced an important joint venture to develop digital pathology systems that can automate primary diagnosis, among other benefits.

The new joint venture is called **Omnyx, LLC** (*www.omnyxpath.com*). GE Healthcare and UPMC will each invest $20 million in the venture. Goals of this new enterprise are ambitious. It expects to develop a digital pathology system that can perform whole-slide scanning in 30 seconds. Omnyx believes it can have the digital pathology system finished with the FDA approval process and ready for market within two years.

➤Enhanced Workflow

Gene Cartwright, a veteran GE executive who will be the Omnyx CEO, calls the new digital pathology system a necessary and evolutionary change for pathology. George K. Michalopoulos, M.D., Ph.D., Chairman of Pathology at UPMC, described the digital pathology system as fast enough to "incorporate into the work flow" of a hospital-based pathology department that typically handles 1,000 slides daily. GE and UPMC estimate that whole-slide imaging and digital pathology represent a $2 billion market.

This development is significant for at least three reasons. First, it represents a major new corporate initiative to expand General Electric's presence in anatomic pathology and *in vitro* diagnostics (IVD). GE is already a major global player in digital systems for radiology imaging and cardiology imaging.

Second, the willingness of GE to partner with an academic medical center, and the $40 million investment of the two partners, demonstrate its conviction that anatomic pathology is ready to "go digital." It is widely-recognized that pathology has lagged behind radiology in moving to a fully-digital workflow. GE's timing for entry into pathology digitization signals that it believes it can now deliver digital products that will enhance pathologists' work flow.

Third, General Electric's choice of UPMC as its partner is a validation of the vision of two pioneering pathologists there. Both Michalopoulos and Michael Becich, M.D., Ph.D., Professor and Chair of the Department of Biomedical Informatics at the University of Pittsburgh School of Medicine (*www.dbmi.pitt.edu*) have been at the forefront of efforts to create effective digital pathology systems, reaching back into the 1990s.

An Experienced Partner

Recognizing the opportunities that digital imaging offers to pathologists, Becich has worked to develop a company like Omnyx for at least 10 years and will serve as a senior consultant to Omnyx. In 1997, he and other pathologists at UPMC founded **InterScope Technologies, Inc.**, in Wexford, Pennsylvania, to develop integrated systems for slide imaging, case flow, and clinical data management in anatomic pathology. **Trestle Instrument Systems** acquired InterScope in 2005 and was itself eventually acquired by **Carl Zeiss MicroImaging GmbH** (a unit of **Carl Zeiss AG**) in 2007.

"UPMC has been a pioneer in digital pathology since we founded InterScope in 1997," Becich told THE DARK REPORT. "Interestingly, in partnership with UPMC, InterScope did a first run at this technology. However, as a small start-up and lacking the deep financial pockets of a GE or a UPMC, it wasn't able to finish the clinical trials required to gain FDA approval. We hope to apply the lessons learned from all this prior experience in developing Omnyx."

The Omnyx digital pathology system is expected to allow clinicians to share images via the Internet and work together to interpret results using advanced algorithms. The system is designed to support improved clinical services by pathologists while generating increased productivity by streamlining workflow and allowing pathology information to fully integrate with patients' electronic medical records.

Bruce A. Friedman, M.D., Active Emeritus Professor, Department of Pathology at the **University of Michigan** in Ann Arbor, commented on the significance of the joint venture in his blog (*www.labsoftnews.com*) on June 5. "I have published a number of previous notes about the entrepreneurship of UPMC," observed Friedman. "Dr. Mike Becich and his colleagues have also established the pathology department at UPMC as a national leader—not only in pathology imaging—but in all of pathology informatics. From my perspective, the deployment of practical whole slide imaging systems is a key to the future success of surgical pathology."

Seeking FDA Approval

"Currently, this technology is largely being used for education and training," Becich explained. "What will make the market explode is getting certification from the Food and Drug Administration (FDA) to use these instruments for primary diagnosis. Getting the FDA to approve this technology as a medical device will allow pathologists to use imaging as the primary diagnostic mode in the same way radiologists look at images as part of their work flow."

"The workflow improvements alone are significant," he stated. "Most large pathology practices operate in more than one location. The pathology practices at UPMC operate in 20 hospitals. We do our histology in centralized laboratories, which means these slides must be distributed back out to the hospitals. Like most centralized labs, we have a courier distribution system, which has its own inefficiencies. Further, if we have to do consults, we must package the slides and mail them among locations. Of course, glass slides sometimes break or become lost. But having a digital solution allows us to solve all of these problems at once.

"From an productivity standpoint, there would be an opportunity for pathol-

GE-UPMC's Omnyx Joint Venture Aims to Develop Fully-Digitized Pathology Imaging System

WHOLE-SLIDE IMAGING (WSI) SYSTEMS—also called digital slide systems or virtual microscopes—are becoming increasingly capable. The arrival of a system that can rapidly digitize large numbers of slides could have a profound effect across the pathology industry.

"While the business implications of digital pathology systems are important, a significant factor in the joint venture is the ability to develop systems to improve healthcare quality and patient safety," explained Michael Becich, M.D., Ph.D., Chair, Dept. of Biomedical Informatics at UPMC. "There are tremendous quality and patient safety implications when you can put digital methodologies in place in the diagnostic pathway.

"A good example is diagnosing a small biopsy," he continued. "Typically, a technologist will cut a small biopsy sample into ribbons and place 10 or 12 duplicates of the tissue on one glass slide for the pathologist to view. But what system guarantees that the pathologist actually looked at every tissue piece on the slide? The technology we are putting forward in this joint venture would ensure that the pathologist does view everything and does not overlook any tissue presented on the slide.

"Digitizing pathology slides also generates another significant benefit: increased productivity through improved work flow," added Becich. "Digitized images allow pathologists to be more efficient because they can review the old pathology of a patient directly alongside the new pathology of that patient. Compare that with the current use of glass slides. To review the patient's earlier pathology, it is necessary to pull the glass slides from storage or archives. This takes time, which is a critical factor for pathologists, who are already burdened with heavy workloads that continue to increase.

"The digital library of pathology images also means that a pathologist has ready access to all diagnostics images, regardless of his/her physical location," noted Becich. "It also means that, as a pathologist calls up the patient's latest pathology image, the digitized pathology system can automatically load and present a patient's older pathology images from earlier treatments. This feature enhances the productivity of the pathologist, while improving patient care, since the pathologist has ready access to all of a patient's previous pathology slides."

ogists to be more efficient while also handling higher volumes of cases," observed Becich. "Potentially, the largest reductions in workforce could occur with the ancillary staffs. This includes the couriers who transport the glass slides throughout the system. It also includes the technologists who file slides when they are returned, retrieve glass slides from storage, and who also recut specimens when necessary. Digitized pathology systems will reduce or eliminate the need for this labor."

THE DARK REPORT observes that the creation of Omnyx is a major milestone on the road to fully digitized pathology systems. It marks the long-anticipated entry of General Electric into anatomic pathology and *in vitro* diagnostics. With one of the world's largest businesses in radiology and imaging, GE brings considerable clout, credibility, and experience to the Omnyx joint venture.

Plus, the $40 million bet that GE and UPMC are placing on Omnyx is a sign that the two partners are confident they can meld GE's considerable technology base and physician work flow experience with the digitized pathology solutions developed at UPMC to create a next-generation digitized pathology system. Now the challenge is to gain FDA approval and then convince pathologists that the time for fully-digitized pathology has arrived. TDR

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New Senate Bills Include Repeal of Competitive Bid

Bills would kill lab competitive bidding demo, eliminate cut to physician fees, and extend TC

CEO SUMMARY: One proposed Senate bill would repeal the laboratory competitive bidding demonstration project, replace the 10.1% cut to physician fees with a 1.1% increase, and extend the so-called technical component (TC) grandfather clause. Senator Max Baucus (D-Montana), Chairman of the Senate Finance Committee, is sponsor of the bill (called S 3101). Congress is under pressure to pass a Medicare funding bill before July 1, 2008, when the 10.1% reduction in physician fees will occur.

EFFORTS TO DERAIL the Medicare Competitive Bidding Demonstration Project for Part B Laboratory Services have shifted from a federal court in San Diego, California, to the nation's capital in Washington, DC.

With Congress gearing up to pass a Medicare funding bill for fiscal 2008, there is optimism that a clause to repeal the Medicare Laboratory Competitive Bidding Demonstration Project may be included in the final legislation passed by Congress.

Competitive Bidding Repeal

Source of this optimism is a Senate bill introduced on June 6. This bill includes a clause to repeal Medicare Competitive bidding for Part B Laboratory Services. Also included in the bill, "The Medicare Improvement for Patients and Providers Act of 2008" (S 3101), is a provision to avert a 10.1% cut in the Medicare physician fee schedule, and an extension of the so-called "technical component (TC) grandfather clause" for 18 months.

All three provisions are significant and positive developments for the lab industry, said Alan Mertz, President of **American Clinical Laboratory Association** (ACLA), in Washington, DC.

Senator Max Baucus (D-Montana), introduced S 3101. Baucus is the Chairman of the Senate Finance Committee. Mertz reports that Senator Chuck Grassley (R-Iowa) is sponsoring a Republican version of the bill that includes similar language for repeal of Medicare competitive bidding.

"We're very pleased with this bill, and, of course, it would be significant to have both sides of the aisle supporting a bill that would repeal the competitive bidding project," Mertz said. "But, as it is written now, S 3101 is a legislative triple play for important laboratory services and a grand slam for Medicare beneficiaries.

"The three provisions are significant because each one affects the lab industry in a different yet substantial way," he noted. "First is the competitive bidding demonstration, which would be eliminated. Second is stopping the cut in the Medicare physician fee schedule and adding an increase to the fee schedule. And third is getting the TC grandfather clause continued.

"All the provisions in this bill have a good chance of passing because the physician fee schedule cut is scheduled to take place July 1," Mertz added. "That means there is urgency in Congress to pass this bill. You could say we have a good chance of being on this train which appears to be leaving the station.

"All physicians, including pathologists, are interested in getting Congress to stop the 10.1% cut calculated by the physician fee schedule," he explained. "And currently, the Senate bill calls for stopping the 10.1% cut and adding a 1.1% increase to the physician fee schedule.

"The TC grandfather clause extends the ability of independent labs to bill Medicare directly for the technical component of surgery pathology services," Mertz continued. "Without this authority, labs would have to bill the hospital and try to get the hospital to reimburse them, which can be difficult. Maintaining the ability to bill Medicare directly assures laboratories of payment for those services.

"The problem is that the authority for direct billing for TC keeps expiring and we have extended it several times now," he said. "We want to get it extended permanently but short of that we have to keep extending it temporarily.

Educating Congress

"By including three very positive provisions in this bill, this legislation shows our effort to promote the work of labs in Congress is starting to pay off," Mertz added. "The fact is we now have champions in Congress that we never had previously. When I got here five years ago, it didn't seem that we had enough folks in Congress to champion our causes. But this campaign against competitive bidding has had a real silver lining in helping us get champions for S 3101—as well as for the future. In addition, the 'Labs Have Value' educational campaign has also helped.

Because it is unlikely that Congress will allow Medicare physician fees to be cut by 10.1%, a Medicare funding bill is likely to be passed. Repeal of laboratory competitive bidding has a growing number of sponsors in both houses, which is why there is optimism that the final Medicare bill will include repeal. TDR

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Update on Competitive Bid Lawsuit in San Diego, CA

Since April, when Federal District Court Judge Thomas J. Whelan issued a preliminary injunction halting the competitive bidding demonstration that was scheduled to begin in San Diego on July 1, federal attorneys have been studying their legal options. *(See TDR, April 14, 2008.)*

On June 2, the parties in the case jointly requested 60 days to respond to the judge's order. The plaintiffs are **Internist Laboratory**, **Sharp Healthcare**, and **Scripps Health**. The defendant is Michael Leavitt, Secretary of the federal Department of Health and Human Services (HHS).

"In compliance with the injunction, defendant has ceased all activities related to implementing the project," said the joint motion from the defendants and plaintiffs. "In addition, defendant, through the Centers for Medicare and Medicaid Services ("CMS"), is still in the process of considering what course of action to take in light of the Court's ruling. It remains possible that CMS will ultimately decide on a course of action that would render further litigation unnecessary."

"The court ruling in April was important because it stopped the bidding demonstration project from going forward and stopped CMS from using those bid documents to revise the fee schedule," observed Alan Mertz, President of the American Clinical Laboratory Association (ACLA) in Washington, DC. "But the court case ultimately doesn't stop the demonstration project. The government could have proceeded with new rule making to try to do the project, even though it would take some time to do. So, statutory repeal is the ultimate strategy to stop the demonstration project."

ISO 15189 Work Advances At Meeting in Vancouver

Delegates to ISO Technical Committee 212 gathered for their annual working session

CEO SUMMARY: Laboring quietly out of the public eye, an international work team of professionals, including representatives from the CDC, the FDA, and global* in vitro *diagnostics (IVD) manufacturers, has spent the past 14 years developing an important series of quality and safety standards for medical (clinical) laboratories. Here's a report on events at the most recent international assembly of ISO Technical Committee 212, which gathered earlier this month in Vancouver, British Columbia.

EARLIER THIS MONTH, VANCOUVER, BC, was a hotbed of quality management and laboratory safety activity. Members of ISO Technical Committee 212 and observers from across the globe gathered to continue the work of international standards for clinical laboratory testing, including ISO 15189

First up on May 31-June 1 was the "Quality Conference Weekend Workshop," offered by the **University of British Columbia** (UBC) Department of Pathology and Laboratory Medicine and open to the laboratory public. It was organized by Michael Noble, M.D., Professor and Chair, Clinical Microbiology Proficiency Testing program and Program Office for Laboratory Quality Management at the UBC Department of Pathology and Laboratory Medicine. THE DARK REPORT conducted a session at this workshop.

Unfamiliar Topics For Labs

This quality workshop offered a number of topics and experts seldom heard at laboratory programs in the United States. These topics ranged from root cause analysis to risk management tools, such as "failure mode and effects analysis" (FMEA). Collectively, these presentations provided insights into how laboratory operations will evolve toward a more sophisticated environment of evaluating both analytical and operational processes.

For example, failure mode and effects analysis is a risk management tool that can be used to predict the effects of problems that could develop in the processes being studied. "Fault tree analysis" (FTA) is a complementary risk management tool and can be used to identify problems in laboratory testing processes, both prospectively and retrospectively.

The presentation on FMEA and FTA was delivered by Donald M. Powers, Ph.D., who is the Chair of ISO Technical Committee 212 (TC 212). Powers is the principal of **Powers Consulting**, based in Pittsford, New York. He served as a clinical chemist at **Hahnemann University** in Philadelphia and worked for many years at *in vitro* diagnostics (IVD) firms such as **Ortho-Clinical Diagnostics** and **Kodak**.

Powers explained the evolution of risk management in the automobile and medical

device manufacturing industries. "It was in the early 1990s that failure mode and effects analysis was adopted by IVD manufacturers for risk management purposes," observed Powers. "In 2006, FMEA arrived in healthcare. New **Joint Commission** directives require healthcare organizations to include FMEA in their programs to prevent or eliminate errors and reduce risk to patients."

Significant Development

FMEA's arrival in healthcare is a significant development and will eventually work its way into clinical and pathology laboratory operations. THE DARK REPORT will be providing further intelligence about fault mode and effects analysis, fault tree analysis, and similar disciplines that are focused on improving processes and identifying sources of errors.

Another presentation with implications for laboratories in the United States was delivered by Gregory J. Flynn, M.D., pathologist and Managing Director of the Quality Management Program–Laboratory Services, of the **Ontario Medical Association** in Toronto, Canada.

Flynn discussed how and why the province of Ontario had implemented a new, more rigorous scheme of laboratory accreditation and regulation. " Five years ago, provincial health authorities decided to base laboratory accreditation in Ontario on ISO 15189," stated Flynn. "By the end of 2008, there will be at least 200 laboratories that have achieved ISO 15189 accreditation."

Ontario Lab Accreditation

One consequence of Ontario's use of ISO 15189 for laboratory accreditation has been a shake-out of smaller laboratory companies. "There has been a decline in the number of small lab firms that operate in Ontario," explained Flynn. "Smaller labs have chosen not to devote the resources and management involvement necessary to achieve accreditation under ISO 15189. Instead, they either closed or were purchased by larger lab companies."

Following UBC's "Quality Conference Weekend Workshop," ISO Technical Committee 212 convened and conducted sessions on June 2, 3, and 4. Technical Committee 212 (TC 212) was responsible for developing ISO 15189, along with 22 other international standards for clinical laboratories and IVD manufacturers.

Official participants on TC 212 are delegates representing medical laboratory and IVD interests from 33 countries and several international organizations, such as WHO. Registered observers are allowed to monitor the plenary sessions and offer comments in working sessions. There were approximately 120 delegates and observers present at the opening plenary session on June 2.

Plenary and working sessions over the next several days provided invaluable insight about ISO 15189 and its ongoing development. Because an ISO standard has global credibility and because of momentum that has built since ISO 15189 was published in 2003, pathologists and laboratory directors in the United States and internationally will want to stay informed on this subject.

Lab Standardization

First, a quick history. It was in 1995 when, under the sponsorship of the **Clinical and Laboratory and Standards Institute** (CLSI, then NCCLS), delegates from national standards bodies around the world came together with a common interest in improving laboratory quality by developing international standards specific to medical laboratory testing. This group of pioneers received official recognition as a technical committee of the **International Organization for Standardization** (ISO), and began work on a body of standards that included ISO 15189, which was published in 2003.

Another little-known fact among the laboratory profession is that ISO 15189 is just one of many ISO standards for which the committee is responsible. So far TC

212 has published 17 standards, with six more to be published in the next year. A few of the subjects encompassed by TC 212's working charter:

- ISO TS 22367: Reduction of error through risk management and continual improvement
- ISO 22870: Point-of-care testing
- ISO 15190: Requirements for Safety
- ISO 18113: Information Supplied with IVD Medical Devices (Labeling)
- ISO 15198: Validation of User Quality Control Procedures by IVD Manufacturers
- ISO 15197: Requirements for blood-glucose monitoring systems for managing diabetes mellitus
- ISO/TS 25680: Calculation and expression of measurement uncertainty for medical laboratories
- ISO 17511: Traceability of values assigned to calibrators and control materials

Single Global Standard

In upcoming issues of THE DARK REPORT, additional intelligence briefings will provide more depth and detail about this comprehensive effort to align technologies and processes across the manufacturing, laboratory medicine profession, and patient self-testing segments based on ISO standards. These efforts are undertaken with a goal of creating global standards that will be supported by government regulatory agencies of most nations.

Also, the U.S. Technical Advisory Group to ISO TC 212 welcomes more participants willing to contribute their expertise. Individuals with experience in clinical laboratory medicine or *in vitro* diagnostics manufacturing are needed to formulate the U.S. positions on the international standards or to participate in developing or revising the standards. Clients and readers of THE DARK REPORT interested in participating should contact editor Robert L. Michel at *rmichel@darkreport.com*. He will facilitate contacts with CLSI or other national standards organizations. TDR

ISO "Certification" Versus "Accreditation"

IT IS IMPORTANT FOR LABORATORY DIRECTORS AND PATHOLOGISTS to understand the concepts of "accreditation" and "certification" as it applies to ISO:15189 Medical Laboratories.

This month, in an article in *Quality Magazine*, author Roger Muse offered the following insights about "accreditation" versus "certification":

Among the several terms that have been identified for third-party conformity assessment activities, two rise to the top because of common usage:

Accreditation is a "third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks", as defined by ISO/IEC 17011 Conformity Assessment–General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.

Certification is a "third-party attestation related to products, processes, systems or persons," as defined by ISO/IEC 17000 Conformity Assessment–Vocabulary and General Principles.

The hierarchy is structured in such a way that accreditation is one step higher than certification. Accreditation is reserved for those bodies performing some type of certification service. This might be an ISO/IEC 17025 accredited lab issuing an accredited calibration or testing certificate, an accredited certification body issuing an ISO 9001 (management system requirements) certificate, or an accredited product or personnel certifier whose responsibility is to certify a product.

Given the global awareness of the ISO management system standards, certification is most often associated with ISO 9001 and the environmental management systems standard ISO 14001. However, accredited certification programs exist for a range of management systems.

CMS Expected to Revise Condo Lab & TC/PC Rules

➤Rule changes could come this summer and may also involve physician self-referral

➤➤CEO SUMMARY: Expectations are that the Centers for Medicare & Medicaid Services (CMS) will take further action to rein in anatomic pathology arrangements used by physicians to capture revenue from their patient referrals. This may happen as soon as next month, when CMS publishes the 2009 Medicare Physician Fee Schedule (MPFS) Update and requests public comment on proposed new rules. Attorneys tracking these developments believe that both anatomic pathology condo labs and TC/PC arrangements are likely to be the subject of these new rules.

WITHIN THE NEXT FEW MONTHS, federal officials are likely to publish the proposed 2009 Medicare Physician Fee Schedule (MPFS) Rule and ask for public comment. Certain to be in the bull's eye of federal rulemakers are anatomic pathology (AP) condominium (pod) laboratories and other types of pathology arrangements involving referring physicians.

"At a recent conference of the **American Health Lawyers Association** (AHLA) in Washington, DC, it was clear that the **Centers for Medicare & Medicaid Services** (CMS) continues to work on regulations intended to cover anatomic pathology (AP) condo/pod labs," said Jane Pine Wood, an attorney with **McDonald Hopkins**, a national law firm in Cleveland, Ohio. "CMS likely will do something this summer as part of developing the physician fee schedule for 2009. I believe we will see specific proposals from CMS that will go through the formal rule-making process.

"One speaker at the AHLA conference was Donald H. Romano, Director of the Division of Technical Payment Policy at CMS," noted Wood. "In his remarks, Romano explained that CMS will likely go through formal rule making and will be considering revisions to the Stark Law and also the ancillary service exemption. CMS will consider what Congress meant when it originally created that exemption.

➤Patient-Care Issues

"Romano discussed CMS' concern regarding Congress' intent when it developed the ancillary service exemption," explained Wood. "Romano's comments indicated that CMS believes Congress' intent was to protect a situation where a doctor, when seeing a patient in his/her office, orders ancillary services for that patient from the doctor's on-site ancillary services. The patient waits in the office and, when the results are ready, the doctor could use these results to help diagnose the patient. Romano indicated this situation makes sense as an exemption that would fit Congress' intent.

"In addition, Romano gave an example of a patient who is referred for an MRI

and the physician making the referral has an ownership interest in the company that offers the MRI," Wood explained. "Based on Romano's remarks, it appears as though CMS is asking questions, such as: 'Where is the patient convenience in that? How is that related to the patient care visit?'

What Did Congress Intend?

"Given Romano's presentation at the AHLA conference, CMS is clearly considering what Congress intended to cover when it passed Stark and anti-markup laws," observed Wood. "This intent includes services that have a patient convenience factor and that promote diagnosis and care during the same patient visit.

"When an ancillary service is not related to patient convenience or diagnosis in that visit—and could just as easily have been ordered from a free-standing imaging center or from a hospital laboratory—then CMS appears to be challenging whether such an arrangement was what Congress had in mind when it passed this legislation," stated Wood.

"In general, comments at the AHLA conference were not as specific as I would have liked," Wood added. "But one could infer, after listening to Romano's remarks, that these are the steps CMS is considering and CMS is not finished with this topic.'

"However, CMS still must deal with the 'moving target' aspect of AP services performed as an ancillary service provided by referring physicians to their patients," continued Wood. "Even as CMS issues rules to address AP condo/pod laboratories that are physically located off-site from the physicians' office, these same federal officials know well that a growing number of AP labs are now located within physicians' offices. Physicians can easily move things within their offices and get away from the anti-markup rule. So, now the question facing federal rulemakers is: 'How do you address this situation where the pathology laboratories are physically located in physicians' offices?'

"There is an exemption under the Stark Law for in-office ancillary services and CMS is looking at what Congress intended when it created this exemption," Wood continued. "Since I have not recently read the Congressional record of the debates regarding the original Stark legislation as it was enacted in 1989, I will not speculate as to the intent of Congress. Further, healthcare has changed since 1989. In the late 1980s, urologists were not operating anatomic pathology labs. There were urologists doing simple urinalysis in their offices but not operating AP labs. So, the market for pathology services has changed greatly in the decades since Congress passed the Stark laws."

Rick Hindmand, a health law attorney in the Chicago office of McDonald Hopkins, agreed that officials at CMS seem to be looking more closely at condo/pod labs and other contracts between referring physicians and pathologists. "With the passage of time, CMS is becoming more sophisticated in how it views AP condo/pod labs and in-office pathology laboratory arrangements," Hindmand commented.

Patient Care And Diagnosis

"The in-office ancillary services exception currently does not distinguish between a pathology laboratory arrangement set up to facilitate patient care and diagnosis, on the one hand, and a pathology lab arrangement designed for financial gain by allowing a physician to refer to a facility in which he or she has an ownership interest on the other hand," Hindmand said. "Moreover, CMS could be considering a broader-based change to ancillary service arrangements than new rules that would primarily affect pathology. In either case, forthcoming changes are likely to have a significant effect on existing arrangements pathologists have with referring physicians."

Wood and Hindmand are not alone in warning the physician community that CMS will continue to take steps to rein in various ancillary service arrangements.

Predictions on How Federal Officials Will Act to Curb Pathology In-House Ancillary Service Arrangements

PHYSICIANS CURRENTLY OPERATING ANATOMIC PATHOLOGY (AP) LABORATORIES are getting the same message as pathologists about the intent of federal healthcare officials to curb or ban ancillary service arrangements that are considered abusive.

In a recent article published in *EndoEconomics*, health attorneys Peter M. Kazon and Catherine A. Martin of **Alston & Bird, LLP**, in Washington, DC., warned gastroenterologists about changes that may come when the Centers for Medicare & Medicaid Services (CMS) issue new rules governing ancillary service arrangements, including anatomic pathology laboratories.

Anti-Markup Rule Changes

Kazon and Martin reviewed the 2008 Medicare Physician Fee Schedule (MPFS) Final Rule, which involved changes to the anti-markup rule. The two attorneys wrote: "When fully implemented, these restrictions may curb the growth of condo/pod laboratory arrangements, where the performing pathologist is located outside the referring physician's office, by eliminating the economic incentive for the referral. This new provision applies to both the technical component and the professional component of a diagnostic service."

Kazon and Martin advised readers that CMS may be considering taking other action to curb what it considers to be abusive practices. "Relationships between referring physicians and pathologists are likely to continue to garner the attention of CMS," noted Kazon and Martin. "It seems unlikely that CMS will retreat from its continued fight against what it views to be highly problematic physician relationships.

"There are several reasons to expect this is the case," continued the attorneys. "First, federal authorities have indicated increasingly that they recognize that physicians' economic interests in ancillary facilities have the impact of increasing utilization and costs. In the MPFS Final Rule, CMS noted that a variety of studies had shown a link between physician's economic incentives and increasing utilization. Not only has CMS recognized this fact, but the Medicare Payment Advisory Commission ("MedPAC"), which advises Congress on health care issues, has noted the same thing. Moreover, in the original proposal of the anti-markup rule, CMS did not distinguish between in-office procedures and those done outside the office; rather, it would have imposed an anti-markup requirement on all services not performed by a full-time employee."

As a result, the authors conclude that CMS may be considering taking additional action directed at the in-office ancillary services exception and such changes could have an effect on pathology services.

Attorneys Peter M. Kazon and Catherine A. Martin of **Alston & Bird, LLP**, based in Washington, DC, are also alerting physicians to expect further regulation by CMS on ancillary service arrangements, particularly those involving anatomic pathology services. *(See sidebar on this page.)*

Will CMS be successful in stamping out the more egregious and abusive forms of in-house ancillary service arrangements involving pathology? That remains to be seen. However, at the least, pathologists and specialty physicians, including urologists and gastroenterologists, are on notice that major changes lie ahead. **TDR**

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

GE Healthcare's digital pathology joint venture with the **University of Pittsburgh Medical Center** (UPMC), announced on June 5, is not the only *in vitro* diagnostics (IVD) investment by GE during 2008. Just this May, GE paid $738 million to acquire **Whatman, PLC**, of Kent, England. With annual sales of $230 million, Whatman offers products described by GE as "breakthrough protein array technology and FTA technology to capture, archive and purify DNA at room temperature enabling it to provide novel solutions for the analytical, healthcare and bioscience markets." Although GE noted publicly that it viewed Whatman as an acquisition that would strengthen its presence in the broad life sciences field, Whatman's protein microarray and DNA technologies can also be used in clinical molecular diagnostics.

MORE ON: GE and IVD

"I believe there is still a lot of interest in acquiring and expanding in IVDs at GE," said Manfred Scholz, Ph.D., President of **Scholz Consulting Partners** of Medford, Massachusetts. "However, the focus at GE seems to be more on pharmaceutical companion markers than acquiring a large-scale IVD business. GE seems to have a bias toward drug discovery and development–related technologies, rather than traditional IVDs. So I don't think there will be an **Abbott**-like acquisition by GE any time soon. Acquisitions by GE are always driven by financial considerations, especially growth and margin."

SONIC ACQUIRES GERMAN LAB FIRM

Sonic Healthcare Ltd. announced earlier this month that it would acquire 100% of the **Labor 28 Group** in Berlin, Germany. Labor 28 is an independent lab company based in Berlin and serving the surrounding metropolitan area. This is the third laboratory company in Germany that Sonic has acquired in recent years.

GENOME PROJECT ADDS 3 COMPANIES

Three companies that pioneered gene sequencing technologies have joined the 1000 Genomes Project, an international effort to build a detailed map of human genetic variation for research. The companies are: **454 Life Sciences**, a **Roche** company in Branford, Connecticut; **Applied Biosystems**, an **Applera Corp.** business in Foster City, California; and **Illumina Inc.**, in San Diego, California.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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...why clinical and pathology laboratories in Canada are "unraveling at the seams" due to a "host of problems," as described by the President of the *Canadian Association of Pathology* (CAP).

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That's all the insider intelligence for this report. Look for the next briefing on Monday, July 7, 2008.