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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Employers, Payers Are Challenging 'High' Test Prices

ONE NATIONAL TREND IN CLINICAL LABORATORY TESTING that has not yet gotten wide play outside the pages of THE DARK REPORT is the emergence of what might be termed a "war" by national and regional health insurers against the "higher" prices often charged by hospital laboratories.

This is a key strategic shift in the managed care contracting marketplace. This war has the potential to seriously undermine the financial underpinnings of hospital laboratories, particularly those hospitals and health systems which have flourishing laboratory outreach programs. Similarly, pathology groups that are hospital-based are equally at risk, since they often market their testing services in tandem with the laboratory of their parent hospital or health system.

The "war" metaphor aptly characterizes what some knowledgeable lab experts believe is the motivation behind important changes in how labs can bill for services provided to patients covered by the BlueCard program. These experts believe the primary goal of the BlueCard changes is to exclude local laboratories as providers to the greatest extent possible and, at the same time, significantly reduce the price at which these lab tests are reimbursed.

The details about the BlueCard changes that we provide on pages 3-9 should be evaluated against the assumption—noted above—that the motive behind the changes is to restrict the access of local labs to BlueCard patients while reducing the amount of reimbursement paid for lab testing to the greatest extent possible, using in-network vs. out-of-network status as one criteria.

At issue in this payer war is the fact that many hospital laboratories bill for lab tests using their hospital inpatient price schedule. This has caught the attention of employers, particularly those employers who self-insure. They notice that the price charged by a hospital laboratory (that is using its inpatient fee schedule) can be much higher than the Medicare Part B price. Those prices are also substantially higher than the deeply-discounted prices the employer may be paying to one or both of the large national lab companies.

At a time when the increased annual cost of health benefits is a burden on employers, it should be no surprise that they are becoming aggressive at challenging those lab providers they consider to be "high-priced" when compared to labs offering them rock-bottom low lab test prices. For this reason, hospital lab administrators should heed the warning that it may be timely to revisit their lab test pricing strategy and take proactive steps to offer more competitive prices. TDR

New BlueCard Policies Affect Lab Test Claims

Many local clinical labs will have less access to the 100 million members of Blue Cross plans

CEO SUMMARY: This new policy from the Blue Cross and Blue Shield Association (BCBSA) becomes effective on October 14, 2012. No longer can a local lab provide service to a member under the BlueCard program and be paid by the local plan in the region where the service was provided. Some regional BCBS plans have already implemented the new policy. In these regions, labs report significant difficulties in getting claims accepted. Further, some payers are sending the payment for lab tests directly to the patients.

THERE'S BAD NEWS AHEAD for clinical laboratories now providing lab testing covered under the BlueCard program offered by the regional **Blue Cross and Blue Shield** plans located across the United States.

The BlueCard program allows a member from any regional BCBS, when traveling or living outside that region, to obtain healthcare from hospitals and physicians located in other states and regions. In turn, clinical laboratories have been able to submit claims to the Blue plan in the state where the specimen was processed. That claim was paid directly to the laboratory.

However, this policy on service and claims—that was long-established and successful for members and providers alike—comes to an end on October 14, 2012. That is the date when the **Blue Cross and Blue Shield Association** (BCBSA) mandates that regional BCBS plans change how they reimburse for laboratory testing performed for patients who are accessing clinical care outside their home state or home region.

This change will have significant impact on the nation's local laboratories. That's because approximately 100 million Americans are insured by the regional BCBS plans and many participate in the BlueCard program. This is almost one-third of the population of the United States! Loss of access to these BCBS members will be a significant setback to most local laboratory organizations and hospital laboratory outreach programs.

The new mandate overturns a successful aspect of the BlueCard program that has operated for almost 50 years. During this time, local clinical laboratory organi-

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

zations have generally had access to provide lab testing services to these patients under the BlueCard program and get paid in a long-established and reliable fashion.

Because six of the 38 regional BCBS plans have already implemented the new claims and reimbursement policy in advance of the October 14 date, the consequences of this change in payment policy can be seen. Clinical laboratories operating in those states and regions report that the new policy is triggering disruptions in how lab test claims are filed and reimbursed by certain BCBS plans.

Of equal significance is the fact that several of these regional Blues are ignoring the patient's assignment of payment to the provider and sending payment for out-of-network lab tests directly to patients. That is generating new problems, both for patients and for the laboratories which provided the laboratory testing services.

Providers, including clinical laboratories, are being told that each of the 38 plans are independent insurers and must be contracted with separately in order to obtain an in-network status for the adjudication of claims. Yet, in contrast to standard protocol for billing independent plans, providers billing out-of-network Blue plans are being asked to retain a cross reference of each Blue plan's regional map, so that claims may be directed to the plan in whose area the specimen was drawn as opposed to the Blue plan noted on the beneficiary's insurance card.

CCLA Sent Letter

This situation has attracted the attention of major clinical lab industry associations across the nation. On January 23, 2012, the **California Clinical Laboratory Association** (CCLA) sent a letter to the BCBSA to express its concerns. CCLA requested interactive engagement with BCBSA and all stakeholders to develop a mutually satisfactory resolution.

For its part, in February, the **American Clinical Laboratory Association** (ACLA) prepared a draft of a letter to BCBSA that laid out its perspectives on the problems already experienced by labs and patients in the early implementation of the revised BlueCard policies. Although that draft was circulated among a number of member laboratories, as of this date, it is believed that ACLA has not sent this letter to BCBSA.

Problem For Labs

The problem for independent clinical laboratories was described on a blog published by **XIFIN, Inc.**, the revenue cycle management company based in San Diego, California. Posted on June 12, 2012, and titled "Who, if anyone, benefits from the dismantling of the BlueCard® program?", XIFIN wrote:

In May of 2010, the BCBS Association notified Blue Plans of a change to the BlueCard® program that would require ancillary claims to be filed to their local plans for independent clinical lab, DME/HME, and specialty pharmacy. For independent clinical labs the "local plan" was defined as the plan in whose service area the specimen was drawn as opposed to the service area in which the work was performed.

This policy change opens up a Pandora's Box of problems for patients, laboratories, benefits administrators, and the 38 Blue plans. The provider's home Blue plan historically forwarded the claim through the BlueCard program to the member's own Blue plan to adjudicate the claim, and the member's cost-sharing amount was calculated at the "in-network" rate based on the provider status of the performing laboratory and the plan to which the claim was submitted (i.e., the laboratory's "home plan").

With the elimination of the BlueCard program, if the specimen is not collected in the same plan region where the laboratory services are performed, the Blue plan for the state where the analysis and clinical assessment services are performed will no longer forward the claim to the appropriate plan...

Understanding How the New BCBSA Policy Changes How Labs Get Paid for BlueCard Tests

FOR MANY DECADES, THE BLUECARD PROGRAM allowed members of regional Blue Cross and Blue Shield (BCBS) health plans to travel almost anywhere in the United States and receive health care in that locality as an "in-network member." Under existing BlueCard policies, it was easy for any local laboratory to provide services to these traveling BCBS members and be paid directly by the BCBS plan in their community.

However, the BCBS Association is about to change that long-standing policy in regards to clinical laboratory testing, DME/HME, and specialty pharmacy. Essentially, the new policy links site of service to where the laboratory test specimen was collected and requires the laboratory to bill that regional BCBS plan. Despite the fact that the member has BlueCard coverage, now the policy will be to reimburse the patient instead of the laboratory as an out-of-network service and possibly require the patient to pay higher out-of-pocket costs when using medical services outside his or her home BCBS region.

Current BlueCard Policy

- BCBS patient from Illinois goes out of state, has lab test performed in, say, Georgia.
- Specimen is collected in Georgia, lab test is performed in Alabama and the Alabama lab sends claim to its local BCBS regional plan in Alabama.
- Per BlueCard program, local BCBS calculates reimbursement at the "in-network" rate based on the provider status of the performing laboratory and the plan to which the claim was submitted (i.e., the laboratory's "home plan").
- Lab in Alabama which performed the test is reimbursed directly at "in-network" rates by Alabama BCBS.
- BCBS member has minimal out-of-pocket cost for using medical services away from his or her home region.
- Member's BlueCard benefit provides him with "in-network" services in any region within the United States.

Revised BlueCard Policy *(eff. 10-14-12)*

- BCBS patient from Illinois travels out of state, has lab test specimens performed in, say, Georgia.
- If the specimen is collected in Georgia, but the lab test is performed in another state (say, Alabama, for instance), then the lab in Alabama cannot forward the claim to the BCBS plan in Alabama.
- Rather, the Alabama lab must retain a record of where the specimen was drawn;
- Alabama lab must submit the claim to the BCBS plan in Georgia, where the specimen was drawn.
- BCBS plan in the state where the specimen is drawn will issue reimbursement at the "out of network" rate.
- Patient will pay higher out-of-pocket costs for the lab test.
- Patient may get the lab test payment check from the BCBS plan. This requires the clinical lab to collect those funds directly from the patient.

The problems caused by this new mandate were discussed at the *Executive War College on Lab and Pathology Management* last May by Michael Snyder. He is Vice President Laboratory Services, **Medical Spend Management, LLC**, in Flemington, New Jersey, and is knowledgeable about managed care contracting.

"Here's how it works," said Snyder. "Let's say a clinical lab in New Jersey is contracting with **Horizon Blue Cross and Blue Shield of New Jersey**. If Horizon has a

member who vacations in Florida during the winter and that member needs lab work done, normally the member would use his or her BlueCard and be treated by a physician under contract to a Blues plan in Florida. The bill for any lab work performed from the specimen collected in Florida would be paid as if the consumer were in New Jersey as long as the lab provider was a participating provider in a BCBS plan.

"But, Blue Cross and Blue Shield of Florida has revised its policy for BlueCard claims administration with respect to lab services," Snyder said. "Therefore, if the rendering lab is outside of the BCBS-Florida network, even though the lab is a participating provider with BCBS in another market (for example, a lab in Tennessee that provides services to doctors in Florida), the patient's claim is treated as out-of-network.

Changes To BlueCard Terms

"While this change in policy, by itself, represents a potential for additional out-of-pocket expense for the plan member, the problem is further compounded by the fact that not all BCBS plans are prepared for the policy change," Snyder explained. "And, not all BCBS plans are administering the policy in the same manner.

"It is entirely the right of the plan to make and execute policies with regard to benefit administration," he commented. "However, it is also the responsibility of the plan to administer those policies in a fair and equitable manner that protects the patient/member. The implementation of the new BlueCard policy with respect to lab services is confusing to providers and puts the patient in the middle with respect to claims payment."

At a minimum, lab administrators and pathologists in regions where snowbirds winter should take steps to understand the financial consequences of this new BlueCard policy. TDR

—Joseph Burns

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Is Blue Cross Reneging On BlueCard Promise?

IT MAY BE A SIGN OF THE TIMES that even the Blue Cross and Blue Shield Association (BCBSA) is willing to alter a well-established value proposition of the BlueCard program it provides to its members and to the employers who purchase its health plan services.

In changing the terms of how ancillary providers are reimbursed as part of the BlueCard program, it appears that the new policy may require BlueCard holders to pay more out of pocket when they receive healthcare services outside their home region. Here is the language from the BCBSA website (*http://www.bcbs.com/shop-for-health-insurance/coverage-home-and-away.html*):

BlueCard® Program

When you're a BlueSM member, you take your healthcare benefits with you—across the country and around the world. The BlueCard Program gives you access to doctors and hospitals almost everywhere, giving you the peace of mind that you'll be able to find the healthcare provider you need. Within the United States, you're covered whether you need care in urban or rural areas. Outside of the United States, you have access to doctors and hospitals in nearly 200 countries and territories around the world through the BlueCard Worldwide® Program.

Take Charge of Your Health Wherever You Are

BlueCard allows you to choose from PPO or traditional/indemnity service. After you receive care, you should:

- *Not have to complete any claim forms.*
- *Not have to pay upfront for medical services, except for the usual out-of-pocket expenses (non-covered services, deductible, co-payment and coinsurance).*
- *Receive an explanation of benefits from your Blue plan.*

Blue Cross Execs Discuss Reasons for New Policies

Significant changes to the Blues' decades-old BlueCard program put local labs at disadvantage

CEO SUMMARY: In recent months, officials from the Blue Cross and Blue Shield Association (BCBSA) have responded to the concerns about new billing protocols for services provided as part of the BlueCard program and voiced by such clinical lab associations as the California Clinical Laboratory Association (CCLA) and the National Independent Laboratory Association (NILA). BCBSA executives have suggested that clinical laboratories would be welcome to participate in a national partnership arrangement.

BY ALL APPEARANCES, the BlueCard program offered to members of regional **Blue Cross and Blue Shield** (BCBS) plans has been a simple and effective benefit. For decades, it has allowed members of one regional BCBS plan to access care when they travel or live in areas outside their home BCBS region.

However, in May 2010, the **Blue Cross and Blue Shield Association** (BCBSA) sent notification to the 38 independent BCBS programs of a change in how ancillary claims were to be filed by clinical laboratories, DME/HME, and specialty pharmacy. Effective date for this new policy is October 14, 2012. Several regional BCBS plans have already implemented the new policy.

Identifying Preferred Labs

The new BCBSA policy imposes a complicated requirement on clinical laboratories. In a letter to the BCBSA sent on January 23, 2012, Lori Dean Yokum, President of the **California Clinical Laboratory Association** (CCLA) wrote:

For independent clinical labs the local plan was defined as the plan in whose service area the specimen was drawn as opposed to the service area in which the work was performed. While this policy may be reasonable for services delivered to the enrollee within the plan's service area by providers such as physicians, hospitals, DME/HME, and pharmaceuticals, it is not practical for independent clinical labs—which draw specimens in several local plan service areas, but perform the services in one physical location—to contract with up to 38 BCBS plans.

Of note, in speaking with numerous state Blue plans, it is also evident that there is no consensus among the Blues regarding the appropriateness of this policy change and many plans are opposed to its implementation as well as the way in which it was imposed by the Association.

For clinical laboratories that serve BCBS members under the BlueCard program, there are two key elements of BCBSA's policy changes. First, the lab must bill the regional BCBS plan where the specimen was drawn (and not the local BCBS where the laboratory that performed the test is located—as has been current practice).

Second, the new BCBSA policy now defines these BlueCard claims as out-of-

network, thus reducing the reimbursement paid to the clinical lab that performed the test. At the same time, the new policy entangles the patient in the billing and reimbursement process because it often requires him or her to pay more out-of-pocket for these lab tests.

"The BCBS Association, while asserting the independence of the plans, has introduced a completely new set of complex rules regarding claims jurisdiction unassociated with beneficiary contracts, lacking regulatory authority or the ability to be reasonably implemented," wrote Lâle White, CEO of **XIFIN, Inc.**, in a blog posted on the company's website. "And in so doing, the Blue plans attempting to implement this plan are running afoul of state and federal regulations; from non-adherence to HIPAA electronic standards to ignoring state assignment laws."

To Clarify Existing Policy

For its part, the BCBSA insists that the new BlueCard policy was necessary and simply a clarification of existing policy. "The May 17, 2010, memorandum referenced in your letter clarified an existing requirement that claims must be filed to the local Blue plan where services are rendered," wrote Lee Ann Morris, Senior Associate Counsel of BCBSA.

Morris sent this letter on February 23, 2012, to Jeffrey Sherrin, attorney for the **National Independent Laboratory Association** (NILA). She also wrote: "The clarification provided that, for independent clinical labs, the location where the specimen is drawn determines where the services are rendered. This requirement supports Blue plans' ability to effectively manage their provider network arrangements to support lab services provided within their respective service areas."

In an email to THE DARK REPORT, Kelly Miller, BCBSA's Managing Director, Strategic Communications, explained that in 2010, the association changed the policy to clarify questions involving claims coming from independent clinical laboratories (ICLs).

Filing Lab Test Claims

"The process has always been that claims should be filed to the local plan in whose service area the specimen was drawn," stated Miller. "In 2010, Blue plans were instructed that as, of October 2012, plans must route and process claims accurately for these services—meaning claims should go to the local plan where the specimen was drawn. If the claim was filed incorrectly, the plans would return the claim to the ICL [independent clinical laboratory] for proper routing to the local plan."

BCBSA officials have indicated that a "national partnership agreement for the Blues system" would be one way for independent clinical laboratories to work with the Blues. Miller also mentioned this option in her email to THE DARK REPORT.

"There are opportunities for organizations to participate in national partnerships with Blue plans through the BCBSA," stated Miller. "The association's Strategic Cost Management team holds the role of Group Purchasing Organization (GPO) for Blue plans. Leveraging a rigorous sourcing process, the GPO contracts nationally across a limited number of ancillary provider categories."

Identifying Preferred Labs

The concept of a national partnership agreement with BCBSA that would allow local clinical laboratories to participate as in-network providers is being considered by several lab associations and lab industry consultants. In the meantime, lab administrators and pathologists are left to cope with the impact of BCBSA's revised policy that affects services provided to BlueCard holders.

Attorney Jeffrey Sherrin represents the National Independent Laboratory Association on this matter. He said it is difficult to estimate the effect that the new

BCBSA policy will have on local clinical laboratories.

"A clinical laboratory will need to assess how the different regional Blues within its service area treat out-of-network referrals compared to the current BlueCard protocols," he said. "A clinical lab needs to understand whether it will get reimbursed and through what hoops it must jump to successfully collect those payments.

"The letter I received from Ms. Morris of the BCBSA acknowledges the issues we raised in our letter to her association about inconsistencies in the implementation of this program," explained Sherrin. "In this letter, she also points out that the association doesn't interfere in contract decisions made by the local BCBS plans or in any billing and reimbursement arrangements.

In Network or Out?

"Unfortunately, the letter from Ms. Morris doesn't address the primary question about whether a lab should be admitted to the network," he added, "as well as whether the Blues plans should treat lab test claims as in-network claims so that labs can be paid at the in-network rate."

"One troublesome issue is that Morris' letter to NILA can be read in such a way that it looks like BCBSA is trying to protect those labs considered to be in-network," observed Sherrin. "There is the implication that the Blues plans have decided to contract with certain labs exclusively.

"What's the reason for changing these long-standing protocols?" Sherrin asked. "Is the goal to restrict access? The new policy certainly seems to secure the position of in-network labs at the expense of all the other laboratories which have provided testing to BlueCard members.

"It should also be mentioned that this creates an issue in circumstances where specialized tests have been ordered," he continued. "Most laboratories need to refer this work to reference and esoteric laboratories located in other states. But the new policy says that the lab performing the test must submit the claim to the Blue plan in the region where the specimen was collected."

The fact that several lab industry associations took the step of formally presenting their concerns in the form of letters to the BCBSA is good evidence that this issue is expected to have a negative impact on many local laboratories. TDR

—Joseph Burns

Contact Jeffrey Sherrin at 518-462-5601 or jsherrin@oalaw.com; Kelly Miller at 202-626-4825 or Kelly.Miller@bcbsa.com; Lâle White at LWhite@xifin.com or 858-793-5700.

Technical Issues Require Attention

TO ADOPT THE NEW POLICY CHANGES to the BlueCard Program, regional Blue Cross and Blue Shield (BCBS) plans will need to address several important technical issues associated with how clinical laboratory test claims are accepted and processed.

"For example, some regional BCBS plans have suggested non-standard protocols in order to process claims subsequent to the discontinuation of the BlueCard policy," observed Lâle White, President and CEO of XIFIN, Inc. "Labs affected by these issues could challenge them in an effort to get these regional Blue plans to conform to established electronic and billing standards.

"There are also some regional Blues plans that require out-of-network clinical laboratories to submit claims on paper," she continued. "Requiring a claim on paper runs afoul of the requirement that providers and payers are to submit and process claims electronically.

"We are also aware of certain regional BCBS plans that—when they deem a patient went out of network—they issue payment directly to the beneficiary instead of to the provider," said White. "There are 12 states that have laws requiring plans to honor the assignment of benefits. This is a claims processing policy that labs could legitimately challenge."

CEO SUMMARY: Digital pathology holds the promise of interconnecting pathologists around the globe in ways that advance diagnostic accuracy and improve patient outcomes. One pioneering digital pathology collaboration involves the pathology departments at the medical schools of the University of California, Los Angeles (UCLA) and Zhejiang University in Hangzhou, China.

Disruptive technology will contribute to transformation of pathology

Digital Pathology Enables UCLA–China Lab Connection

PART ONE OF A SERIES

By Robert L. Michel

DIGITAL PATHOLOGY WILL BE BOTH disruptive and transformational to the profession of anatomic pathology. The good news is that early signs point to a transformation that will be beneficial to the profession at large and most pathologists individually.

Over the past 36 months, clients and regular readers of THE DARK REPORT have read our briefings about the experiences of first-mover pathologists who have acquired digital pathology systems and now use this technology in unique and innovative ways. In almost every case, these pioneering pathologists will candidly acknowledge the specific limitations of the technology at this point in its development.

At the same time, most pathologists who are hands-on users of digital pathology systems will then enthusiastically make the case for how and why digital pathology systems expand their capabilities as physicians and help them to practice a higher level of laboratory medicine.

Here in part one of a series on the disruptive and transformational potential of digital pathology, I am writing in the first person in order to better communicate to you the way histopathology's innovators are using digital pathology to forge new paths in more accurate diagnosis. These applications are consistent with personalized medicine and the expanding field of companion diagnostics.

In particular, I will focus on the unique and ground-breaking relationship between the Department of Pathology and Laboratory Medicine at the **University of California at Los Angeles (UCLA) School of Medicine** and the Department of Pathology at the **2nd Affiliated Hospital of Zhejiang University (SAHZU) School of Medicine**, located in Hangzhou, China.

The anchor to this international histopathology collaboration is a digital pathology system. Via digital pathology, for the past 18 months, pathologists at the two academic center hospitals on each side of the Pacific Ocean have been able to share cases and work together to provide subspecialty pathology expertise in a way that advances patient care.

In October, 2011, I had the opportunity to travel to Hangzhou, China, to speak at the *17th Congress of the Chinese Society of Pathology and the 1st Annual Meeting of Chinese Pathologists*. My presentation, travel and some pathology laboratory site visits were arranged by the Anatomic Pathology Group at **Thermo Fischer Scientific**.

I mention this because, in China, it is the pathology vendors who act as primary agents in fostering an exchange of knowledge that benefits pathologists, clinical chemists, and laboratory scientists. Further, this is a country where personal relationships matter greatly in business and medicine.

Some of you have read my impressions gained at the pathology congress, which were published at *DarkDaily.com*. *(See "Anatomic Pathology in China Is a Booming Growth Industry," October 24, 2011.)* While in Hangzhou, I visited the pathology department at SAHZU.

This give me a first-hand look at the Chinese lab side of the digital pathology collaboration between UCLA and SAHZU. Prior to my departure for China, I spoke with Scott Binder, M.D., who is the Senior Vice Chair of Pathology and Laboratory Medicine, Geffen/UCLA School of Medicine.

➤Managing The Collaboration

Binder coordinates the pathology collaboration between his department and the pathology department of SAHZU. This arrangement has been active since the beginning of 2010. The digital pathology system used at both laboratory sites is manufactured by **Aperio Technologies, Inc.**, of Vista, California. While in Hangzhou, Aperio's representatives were most helpful in the arrangements for the site visit to the SAHZU histopathology laboratory.

The digital pathology arrangement between SAHZU and UCLA developed as a result of a larger collaboration agreement

between the two universities that was instituted about eight years ago. Under this master agreement, the medical schools of the two universities have been cooperating in a number of faculty exchanges and training programs. *(See sidebar on page 13.)*

These basic facts were confirmed during my site visit to the pathology department at SAHZU in Hangzhou. By the standards of the United States, this is a large hospital. It has 1,750 beds, which is more than any single hospital site here in this country.

Each year, the 2nd Affiliated Hospital services an average of 38,000 inpatients and 1,300,000 outpatients (that includes ER visits). The Zhejiang University Medical School involves a total of six hospitals with 7,700 beds and handles 238,000 inpatients and 8.8 million outpatients annually. Revenue is almost US $1 billion per year.

More Demand for Healthcare

During my site visit, I met with Li-Rong Chen, M.D., Ph.D., Director, Professor, Chief Doctor, Department of Pathology, at SAHZU. He provided a concise overview of his pathology laboratory. The first point he emphasized is that the demand for healthcare by China's middle class is increasing at a steady pace.

"In the Hangzhou metro, there are 6 million residents," he noted. "In this province live 47 million people and we are only about 130 miles from Shanghai, which is in a province of 22 million residents. These population numbers indicate why the demand for quality health services is increasing."

There are 16 pathologists, including residents, in Chen's histopathology department at SAHZU. "We process about 500 tissue blocks daily and diagnose about 43,000 surgical cases annually," said Chen. "We also handle approximately 30,000 cytology cases per year."

The digital pathology arrangement with UCLA has brought important benefits to the anatomic pathologists in Hangzhou. "Here in China, there is an urgency to bring the practice of medicine up to the standards of care common in Europe and the United States," observed Chen. "Pathologists have the opportunity to contribute by improving the accuracy of the diagnosis. In specific cases, we are also involved in helping physicians select the most effective therapies."

Tumor Cases

Not surprisingly, the digital pathology arrangement between SAHZU and UCLA has quickly centered upon tumor support. "We are using the digital pathology system to share images of specific cases with the subspecialist-pathologists at UCLA," stated Chen. "This regular interaction between our two groups of pathologists is part of the mission to advance the training and skills of pathologists in this country."

As part of my site visit, I was introduced to G. "Jenny" Wang, M.D., Ph.D., who is a chief pathologist at SAHZU. She handles the digital pathology system and creates the digital images that are shared between her lab and the pathology department at UCLA.

"Like any technology, we've had to work through some challenges," she commented. "The basic functions of scanning glass slides, archiving the images, and viewing digital pathology images were rather easy to master.

Transmitting Digital Images

"Once the glass slides for a case are digitized, these images can be transmitted to the pathologists at UCLA for a second opinion or a sub-specialist consultation," noted Wang. "At this time, we are referring between 10 and 15 cases per week and the number of case referrals is increasing."

Wang stated that live sessions between the SAHZU and UCLA pathologists are evolving into something similar to the tumor boards conducted regularly at many

hospitals. "By video conference—supported by the digital pathology images—pathologists at both laboratories are able to discuss the case and interact," she said.

"Such close interaction is one way our pathologists can gain subspecialty skills and expertise without having to travel and study abroad," she explained. "The sharing of this knowledge is helping us with patients here at our hospital."

Wang noted that pathologists do meet regularly with patients to discuss their diagnosis, and—for certain types of cancers—explain what types of therapies might be appropriate. "Patients in China want to choose a hospital that is known for quality healthcare," observed Wang. "They do understand the role of pathology in improving the accuracy of their diagnosis.

Second Pathology Opinion

"In fact, patients here can have the choice of a second pathology opinion," she added. "That can happen in one of three ways. One, our clinic's physicians can recommend that a pathology second opinion be obtained.

"Two, our pathologists may recommend referral of the case for a pathology second opinion," Wang said. "Third, we have times when a patient will request that we obtain a pathology second opinion."

Patient engagement is a feature of healthcare in China. As noted earlier, the growing middle class is interested in purchasing top quality healthcare. For that reason, hospitals are taking steps to establish their reputations as the provider of first-rank healthcare.

In fact, this was one reason for the collaboration agreement between the medical schools of Zhejiang University and UCLA. In China, the "UCLA brand" is recognized by consumers and Zhejiang University wants to leverage that brand recognition. For the same reason, the UCLA affiliation is valued by the pathologists at SAHZU.

"We are sending pathologists to Los Angeles to train at UCLA," observed Chen. "This gives them access to all the innovations happening in laboratory medicine today, particularly in molecular diagnostics and genetic testing. Pathologists from UCLA are also coming

Pathology Collaboration Part of Existing Agreement

HOW THE TWO PATHOLOGY DEPARTMENTS in Hangzhou and Los Angeles came together is part of a larger story. For almost a decade, UCLA and Zhejiang University have had an agreement to "promote, exchange, and collaborate in research, technology, and professional training."

This agreement extends to the medical schools at both universities. An interesting aspect of the relationship between the two medical schools is recognition of the importance of an accurate diagnosis. "All the treatments, remedies, and therapies start from the diagnosis," noted Chen Gongxiang, Ph.D., Director of SAHZU's Center for Clinical Laboratories. "If you have a correct diagnosis, then you can have better treatment. For the Chinese doctors, they'll have more opportunities to learn U.S. ways, U.S. systems, and they can change their habits of working and improve their skills."

Chen was quoted in a UCLA newsletter, which also highlighted the development of a "joint diagnostic center" between the two institutions that emphasizes tissue-based laboratory diagnostics. This is the initiative that utilizes digital pathology to link pathologists on both sides of the Pacific Ocean.

"It was the ongoing advances in Internet technology, informatics, and digital pathology systems that allowed us to develop a more active pathology consultation service between the two medical centers," he continued. "Both laboratories have the Aperio digital pathology system and are using it to create whole slide images that can be simultaneously viewed by pathologists at 2nd Affiliated Hospital and here at the UCLA Medical Center."

here to Hangzhou to conduct lectures and provide training to our laboratory staff."

Vision of Pathology In China

Chen has his own vision for the future of his pathology department. "I would like to use our capability in digital pathology to establish a digital pathology network that links us to hospitals in our region," he said. "It is a way that we can help with the primary diagnosis of patients."

Chen is referring to the shortage of pathologists and lab scientists in his country. China's Ministry of Health provides a number of 14,000 public hospitals, plus 5,700 private hospitals in China, served by only about 20,000 pathologists. Thus, unlike in North America and Europe, where nearly every critical care hospital has pathologists on site, there are hospitals in China that lack an in-house anatomic pathologist.

For Chen, this is the opportunity for his pathology department to engage with other hospitals and provide help in establishing the primary diagnosis. The enabling tool for this service will be the use of digital pathology systems.

"It is part of our vision that our pathology department can use digital pathology systems to provide clinical services to other hospitals in our region."

The glass slides processed at the community hospital can be digitally scanned at that site and transmitted to the pathology department at SAHZU. The pathologists in Chen's department can read these slides and consult with the referring physicians via videoconferencing and other methods.

"It is part of our vision that our pathology department can use digital pathology systems to provide clinical services to other hospitals in our region," continued Chen. "The clinical service model is feasible and would be similar to how pathologists here at SAHZU and UCLA are now working together.

"Further, ongoing improvements in information technology and digital pathology systems will make it easier for us to establish and operate this type of diagnostic service," emphasized Chen. "In our country, the need for quality anatomic pathology services is great. It is why we think that a pathology network would be utilized by physicians and hospitals in communities around Hangzhou."

Lots Of Enthusiasm

During my site visit to the Department of Pathology at the 2nd Affiliated Hospital of Zhejiang University, the enthusiasm and commitment of Dr. Chen, Dr. Wang, and the other pathologists was quite evident.

At a time when demand for healthcare services is growing very fast, the pathologists at SAHZU have a vision for how they can position themselves to provide top quality diagnostic services. To achieve that vision, they are incorporating the use of digital whole slide images and digital pathology systems into educational programs and clinical consultations.

In so doing, the SAHZU pathologists, via their collaboration with the UCLA pathologists, are demonstrating how use of digital pathology systems will bring closer integration of pathology, even across international borders.

In part two of this series about digital pathology, THE DARK REPORT will provide information about the American side of this China–U.S.A. digital pathology collaboration. Pathologists at the UCLA School of Medicine will share the lessons learned from this trans-Pacific anatomic pathology relationship and its ground-breaking use of digital pathology technologies. TDR

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Lab Site Visits in NZ Show Impact of Lab Contracting

Use of exclusive contracts to drive down cost of lab tests means most cities have one private lab

CEO SUMMARY: In some ways, the story of the New Zealand's health system's 15-year strategy to reduce the cost of clinical laboratory testing is a cautionary tale for public laboratory companies in the United States. During THE DARK REPORT's site visit to several private labs in New Zealand last week, the consequences were easily seen and understood. Well-equipped, modern labs can only deliver a menu of about 150 lab tests and are not encouraged to innovate in ways that advance patient care.

By Robert L. Michel

OVER THE PAST DECADE AND A HALF, the healthcare system in New Zealand has been uncommonly aggressive at squeezing private sector clinical laboratory companies in an effort to achieve significant cost savings.

It is these persistent and ongoing efforts to reduce the reimbursement paid for clinical laboratory testing that makes New Zealand an interesting case study. The district health boards (DHB) in many regions of the country have indeed controlled the year-over-year increase in the cost of lab tests. But this has come at a price.

Sole Private Lab Providers

After more than 15 years of efforts to pay less for lab tests and to restructure lab testing services in city after city, this island nation has left itself with one private laboratory company in almost every region. For that reason, going forward, health program officials now have limited options to leverage the value of medical lab tests in ways that improve patient outcomes and substantially reduce the overall cost of care.

More specific to the interest of executives at public lab companies here in the United States, New Zealand provides a fascinating business case study. It shows how use of sole-source contracting policies—in this case by the regional DHBs—can destroy what was once a vibrant and highly-competitive market with multiple private lab companies jostling to win the lab testing referrals of office-based physicians.

New Zealand's experience in lab test contracting is a cautionary tale for all pathologists, laboratory scientists, and lab administrators. A health system which evolves to allow just one private lab company to provide services in a city or metropolitan area loses a great deal. It no longer benefits from the innovation and clinical service excellence that results when two or more private lab companies compete for the lab test referrals of office-based physicians.

During my visit to New Zealand last week, the consequences of communities reliant on just one private lab provider was quite visible. Among the labs I visited were two private labs—one on the north island and one on the south island.

Because of contract awards by the respective DHBs, each of the private labs that I visited can be considered a "monopoly" provider of lab tests to office-based physicians located in each lab's designated service region. Over the 15 years that DHBs have followed this contracting policy, it is now common to provide a five-year contract term with a renewal clause of another three or five-year term.

Newest Lab Automation

What I found striking on my site visits is that both of these private laboratories had well-designed lab facilities with state-of-the-art lab equipment. Each lab had the newest pre-analytical and analytical automated line for chemistry and immunoassay. In one case, the vendor was **Beckman Coulter**. In the other case, the vendor was **Roche Diagnostics**.

However, these labs are not utilized to their fullest potential. The reason is that their sole-source contracts with their respective district health boards only cover between 125 and 150 routine assays.

What happens to the rest of the lab tests that originate in physicians' offices? The DHBs typically have those reference and esoteric tests sent to local hospital labs in the area. More complex reference testing is handled by a tertiary hospital lab in the north island and another tertiary hospital lab in the south island.

Because the sole-source contract typically encompasses about 125 routine tests (mostly chemistry, hematology, some microbiology, and some histopathology), there is a practical consequence. The contract lab is constrained from introducing new test methologies that might offer improved diagnostic accuracy or a faster time to answer.

At each lab I toured, the pathologists and lab scientists can identify numerous opportunities where their laboratory—as equipped and staffed—could deliver additional value to the referring physicians were they able to introduce improved assays or faster methodologies.

Another consequence of the DHB's contracting policy as it pertains to lab testing is that, in the two cities where I visited private laboratories, all office-based physicians utilize paper test request forms. This requires the labs to hand-enter the data from these paper test requisitions.

By contrast, it was around 1990 that private labs in the United States, at their own expense, began introducing systems that allowed office-based physicians to electronically order lab tests and electronically receive the lab test results. Today, accessed via a web browser, these solutions only need access to the physician's practice management system to pull the demographic data on the patient needed for the test request.

Beyond the immediate cost savings that come from eliminating paper lab request forms and paper lab test reports, these arrangements also improve patient care because of greater accuracy and the fact that the physician can have electronic access to lab test results (via the web brower-based system) as soon as the patient results are posted to the LIS.

Other Ways To Cut Costs

I mention this because, in New Zealand, the contracts crafted by the DHBs are written in such a way that, over the past 15 years, there has been no incentive for the private lab providers to implement similar cost-effective solutions that eliminate paper request forms and paper lab test reports. The benefits are reduced costs associated with lab tests, as well as better physician access to patient lab test data.

It should be added that the district health boards and local physicians are beginning to recognize the deficiencies of the sole-source lab test contract strategy. This may lead to better recognition of the value of having competing private lab providers in the same city or region. At the same time, that would affect specimens flowing to local hospitals. These are complex politics and the end game has yet to be determined. TDR

Florida Law Better Defines Lab Marketing Violations

New state law bans practice of labs putting employees in doctors' offices or leasing space

CEO SUMMARY: Despite clear language in Florida's new state law that bans the placement of laboratory employees in a physicians' office, some clinical lab companies want to continue the practice of placing specimen collectors in physicians' offices. These opinions were voiced by lab executives during a meeting on June 28 in Tallahassee, Florida, at the offices of the Agency for Health Care Administration (AHCA). Given the clarity of the language in HB 787, early enforcement by state officials is possible.

NOT ALL CLINICAL LABORATORIES in Florida want the state **Agency for Health Care Administration** (AHCA) to enforce a new state law banning the placement of lab personnel in physicians' offices.

These objections were voiced by lab executives at a meeting conducted by AHCA on June 28 in its offices in Tallahassee. The purpose of the meeting was to hear public comment on the new state law that bans labs from placing personnel in physicians' offices.

"Some Florida lab companies with representatives at the meeting want to be able to place lab personnel in doctors' offices and have lease-space arrangements with physicians," noted Timothy M. Cerio, a lawyer with **Gray Robinson, PA**, a law firm in Tallahassee, Florida.

Cerio attended the June 28 meeting. He represented **Millennium Laboratories** of San Diego, California, and was one of about a dozen lab industry representatives to attend the meeting. About six or eight labs sent representatives to the meeting. At least one hospital and one health plan sent representatives as well, he said. Representatives of some labs attended via conference call.

House Bill 787 became law on July 1, 2012. Prior to that date, the AHCA had regulations in place to prevent labs from placing personnel in physicians' offices. *(See TDR, June 4, 2012.)*

"Some laboratory companies that did not follow these AHCA rules previously, also opposed the passage of HB 787 during the recent legislative session," commented Cerio.

A Patient Care Benefit?

"Millennium Laboratories believes the law should be enforced because there is no reason for a lab company to have a collector in a physician's office or to have a lease-space arrangement to allow a collector in a physician's office as some labs do," he explained.

House Bill 787, "An Act Relating to Health Care Facilities," prohibits labs from providing employees, contractors, or any personnel (including those from independent staffing companies), from

performing any functions in a physician's office. The law is intended to stop the practice of having labs collect patients' specimens in physicians' offices.

"Some labs claimed there is a patient care benefit and that it is convenient for patients to have lab personnel in physicians' offices" explained Cerio. "But, in fact, often these arrangements simply allow labs to get all the physician's referral business in return for the provision of free labor, and that, by definition, is an illegal kickback.

"The new Florida state law requires vigorous enforcement," he continued. "It also calls for fines of as much as $5,000 per violation."

New Law Provides Clarity

Molly McKinstry, AHCA's Deputy Secretary, said, "The law is designed to eliminate any questions about kickbacks between labs and physicians.

"As a result of this law," stated McKinstry, "when AHCA staff conducts investigations, we will have more clarity about what is and is not acceptable.

"The question about kickbacks is difficult because we do not have many regulatory citations in this area," she said. "But the issue of kickback is clearly on the minds of some people in the laboratory industry, and so we will monitor the complaints and any compliance issues that we identify."

On the question of whether the legislation is needed because labs have flouted the rules in the past, McKinstry said, "I would not say they were flouting the rules. But we can say that, because we previously didn't have this level of detail in a statute, we fielded many questions from labs about what they can do and whether certain activities are permissible. In the past, many questions fell between the lines of the regulations. The language of the new law adds clarity on these points.

"The new law improves the definition of the requirements," added McKinstry. "It makes clear to providers and to the agency that certain situations are prohibited. Clarity is better because now everyone knows the rules."

New Law Has "Teeth"

Florida's new law has very specific language to describe the laboratory marketing and sales practices that are prohibited. It also has specific penalties. It was the intent of lawmakers to put "teeth" into this new law. Thus, lab companies operating in the state are now on notice that continuing to use these arrangements in physicians' offices can subject them to enforcement action. TDR

—Joseph Burns

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Florida Governor Wanted Comments

WHEN FLORIDA GOV. RICK SCOTT signed House Bill 787 into law, he sent a letter to Secretary of State Ken Detzner asking that state officials get comments from clinical laboratory industry representatives on the recently-passed anti-kickback law.

"Current interpretation of the anti-kickback law as it relates to the use of trained specimen collectors and the lease of space in physicians' offices merits further scrutiny," he wrote. "To that end, I will direct the Secretary of the Agency for Health Care Administration [AHCA] to work with representatives of the clinical lab industry to examine this issue and develop alternative approaches to regulating this area of health care law."

On June 28, officials from the AHCA met with lab industry representatives at the AHCA offices in Tallahassee. Among the labs that were represented at the meeting were **Aegis Sciences Corporation**, **Alere**, **Dominion Diagnostics**, **Granite Labs**, **Laboratory Corporation of America**, Millennium Labs, **Quest Diagnostics Incorporated**, and **Sarasota Memorial Hospital**.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It is with sadness that we report the death of pathologist Joel A. Sonnier, M.D. A victim of murder, his body was discovered in his home in Lubbock, Texas, on July 10. The housekeeper and the gardner made the discovery and called the police. Lubbock police announced the murder, but have no suspects as of this date. Sonnier, 57, was Chief of Pathology at **Covenant Health System** in Lubbock. In a strange twist, Sonnier's murder came two years to the day that his ex-wife, Becky Gallegos, was murdered. It was on July 12, 2010, that she was murdered by her then-husband, Ferman Juan Gallegos, who then shot and killed himself. Police ruled that the motive in this case was a marital dispute. Authorities say there is no connection between the two murders.

MORE ON: *Sonnier*

In his pathology career, Sonnier was respected for his leadership skills. He had served as President of **AmeriPath, Inc.**, several years prior to its acquisition by **Quest Diagnostics Incorporated**. He had previously been in private practice at **Unipath LTD**, located in Dallas, Texas.

ONTARIO HOSPITALS FORM REGIONAL LAB NETWORK

Consolidation and regionalization of hospital laboratories continue in the province of Ontario, Canada. Last month, **Hamilton Health Sciences** and **St. Joseph's Healthcare Hamilton** announced the formation of a regional laboratory network that will operate as part of the area's Local Health Integration Network (LHIN). Also participating will be **Joseph Brand Memorial Hospital**, the **Niagra Health System**, **West Lincoln Hospital**, and a rehabilitation center. The objective of the regional lab network is to foster best practices, organize specialized testing around two lab hubs, and help participating hospital labs cope with the expected shortage of skilled laboratory scientists due to retirement and other factors.

TRANSITIONS

• Earlier this month, **Ernst & Young** announced the selection of Tonya Mallory as "Entrepreneur of the Year" for the Greater Washington Region. Mallory is co-founder and CEO of fast-growing **Health Diagnostic Laboratories, Inc.**, (HDL) of Richmond, Virginia.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 6, 2012.