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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

Economics of Lab Testing to Be Challenged

BY ANY MEASURE, 2012 IS SHAPING UP TO BE A YEAR OF MAJOR CHANGE for healthcare and the clinical laboratory testing industry. Unfortunately, an early reading of the tea leaves indicates that the outcomes are not likely to be favorable for most clinical laboratories and anatomic pathology groups.

Let's start with one bright spot in laboratory medicine. Recent years have seen a slew of new molecular and diagnostic tests with capabilities that allow pathologists and clinical laboratory scientists to make a more accurate diagnosis of disease earlier, and then help the physician select the best therapy for the patient.

Certainly this is true for infectious disease testing, one of the first major success stories associated with expanding clinical use of genetic and molecular technologies in diagnosis. Similarly, oncology is benefitting from the more precise diagnostic tools that incorporate analysis of DNA, RNA, and proteins.

But there is a big downside to the acceptance and widening use of genetic and molecular assays in clinical diagnostics. It is the growing cost of such testing. Payers, both government and private, believe they must take active steps to control growth in this sector and better manage what they consider to be budget-busting costs associated with genetic and molecular diagnostics.

As you will read on pages 3-6 of this issue of THE DARK REPORT, Medicare's biggest carrier, **Palmetto GBA**, recently issued two draft LCDs (Local Coverage Determinations). Essentially, if enacted on February 27, 2012, Palmetto would begin rejecting claims for molecular diagnostic tests and laboratory-developed tests (LDTs) that lack a local or national coverage decision by Medicare—unless these assays meet a specific set of regulatory and coding criteria. That is certainly a threat, particularly if Palmetto ends up implementing a more restrictive policy on molecular diagnostics and LDTs on that date and other local Medicare carriers and private payers adopt similar reimbursement policies.

At the same time, don't forget that there are at least three separate proposals circulating in Congress that would significantly reduce funding for Medicare Part B laboratory test fees. Given the cumulative impact of all the decisions to be made next year by legislators, Medicare carriers, and private payers, it is safe to predict that much less money will be paid to labs as a result of new policies and new Congressional budget decisions. TDR

Medicare Carrier Plans to Reject Molecular Claims

In February, Palmetto intends to cease accepting code-stacked molecular test claims

CEO SUMMARY: In September, Palmetto, a Medicare carrier serving California and seven other states, made public two draft local coverage determinations (LCDs) that revamp its coverage guidelines for molecular diagnostic tests (MDT) and laboratory-developed tests (LDT). All labs submitting claims to Palmetto would need to apply to Palmetto for each MDT or LDT it plans to submit for payment and await a decision. If Palmetto approves an application, the lab could resume filing MDT and LDT claims.

IT'S THE LATEST PAYER ATTEMPT to control the soaring cost of molecular and genetic testing. Recently, the nation's largest Medicare carrier announced a draft proposal that would significantly restrict how clinical laboratories and pathology groups could file claims for many molecular diagnostic tests (MDT) and certain laboratory-developed tests (LDT).

On September 28, **Palmetto GBA**, of Columbia, South Carolina, published two draft Local Coverage Determinations (LCD). They are: DL 32288, Molecular Diagnostic Tests; and, DL 32286, Non-Standardized Organ or Disease-Oriented Panels.

If approved, both proposals would become effective on February 27, 2012. The comment period for each proposal opened on October 14 and closes on December 5, 2011. Pathologists and laboratory directors who wish to comment on these proposals can use the Palmetto address in the sidebar on page 6.

The draft language of Palmetto's LCD says that no molecular diagnostic test would be considered for reimbursement if it is not explicitly covered by: 1) a national coverage determination (NCD); 2) a local coverage determination (LCD); or, 3) a Palmetto coverage article.

Instead, after the February 27 effective date, clinical labs and pathology groups would apply to Palmetto for coverage for each individual MDT and await approval before submitting any claims for MDTs.

The second LCD draft published by Palmetto states that it would not allow laboratories to submit claims for all non-standardized organ or disease-oriented

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laboratory developed test (LDT) panels unless certain criteria are met. Again, Palmetto said labs would need to apply for coverage for each individual LDT and await approval.

Plan Could Stifle Innovation

Medicare carriers use letters and coverage determinations to communicate changes in provider payment policies. Last year at this time, Palmetto required providers to submit additional data to be reimbursed for molecular tests. *(See sidebar on page 5.)*

The two proposed LCDs announced by Palmetto in September are much more significant. "This is an important development with significant implications for the entire laboratory testing industry," observed Rina Wolf, Vice President of Commercialization Strategies, Consulting & Industry Affairs, for **XIFIN, Inc.**, based in San Diego, California.

"These proposed LCDs have the potential to stifle innovation in healthcare," explained Wolf. "They can limit the use of important and successful new diagnostic tools that physicians use to improve patient care and control the cost of care."

Palmetto is the largest Medicare authorized contractor (MAC). It services Medicare providers in California, Hawaii, Nevada, North Carolina, Ohio, South Carolina, Virginia, and West Virginia. Therefore, any coverage decisions made by Palmettto apply only in those states.

However, MACs that serve other states—as well as commercial health insurers—are following the development of these two proposals. Palmetto's final actions to implement these two rules could encourage other MACs and private payers to issue similar rules.

"In fact, Palmetto views itself as the 'go-to' Medicare carrier on issues related to molecular and genetic tests," noted Wolf. "This is one reason why Palmetto is moving more quickly than the other MACs to contain the rising cost and proliferation of molecular and LDTs.

"The proposals put at risk some of the latest developments in health care, meaning molecular and genetic tests," she said. "In recent years, it is laboratory-developed tests that have been at the front edge of personalized medicine, companion diagnostics, and proactive healthcare.

"Physicians rely on molecular and genetic tests to help them diagnose patients and identify the best treatment options for patients with cancer and other debilitating diseases," continued Wolf. "It would be a step backward in patient care in the areas served by Palmetto if these proposals are implemented."

Wall Street is aware of the Palmetto proposals. "Venture capital investors have valid concerns about how these proposed LCDs will negatively impact the clinical and financial effectiveness of molecular and genetic companies operating in the Palmetto region," Wolf said.

"This could make it more difficult for these companies to get the venture capital that they need to develop the next generation of innovations in laboratory medicine," she added.

"Many of these MDTs and LDTs have been in clinical use for years," Wolf continued. "Some are the standard of care today. Palmetto's draft proposals raise questions about whether this is the best way to proceed with any attempt to contain the growth of these tests."

Four Primary Concerns

Pathologists and lab directors should be aware of four primary concerns associated with these draft proposals. First, Palmetto said, if the proposal is approved, it would consider these MDTs and LDTs to be "non-covered" as of February 27, meaning labs would be unable to submit claims for these tests.

This approach has a direct consequence for clinical labs and pathology groups. "If your laboratory cannot submit a claim to Palmetto, then it can't get a denial," Wolf said. "If your lab can't get a

At Heart of the Matter: Palmetto Issues Challenge to Practice of Code Stacking

IN ITS TWO PROPOSALS regarding molecular diagnostic tests (MDTs) and laboratory-developed tests (LDTs), Palmetto GBA is challenging the long-held practice of bundling claims or code stacking. That is the opinion of Rina Wolf, who is the Vice President of Commercialization Strategies, Consulting & Industry Affairs, for XIFIN, Inc., in San Diego, California.

"Palmetto's challenge to the concept of bundling—also called code stacking—is problematic in one sense," stated Wolf. "Credible efforts are already underway to revise the code-stacking method of billing.

"The **American Medical Association** (AMA) is addressing this issue," she said. "The AMA committee submitted new molecular and genetic test codes for placement on the physician fee schedule for next year.

"That means the federal Centers for Medicare & Medicaid Services could accept the AMA committee's pricing recommendations—which they usually do—and that would eliminate some of the stacked codes," predicted Wolf. "But the specific details of this coding reform activity won't become public until CMS publishes the proposed physician fee schedule for 2012, which it is scheduled to do this month."

The AMA's CPT Editorial Panel Molecular Pathology Coding Workgroup (MPCW) was formed in 2009 to recommend new CPT codes for molecular tests. One goal of the working group is to update the CPT codes to reflect new diagnostic technologies and lab tests and, at the same time, eliminate the need for labs to use code stacks when submitting claims.

The codes proposed by MPCW address more than 90% of medically useful MDTs. The AMA has said it will publish an initial set of codes in its CPT 2012 book.

denial, then it cannot move forward with the appeal process.

"Thus, having no appeal means there would be no opportunity for your lab—and other labs—to discuss with Palmetto officials the clinical value of these tests and their importance to patient care," explained Wolf.

Second, labs could find themselves facing demands by Palmetto to recoup earlier payments. That is because Palmetto said it could seek to recover past payments for MDTs and LDTs that it decides are not covered and so should not have been covered in the past.

"Why this Medicare carrier would seek recoupment is a reasonable question," stated Wolf. "The language of the draft LCD says that Palmetto would only consider tests covered from the point in time where its officials felt the evidence supported the test coverage. It appears that this means Palmetto could go back to any point in time in the history of coverage for a specific genetic or molecular assay."

The third concern centers around an equally important issue to those labs that currently perform MDTs and LDTs. It is the need to apply for a coverage decision by Palmetto. Is Palmetto prepared to deal with the surge of requests labs would submit requesting that Palmetto review individual MDT and LDT assays?

"Palmetto said that laboratories could submit applications requesting a coverage review for each MDT and each LDT," said Wolf. "But this aspect of the two draft proposals brings into question whether Palmetto has the capacity and the ability to manage the application process in a timely and fair manner.

"Given the large number of MDTs and LDTs currently in clinical use, it would be expected that Palmetto would be deluged with requests for coverage, accompanied by all the supporting documentation labs

will submit with each request," explained Wolf. "Each laboratory is going to want to open up the application process for each MDT and LDT it performs. Just this aspect of the proposed draft language has the potential to stop payment for these tests for many weeks or months."

The fourth issue of concern is how Palmetto's proposals challenge the concept of bundling—which labs call code stacking. "Palmetto believes there should be one code for one lab test that produces one result, but that's not always the case," stated Wolf.

"It is absolutely legitimate to use code stacking to bill for certain laboratory tests," she continued. "That is when a lab submits claims in a stack and there is a dollar amount assigned on the clinical lab fee schedule for each CPT code in that stack. Medicare carriers pay the sum of that stack. That's the procedure that labs follow nationwide.

Claims Set up for Repricing

"But by preventing labs from submitting claims in a stack, Palmetto is setting up these tests for a *de facto* re-pricing," commented Wolf. "That would happen when Palmetto forced labs to submit these tests with an unlisted code.

"Then, instead of paying the sum of the stack, Palmetto officials can set a reimbursement price for that assay at any level they want," noted Wolf. "In the instances where Medicare carriers tried this in the past, the new prices were substantially less than the sum of the code stacks."

Wolf is sympathetic to the fundamental issues that motivated Palmetto to issue these two draft LCDs. "Consider how many laboratory-developed tests are in clinical use today, along with the rising number of molecular diagnostic tests reaching the clinical market," she continued. "It is easy to see how costs for these tests have risen.

"Therefore, we all understand and appreciate the frustration that Medicare carriers face about rising costs," she concluded. "But this approach to containing lab test costs is certainly problematic for clinical laboratories and pathology groups. Also, it may not be permissable under existing statutes."

It is recommended that lab directors and pathologists write to Palmetto to express specific concerns they have about these two draft LCDs. With the comment period open until December 5, there is ample time for laboratory professionals to offer their thoughts about the consequences of Palmetto adopting these two proposed Local Coverage Determinations. *Contact Rina Wolf at 858-793-5700, or email rwolf@xifin.com.* TDR

In 2010, Palmetto Asked Labs for Info

IT WAS LATE SEPTEMBER 2010 when Palmetto GBA, the Medicare administrative contractor (MAC) in Columbia, South Carolina, said it would require lab providers to submit additional information for certain molecular diagnostic tests (MDTs).

MDTs have complicated the work that Palmetto must do when reviewing claims for these tests, in part because labs often use several current procedural terminology (CPT) codes for one MDT, a practice known as bundling or code stacking.

"The vast numbers of new diagnostic and molecular assays entering the market magnify these issues," Palmetto said when it made the announcement on Sept. 29, 2010. To address the issue, Palmetto asked labs to submit the test or assay name in the description field by December 1, 2010. Claims that did not include this information by that date would be rejected, Palmetto said.

Send Comments to Palmetto:
J1B.Policy@Palmettogba.com
Nita.Collins@Palmettogba.com

Clin Lab Partners' Strategy Is to Leverage Lab Data

Connecticut lab company offers health plans and physicians enhanced lab information services

CEO SUMMARY: At Clinical Laboratory Partners, the strategy is to create and deliver a growing suite of enhanced lab information services to client physicians and payers in the Connecticut market. It wants to differentiate itself from competing lab companies by packaging lab test data in ways that add value to both physicians and payers in this region. It is a strategy that seems to be working, as Clinical Lab Partners reports that it expanded its share of the market by over 200% in the past four years.

ONE CHALLENGE FACING every independent lab company and hospital laboratory outreach program is how to leverage the value of lab test data in ways that create competitive advantage.

In Newington, Connecticut, **Clinical Laboratory Partners** (CLP) is positioned to help its client physicians use lab test information to deliver added value to private health plans in the region. CLP's strategy is to introduce a series of information-based services ahead of national lab competitors.

"Every administrator and pathologist understands that they are in the information business," stated James E. Fantus, the President and CEO of CLP. "However, few lab organizations devote the resources required to package test data into information-rich services that directly help their referring physicians.

"It was about four years ago when our management team decided that, if we made it a priority to improve how we collect and share information, that strategy would give us a competitive edge in our service market," he said.

To achieve this goal, Clinical Laboratory Partners began to collect as much clinical laboratory data as possible. In the past 48 months, CLP has collected data on almost 10 million patients.

This effort is now helping CLP differentiate itself from competing labs in the market. It is capable of delivering a wide array of data to health plans and physicians in a variety of formats that other labs cannot. CLP's sales reps use these information services to win new clients and expand market share.

Serving ACOs With Lab Tests

In addition, Fantus believes CLP will hold the high ground as its client physicians and hospitals form accountable care organizations (ACO). To help manage patient care more efficiently, ACOs are expected to be eager consumers for the enriched information that CLP has at hand.

"Once we decided on this strategy, we found it relatively easy to begin delivering more information and more information-management tools," Fantus said. "One of our first such enhanced informatics serv-

ices was a way to deliver lab test results to the smartphones and iPads of our client physicians. We were the first lab in our market to offer this capability.

"The next step was to use our data for many different purposes," he said. "For example, health plans continually ask us for data they can use to manage patient care more efficiently.

"We are able to provide data sets organized by payer, by doctor, by disease category, or by diagnosis code," continued Fantus. "For example, if a health plan wants to know how many patients have cardiac disease, it gives us an ICD-9 code or a series of codes and we can pull that data for them. Or, we can pull this data based on the physician who cares for those patients."

Chief Information Officer David Molusis explained that Clinical Laboratory Partners stores its information in what it calls a data warehouse. "From our data warehouse, we can pull any management reports needed," he said. "We want to use this data to gain competitive advantage.

"Client physicians can ask us for reports that make it possible for them to study their patient population," noted Molusis. "Better yet, we can deliver reports to them that they can show to health plans to demonstrate why they should qualify for a pay-for-performance bonus, for instance.

➤Value From Lab Data

"Our lab can also deliver different reports to payers based on their patient populations," he added. "We have one large internal medicine group that uses the outcomes we provide to them. Another client uses our information to study its HIV/AIDS patients. The state of Connecticut wants reports on microbiology trends."

Competitors are limited in what they provide to the Connecticut market, Molusis stated. "Routinely, CLP can provide a wider variety of data options to clients," he added. "The big differentiator for us is we let our clients slice and dice the data any way they want.

"If a physician wants to see his or her patients' blood glucose levels over a certain period of time, we can do that," he explained. "Whatever criteria that are requested, such as time period and the test codes to be studied—we return all the results for that patient population according to those criteria. Client physicians love these reports and they tell us that CLP is the only clinical lab that provides them with information in this way, according to the feedback we receive from them."

THE DARK REPORT observes that CLP is on the cutting edge of a trend that is likely to spread as progressive laboratories seek to position themselves as information providers serving the needs of providers managing large groups of patients. TDR

Contact David Molusis at 860-696-8162 or dmolusis@clpct.com.

Clinical Lab Partners Posts Strong Growth

IT WAS IN 1998 when three Connecticut laboratories merged and formed Clinical Laboratory Partners, LLC (CLP), in Newington, Connecticut.

CLP has 85 locations, including six labs. The core lab is in Newington and other lab facilities are located in hospitals and physician group locations.

CLP has 900 employees and does about 12 million billable lab tests annually. Its data warehouse has lab test data on approximately 10 million patients.

According the CLP's President, James E. Fantus, the lab company's market share grew by 20% in the most recent fiscal year. Its revenue rose by 18% and its margin increased by almost 70%.

IVD Update

Abbott Says It Will Split Into Two Firms in 2012

One company will be medical devices and diagnostics, the other company will be pharmaceutical products

FURTHER CHANGES ARE COMING to the *in vitro* diagnostics (IVD) marketplace. On October 19, **Abbott Laboratories, Inc.**, announced that it would separate into two publicly-traded companies sometime in 2012.

One business will be the medical devices and diagnostics business. It will have about $22 billion in annual sales. Of this total, about $4 billion comes from the diagnostics products division.

Abbott describes the diagnostics division as made up of "worldwide sales of diagnostic systems and tests for blood banks, hospitals, commercial laboratories and alternate-care testing sites. For segment reporting purposes, the Core Laboratories Diagnostics, Molecular Diagnostics, Point-of-Care, and Ibis diagnostic divisions are aggregated and reported as the Diagnostic Products segment."

Second Company Is Pharma

The second business will be the pharmaceuticals company. It will have annual revenue of approximately $18 billion. One blockbuster drug, Humira, accounts for $8 billion of this total.

It is expected that the diagnostics business will keep the Abbott name and a new name will be applied to the pharmaceuticals company. Miles D. White, current CEO of Abbott Laboratories, will be the CEO of the diagnostics company. Richard A. Gonzalez, who currently runs the global pharmaceutical business, will be CEO of the pharma company.

Notably for lab administrators and pathologists, one reason for this split is the fact that the diagnostics business is fast-growing at this time, while the pharma business has lengthy development times. Abbott's board recognized that shareholder value could be increased by separating these two disparate business activities.

Fast Growth for Diagnostics

White, in public comments, described the medical devices/diagnostics products market as growth-driven. He said that about 40% of the sales of these products will be in fast-growing emerging markets. Also, up to 40% of this company's revenue will be paid—not by budget-minded governments and insurers—but by patients.

When measured by sales, Abbott Diagnostics is one of the three largest IVD manufacturers in the world, along with **Roche Diagnostics** and **Siemens Diagnostics**. It has seen very strong growth in its point-of-care testing products and its molecular diagnostics offerings.

Laboratory customers of Abbott are not likely to see many changes as a consequence of this corporate split. That's because it will operate under the same CEO and executive team. Maybe the most interesting question is which business—post-split—will keep the sprawling Abbott Park corporate complex located in the Greater Chicago metro. TDR

On-line access to lab results is most popular feature

At Kaiser Permanente, Real-Time Lab Results Are a Hit with Patients

CEO SUMMARY: Should patients be allowed to see their own lab test results when they are available to their physicians? Kaiser Permanente believes so. Since 2005, Kaiser Permanente has given members real-time access to most laboratory test results in their personal health record (PHR) on www.kp.org. In fact, viewing laboratory test results is the single most popular feature on the site and is used by Kaiser Permanente members more often than any other electronic service the plan offers. Patient access to lab test results has also improved patient safety in important ways.

When it comes to giving patients real-time access to their laboratory test results, **Kaiser Permanente** has a six-year headstart on the federal government's latest reform of lab test reporting requirements.

Since 2005, Kaiser Permanente members have been able to use the healthcare provider's online personal health record (PHR) to view most test results at the same time their doctors are viewing these results. My Health Manager, accessed at *www.kp.org*, takes the PHR to new levels by linking directly to Kaiser Permanente HealthConnect, Kaiser Permanente's electronic health record (EHR).

Since launching this service six years ago, Kaiser Permanente has found that patients love it. In an exclusive interview with The Dark Report, Kate Christensen, M.D., Medical Director of the Internet Services Group, stated, "Of all the online services Kaiser Permanente offers to its nearly nine million members in eight regions across the nation, online viewing of lab test results is the most popular."

Christensen noted that more than 60%, or about 3.7 million, of eligible Kaiser Permanente members (aged 13 and over with Internet access) are registered to use the plan's online service. These members viewed more than 25 million lab test results in 2010 alone.

Kaiser Permanente's decision to give patients access to their lab tests results was prescient. Just weeks ago, on September 12, the federal **Department of Health and Human Services** (HHS) published a proposed revision to CLIA rules that would allow all clinical laboratories to send laboratory test results directly to patients.

The HHS proposal is subject to public comment and revision before it becomes final. The language of HHS' proposed rule would direct clinical laboratories to provide lab test results to patients or designated personal representatives upon request. This represents a major change to existing CLIA and HIPAA regulations.

Kaiser Permanente's experience with giving patients access to lab test results affirms that the DHHS proposed rule is a step in the right direction. "Kaiser Permanente has found that making lab tests available to members offers four distinct advantages to health systems," explained Christensen. "First, it improves patient satisfaction. Second, the service helps Kaiser Permanente retain its members by empowering them to be more knowledgeable healthcare consumers.

➤ Improving Patient Safety

"Third, giving patients real-time access to view their laboratory test results has strengthened the patient-physician relationship in important ways," commented Christensen. "Fourth, giving patients access to laboratory test results helps avoid the problems that occur when physicians fail to inform patients about test results. This fourth benefit may be the most important of all, since it improves patient safety and contributes to better patient outcomes.

"Most of our test results can be immediately viewed by the patient," continued Christensen. "As soon as the results are sent from the laboratory to KP HealthConnect, patients can view them through their online personal health record

"It is important to understand that certain lab test results are blocked so that the patient cannot view them," she explained. "California state law mandates that certain lab results must be blocked from the patient. In other cases, the physician needs to have a conversation with the patient about the lab test results.

"In California, state law forbids the release of information in four categories: Malignancy, HIV, infectious hepatitis, and drug abuse," she said. "Other test results need to be discussed before the patient sees them or they need to be revealed in the context of a physician-patient discussion, such as some of those from genetic testing. Instead of being

automatically released, those results can be accessed after the discussion.

"An example of a test result that might be blocked is a diagnosis of cancer," stated Christensen. "That might be blocked for three to five days, depending on the region. The clinician will use that time to talk to the patient about the result. However, if the clinician does not talk to the patient within the designed time period, then the result in the EHR becomes available to the patient on My Health Manager.

Patient Access Policy

"All patients who can access our patient portal, My Health Manager, can view their results," Christensen said. "By 'all' patients, we mean members over age 13. Parents can set up a proxy access for children. Essentially, Kaiser Permanente's policy is that all members have access to the information in their electronic health record through their personal health record on *www.kp.org*. By design, Kaiser Permanente's EHR is not a system where clinicians decide which patients can get results and which ones cannot.

"The system complies with federal privacy rules under the Health Insurance Portability and Accountability Act (HIPAA)," noted Christensen. "It is designed to meet Kaiser's goal that all members have access to the data available in their online chart.

"One advantage of giving patients online access to their laboratory test results is that we believe we can eliminate problems caused when physicians do not inform patients about lab test results," added Christensen.

Failure To Report Lab Results

This problem was highlighted in a study that was published in 2009 by researchers at **Weill Cornell Medical College** in New York City. Researchers determined that physicians failed to report clinically significant abnormal test results to patients—or to document that they had informed their patients—in one out of every 14 cases of abnormal results.

There was great variability in how individual medical practices reported abnormal test results to patients. Some medical groups met this requirement with close to 100% compliance. But researchers found that some medical groups failed to communicate as many as one in four abnormal test results to their patients.

The findings of this study were published in the *Archives of Internal Medicine* (June 22, 2009). Lawrence P. Casalino, M.D., who is Chief of the Division of Outcomes Effectiveness Research at Weill Cornell, led a team that analyzed 5,434 patient records from 23 physician practices nationwide.

After the results of this study were published, Christensen wrote to the editors to explain how a patient portal, such as Kaiser Permanente's My Health Manager on *www.kp.org*, allows patients to view results regardless of whether physicians report the results to patients or not. The Casalino study also found that having an EHR did not reduce failure-to-inform rates—and even increased them—if the practice did not use good processes to manage test results.

Patients Have Access

In response, Christensen wrote: "The authors missed an opportunity, however, to point out one potential solution—give the patients access to their test results directly, using a personal health record (PHR) directly linked to the EHR."

In looking back over the success of My Health Manager, Christensen recalled that, in the planning stage, some in Kaiser Permanente were reluctant to let patients see their laboratory test results. "Initially, we heard comments from some physicians and others who thought that doctors would be swamped with phone calls from concerned patients," she said. "However, once this service went live, the volume of phone calls and emails from concerned

Kaiser's Lab Test Reporting Differs Slightly From HHS Proposal on Lab Test Results

IN SEPTEMBER, A PROPOSED NEW RULE that would allow all clinical laboratories to send lab test results directly to patients was published by the federal **Department of Health and Human Services** (HHS). The HHS proposal is subject to comments and revision before it becomes final.

The proposal is slightly different from the system Kaiser Permanente uses, said Kate Christensen, M.D., Kaiser Permanente's Medical Director of the Internet Services Group. "HHS is talking about having laboratories send laboratory test results to patients. That's not what we do," she said.

"Kaiser Permanente has its own laboratories that transmit test results electronically to the patients' electronic health record (EHR), which are immediately populated on patients' personal health record on *www.kp.org*. My Health Manager is the health plan's patient portal on *www.kp.org* and provides selective access to the EHR," she said. "For the most part, when the lab sends the results to KP HealthConnect, patients can look at those results at the same time the doctor gets them.

"But it's important to note that patients are looking in their own personal health record," she added. "The laboratory does not send clinical information directly to members.

"Rather, Kaiser Permanente opens a patient's EHR so that they can look at it, print it, graph the results, or store the results," noted Christensen. "Soon members will be able to download their EHR and send it to another doctor if they want.

"In certain ways, our system may work better than what the HHS is suggesting because the results are provided to the patient in the context of their overall care," Christensen explained. "There are other parts of the EHR that they can see along with the test results.

"For example, there is a list of their diagnoses," she continued. "Soon, they will be able to see their lab results related to each diagnosis. Currently it is listed as data and it is embedded with encyclopedia content that explains the results. Also, the physicians can write a note in the EHR commenting about the lab test results."

patients turned out to be a small and manageable number.

"Another goal was to make it easy for patients to understand their lab test results. Each lab test result posted in the patient's PHR is explained in plain language," she said. "If the patient wants to read more about that test in our health encyclopedia, we provide a link in the PHR to an explanation on *www.kp.org*.

Full Explanations Provided

"Presenting laboratory tests in this manner gives us a teachable moment with the patient," noted Christensen. "Instead of a nurse simply giving the patient a lab test value over the phone, patients can look up the result online. They can then read more about the lab test and the meaning of their results in our Kaiser health encyclopedia on *www.kp.org*. In doing so, each member becomes a more informed patient.

"Patients tell us that they are much more informed as a result of this service," Christensen added. "We know that patients value this feature because they vote with their fingers. Through June of this year, patients used My Health Manager to view more than 15 million test results."

The numbers at Kaiser Permanente tell a compelling tale. A survey was conducted earlier this year and 91% of members registered to use My Health Manager on *www.kp.org* said they were satisfied or very satisfied with the website. These findings are reinforced by actual usage data.

During 2010, Kaiser Permanente members logged into My Health Manager more than 62 million times. Lab test results were viewed 25.8 million times. Overwhelmingly, this was the most-used My Health Manager feature.

By comparison, patients used My Health Manager to send 10.7 million email messages to physicians and other providers. Patients also used the website to fill 8.3 million prescriptions and schedule 2.3 million appointments.

"Patients definitely want the information about their diagnostic test results," she said. "We know that the number of people accessing lab test results has increased steadily and continues to do so. The number of people registering for the patient portal is also rising.

"When patients have the ability to email their doctor, for example, they feel a closer bond with them," she said. "They also are less likely to change doctors, less likely to leave Kaiser Permanente, and more likely to recommend Kaiser Permanente to others.

Demand for Online Tools

"We are learning that there is a huge demand by consumers for practical tools that allow them to manage their health," she added. "Not every member is an active user of My Health Manager. However, back in 2005, when access to lab test results was added—along with the ability for members to use the website to email their doctor—there was a sizeable increase in the number of registrations for both of those services.

"Next year, we plan to allow patients to view summaries of hospitalizations, medication history, and immunizations," Christensen commented.

"When patients have the ability to email their doctor, for example, they feel a closer bond with them," she said. "They also are less likely to change doctors, less likely to leave Kaiser, and more likely to recommend Kaiser to others.

"More importantly, for patients with such chronic conditions such as diabetes, high cholesterol, or high blood pressure, we see early evidence that emailing their physicians has a positive health impact," she commented. "We are not sure what the connection is. It could be that the people who use our online tools are already more engaged in their health. However, it looks like having this kind of access promotes deeper engagement on its own.

Self-Management Tools

"We also have online health programs that offer electronic coaching on such topics as pain, depression, insomnia, and stress," she said. "Patients fill out a questionnaire, then get personalized instructions, suggestions, and self-care techniques. We find that this service also has big impact on patients, which is another positive result of the online self-management tools on *www.kp.org*."

In an article published online in August, "Kaiser Electronic Health Records Connect a Fragmented System," Rob Unitan, M.D., a Kaiser Permanente physician and specialist in pulmonology and emergency medicine, wrote about a diabetes patient who used Kaiser Permanente's PHR to her benefit. She established regular contact with her care team by emailing her blood glucose results two to three times per week. She also took diabetes management classes. Over time, this patient lost 33 pounds and cut her blood sugar from 142 to the high 90s. She could not have achieved this result without the support she received from her care team, including the ability to stay in touch with them online, he wrote.

Step Forward In Patient Care

For Christensen, the two-way communication that is delivered by My Health Manager on *www.kp.org* represents a step forward in patient care. "Delivering information to patients in this way is so much different than how it was when I started

working as a general internist in 1984," she recalled. "At that time, physicians were less accessible to patients.

"Now, it is easier for patients to communicate with physicians," observed Christensen. "We are more open and reachable. There is a better partnership with patients. Plus, we have more tools—such as My Health Manager—to keep patients engaged in these self-care activities. Today, there are more touch points between health systems and patients.

"For hospitals, health systems, and clinical laboratories considering what Kaiser Permanente has accomplished with its on-line PHR, I would recommend that they act confidently and provide patients with as many lab test results as can be done safely and legally," she stated. "Patients are way ahead of most providers in terms of their comfort with getting this information electronically."

Improved Health

THE DARK REPORT observes that Kaiser Permanente's success with its My Health Manger is an important milestone for the laboratory medicine profession. For more than six years, Kaiser Permanente has delivered real-time access to most laboratory test results for millions of patients.

Throughout this time, Kaiser Permanente has gained several important insights. Patients are not only enthusiastic about having access to this part of their electronic health record, but it motivates them to take active steps to improve their personal health outcomes. These are both notable developments and should encourage other clinical laboratories to similarly develop ways to give their own patients fuller access to lab test results.

These are significant findings, given the sheer scale of the patient population utilizing KP HealthConnect on a regular basis. Kaiser Permanente's comprehensive health information system is considered one of the nation's most advanced electronic health records available. It securely connects 8.9 million people to their health care teams, their personal information, and the latest medical knowledge, leveraging the integrated approaches to health care available only at Kaiser Permanente.

Another lesson gained from the experience at Kaiser Permanente is that a substantial number of patients are eager to use a personal health record to monitor their healthcare. Pathologists and clinical laboratory managers may want to study Kaiser Permanente's success with digital personal health records as the basis for developing a clinical and business strategy at their respective lab organizations. With more integration of healthcare informatics and clinical care predicted, that would be a timely management action by clinical labs. TDR

Contact Kate Christensen, M.D., at Kate.christensen@kp.org or 925-595-5616.

Top 10 Features of Kaiser's Digital Health Record System

CURRENTLY, PATIENTS AT KAISER PERMANENTE can use their personal health record (PHR) for a wide variety of purposes.

Kaiser Permanente provided this list of the 10 features that are most popular with its members. At the top of the list, and widely popular by a significant margin, is access to laboratory test results.

1. **Test Results**
2. **Appointments**
3. **E-mail My Doctor**
4. **Prescription Refill**
5. **Facility Directory**
6. **Past Visit Information**
7. **Health Encyclopedia**
8. **Medical Staff Directory**
9. **Act for a Family Member**
10. **My Prescriptions**

Source: Kaiser Permanente, Oakland, California, 2011.

Lab Testing, Pathology Is Fast-Growing in China

➤Asian Tiger is ready to roar as its pathologists eagerly work to build expertise and new capabilities

➤➤CEO SUMMARY: It was record attendance at the major pathology congress which took place in Hangzhou, China, last month. Because of the ongoing growth of China's economy, the demand for healthcare—and for high-quality clinical lab and pathology testing—is rising at an accelerated pace. During his visit to the pathology congress and Chinese hospital labs, your editor gained useful insights about the state of lab medicine in China—and why there will be more collaboration with labs in the U.S.

By Robert L. Michel

FEW WOULD CHALLENGE the statement that China is on its way to developing into the world's single largest market for clinical laboratory testing and anatomic pathology services.

The basic facts are indisputable. It is the most populous nation on earth, with 1.3 billion people. The number of public hospitals in China is about 14,000 and the number of private hospitals is 5,736, according to a statement from China's Ministry of Health. Many of these are huge facilities by U.S. standards, boasting between 1,000 and 3,400 beds.

➤Record Attendance

Last month in Hangzhou, China, a record crowd of approximately 1,200 pathologists gathered for the 17th Congress of the **Chinese Society of Pathology** and the 1st Annual Meeting of Chinese Pathologists. Your editor was there to deliver a presentation about the role of quality management systems (QMS) in histopathology labs.

This was my first trip to China and it was an opportunity to get a first-hand understanding of laboratory medicine in this rapidly-developing nation. The pathology congress conducted sessions over three days and I also had the opportunity to visit a number of clinical laboratories and anatomic pathology labs in hospitals in both Hangzhou and Shanghai.

There was much to see and learn about laboratory medicine in China. This briefing is a first attempt to communicate useful impressions that will help pathologists and clinical laboratory administrators in other countries understand some of the more important drivers of medical laboratory testing in China.

Throughout my visit to China, everyone was friendly and most hospitable. Not only was this true of the pathologists at the congress and during our site visits, but it was equally true of the people we met in the community.

This Asian Tiger is roaring and Chinese pathologists and lab scientists are positive about their opportunity to advance patient care. They recognize that their health system, their laboratories, and their medical skills start from a different level, when compared with world-class

clinical laboratories and anatomic pathology labs in advanced economies.

Chinese pathologists are eager to acquire and use new laboratory technology and instrument systems. My impression is that the majority of pathologists and lab scientists I observed at the pathology congress are actively building their personal skills and expertise. There were over 100 presentations at the Congress and all were well-attended.

Eager to Acquire More Skills

Take this, then, as a starting point for understanding the state of laboratory medicine in China. There is a recognition that the current state can be improved and much work must be done to raise the level of training for pathologists and to add capabilities to their laboratory facilities.

The next useful insight about laboratory medicine in China is that the global *in vitro* diagnostics (IVD) manufacturers play an essential role in helping Chinese pathologists and lab professionals upgrade the capabilities of their laboratories and advance their personal skills. These vendors are introducing their Chinese lab customers to "best practices" in lab medicine, for example.

More specifically, lab suppliers are proactively making "knowledge transfer" a key element of their business strategy in China. Local pathologists welcome this access to the latest information and innovations in laboratory medicine.

Vendors Arrange Site Visits

I saw this repeatedly at the pathology congress and during my site visits. For example, it was **Thermo Fisher Scientific, Inc.**, which helped arrange my presentation at the conference, along with site visits to prominent hospital laboratories in Hangzhou and Shanghai. This included translation services which were essential, since I don't speak Chinese and not every pathologist is comfortable speaking English.

Chinese Pathologists Look To United States for Expertise

WHILE IN HANGZHOU, CHINA, LAST MONTH to participate in the 17th Congress of the Chinese Society of Pathology, the largest international presence were pathologists practicing in the United States. This can be taken as a sign that Chinese pathologists are very interested in the U.S. models of anatomic pathology and laboratory medicine.

The China-U.S. pathology links seemed to center around two elements. First, there was a large contingent of Chinese or Chinese-American pathologists who are practicing in the United States and who were at the pathology congress to deliver presentations on their pathology subspecialty interest. This is evidence of a rich educational exchange in laboratory medicine between the two nations.

The second element involved American pathologists who are actively courting clinical and business relationships with pathologists in China. For example, a number of pathologists from **UPMC Health System** (University of Pittsburgh Medical Center) led sessions at the pathology congress. UPMC's Department of Pathology has a digital pathology consulting arrangement with Kingmed Diagnostics. This is an independent laboratory company based in Guangzhou, China.

Also present at the pathology congress was a pathologist representing the **College of American Pathology** (CAP). CAP offers its laboratory accreditation program in China. It currently has 14 Chinese laboratories which have met its accreditation requirements.

Thanks are also extended to **Aperio Technologies, Inc.**, for arranging my visit to the Chinese pathology laboratory at **Second Affiliated Hospital** in Hangzhou. This pathology lab has a relationship with the pathology department at **UCLA** that

includes use of digital pathology in ways that enable specialist pathology consults and advanced subspecialist training for Chinese pathologists.

I will write about the details of this arrangement in an upcoming issue of THE DARK REPORT. Their collaboration across the Pacific Ocean has been active for more than a year. It provides an early example of how and why some anatomic pathology cases are likely to cross international borders.

Clinical Lab Site Visits

For site visits to clinical laboratories, it was **Siemens Diagnostics** that provided essential help. Because of their relationships, I was able to visit several clinical labs in hospitals in both Hangzhou and Shanghai.

One laboratory site visit was particularly notable, since it was an example of a private medical clinic/hospital organized somewhat along the lines of the concierge medicine practice as it exists in the United States. More will be written on that site visit in upcoming issues of THE DARK REPORT.

As I participated in these activities and site visits, it became clear that IVD companies and lab suppliers are an essential channel for clinical knowledge and state-of-the-art technology. The importance of this to the Chinese laboratory medicine profession should not be underestimated.

For that reason, in the upcoming briefings about these laboratory site visits, it will be important to recognize the role of the vendors who facilitated what turned out to be rich exchanges of information for all parties involved in each site visit.

China's Heathcare System

These insights provide you with some context for what I saw and learned while in China. There are specific elements of healthcare and laboratory medicine in China that are similar to healthcare and lab medicine in the United States.

First, government budgets for hospitals fall short of covering the full cost of operating the hospitals and their associated outpatient clinics. That is one reason why there is a flourishing private market for healthcare. Chinese providers want to attract cash-paying patients as a source of additional revenue.

At the same time, many Chinese patients are skeptical of the quality of care that may be provided by hospitals, physicians, and laboratories in their communities. Thus, providers want "quality hallmarks" that patients will recognize.

For this reason, CAP's lab accreditation program is seen as a differentiator that will be recognized by patients and physicians. Similarly, **The Joint Commission** (TJC) has a program for hospitals in China that is administered by **Joint Commission International** (JCI). There are 12 Chinese hospitals that have achieved JCI accreditation.

It also appears that the clinical laboratory market in China now includes a category of national reference and esoteric lab testing companies. Similar to **ARUP Laboratories, Inc.**, and **Mayo Medical Laboratories**, here in the United States, these are independent laboratory companies that solicit lab specimen referrals from hospitals throughout China.

Reference Testing Lab Firm

One such company is **Kingmed Diagnostics**. Not only has it entered into the digital pathology arrangement with UPMC *(see sidebar on page 17)*, but it is also a CAP-accredited laboratory. It recently earned its accreditation to ISO 15189 through the **China National Accreditation Service for Conformity Assessment** (CNAS).

As these observations indicate, there was much to see and learn during my first trip to China. With significant numbers of Chinese pathologists, Ph.D.s, and laboratory scientists training in the United States, it is logical to assume that these professional relationships will carry forward and form the basis for many more trans-Pacific collaborations involving medical laboratories in China and the United States. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Many experts were impressed when **General Electric Co.** ponied up $587 million to acquire pathology testing company **Clarient, Inc.**, in October 2010. Now comes further insight behind this transaction. At an investment conference in Boston on November 3, John Dineen, CEO of **GE Healthcare**, told the audience that his company—currently generating revenue of $2.4 billion per year in molecular-based medicine—wants to double that number in three to five years.

MORE ON: *GE's Plans*

GE Healthcare has big plans for tissue-based molecular testing. "We're going to put a lot of our resources, both organically and inorganically into the tissue-diagnostic side of this," declared Dineen in his remarks at the **Goldman Sachs Group Inc.**, conference in Boston. He indicated that GE Healthcare is devoting about 20% of its research budget to this goal. Dineen went on to say, "We're diagnosing at a biological level, not a physiology level. We've gone from a physiology, which is 'look at the brain, look at the tumor,' to 'let's understand what's going on in the cells of this tumor. What signals is it sending? What's going on metabolically?' It's another level of resolution." GE Healthcare expects annual growth rates to be 10% or more in molecular medicine.

LABOTIX ACQUIRES iLAS, INC.

Today it was announced that **LABOTIX Automation, Inc.**, of Peterborough, Ontario, acquired **Integrated Laboratory Automation Solutions, Inc.** (iLAS) of Troy, Michigan. The acquisition expands the portfolio of open lab automation solutions that LABOTIX can offer to clinical laboratories.

TRANSITIONS

• **Agendia V.P.**, appointed David Macdonald as CEO. He has been COO at Agendia since April 2010. MacDonald previously held executive positions at **Quest Diagnostics Incorporated**, **Nichols Institute**, **Behring Diagnostics**, and **Nova Biomedical**.

• **Atherotech Diagnostics Lab** of Birmingham, Alabama, recently named Sarah Schiltz to be Vice President of Marketing. She was most recently at **diaDexus** and has held positions at **Cholestech Corporation** (now **Alere**) and **Genzyme Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 28, 2011.