Volume XVIII, Number 16 Monday, November 28, 2011

Exclusive!

Why One Medicare Payer Drew a Bull's Eye on Code Stacking for Genetic and Molecular Tests!

See pages 2-10.

From the Desk of R. Lewis Dark...

Specialized Information Publishers Foundation
EDITORIAL EXCELLENCE AWARD WINNER

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

Molecular Code Stacks Now in the Payers' Bull's Eye

LIKE A STEAM BOILER READY TO EXPLODE FROM TOO MUCH PRESSURE, the nation's health insurers have reached a point of no return on the subject of code-stacked claims for genetic testing and molecular diagnostics assays. Simply put, payers are ready to tackle this sensitive issue.

Payers have reasonable questions about this type of clinical lab testing. Is it sound practice to accept a claim for a laboratory test that does not identify the clinical function of the diagnostic test? Equally relevant, why would labs expect any payer to reimburse a laboratory test claim that didn't include information necessary to identify that the molecular lab test is an appropriate clinical procedure for the patient, given the specific health conditions the attending physician is investigating?

Code stacking claims for genetic tests and molecular assays generally fail to give payers useful information on both of these points. If this were your company, and you were paying the bills, would you consider it good business to accept these claims without challenge and issue payment? Wouldn't you want to understand the clinical purpose and the clinical efficacy of these genetic and molecular tests?

How did health insurers and the clinical lab testing industry get to this point? The process of creating new CPT codes probably has a role in this story. After all, we are more than a decade into the genetic testing era and the CPT coding system is woefully behind today's molecular testing marketplace.

Most pathologists have heard the comment attributed to Otto von Bismarck, a German politician of the 19th Century, who said: "If you like laws and sausages, you should never watch either one being made." Some have hinted that the process and politics of updating the CPT coding system would probably fit Bismarck's description of law- and sausage-making.

The fact remains that current CPT codes do not help labs describe all the tests they perform in support of clinical care. Nor do health insurers get the precise information they need when code-stacked claims for molecular tests are submitted for reimbursement. It is no surprise, then, that, as of March 1, 2012, one important Medicare carrier is stepping up with a plan to provide an interim solution to the recognized inadequacies of existing CPT codes for genetic and molecular tests. It may not be perfect, and it is likely to be criticized and even challenged in court. But it is the shoe that everyone has been waiting to drop. And now it appears that it will. TDR

Palmetto Execs Explain Molecular Test Policies

Goal is to create a process to assess science and clinical value for molecular tests and LDTs

CEO SUMMARY: To create more transparency in the process clinical labs use to submit claims for genetic tests, molecular diagnostic tests, and for laboratory-developed tests (LDT), the nation's largest Medicare Administrative Contractor (MAC) has proposed two new local coverage determinations (LCD). CMS has changed Palmetto GBA's statement of work to include implementing a lab test registry and science review process for genetic, molecular, and laboratory-developed tests.

CLINICAL LABORATORIES AND PATHOLOGY GROUPS that submit claims for genetic tests and molecular assays are going to remember February 27, 2012. That's the date **Palmetto GBA** proposes to implement new policies for molecular tests that utilize code stacked claims.

Palmetto GBA is the nation's largest Medicare Administrative Contractor (MAC). It published two proposed local coverage determinations (LCD) this fall that address how clinical labs submit claims for molecular diagnostic tests (MDT) and laboratory-developed tests (LDT). *(See TDR, November 7, 2011.)*

In recent weeks, Palmetto GBA posted information on its website about what it calls the "Molecular Diagnostic Services Program" (MolDx). Collectively, the two proposed LCDs and MolDx represent important developments for any clinical lab or pathology group that currently uses code-stacked claims to bill for genetic and molecular tests.

Palmetto GBA gives a simple reason for proposing these new policies. "Currently, when a laboratory submits a claim for a genetic or molecular test which is built on a code stack, the payer is unable to identify the specific diagnostic test and how it supports appropriate care for the patient," stated pathologist Elaine Jeter, M.D., who is Medical Director at Palmetto GBA.

"The goal is to provide transparency to the claims process and to have steps in place that allow laboratories to demonstrate the science and clinical utility of

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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

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).

each genetic test and/or molecular diagnostic test," she continued.

It is important for pathologists and lab administrators to understand which areas of the nation will be affected by the proposed LCDs and MolDx. At this time, the three proposals would affect labs only in Medicare Jurisdiction 1 (J1), meaning California, Hawaii, and Nevada.

Two Proposed LDTs

The two draft proposed local coverage determinations (LCDs) are:

- DL32288—LCD for Molecular Diagnostic Tests
- DL32286—LCD for Non-Standardized Organ or Disease-Oriented Panels.

Readers can find the two draft LCDs and more information on Palmetto's website at *www.palmettogba.com*. After January 1, Palmetto will introduce these two LCDs in J11 (South Carolina, North Carolina, Virginia, and West Virginia).

The third proposal is a molecular test registry and reimbursement process that Palmetto calls the "Molecular Diagnostic Services Program" (MolDx). Readers can get information on MolDx by visiting *www.palmettogba.com* and searching for "MolDx." *(See pages 7-10 in this issue of TDR.)*

Other Payers Are Watching

At this time, Palmetto GBA is the only MAC proposing these types of changes to code stacking for genetic and molecular tests. However, other MACs, the **Centers for Medicare & Medicaid Services** (CMS), the nation's commercial health plans, and other private payers could follow Palmetto's lead by adopting similar policies.

As well, it is known that some of the nation's private health plans are taking steps to adopt programs designed to control the volume and complexity of molecular diagnostic and genetic tests. The U.S. market for molecular tests is estimated to be $6 billion to $7 billion annually.

"The window of time for public comment on these proposed LCDs is open and we encourage pathologists and others to submit their comments to us," stated Mike Barlow, Vice President. Comments are due by December 5 and can be submitted at *J1B.Policy@palmettogba.com*.

"It's very important for us to get feedback from the clinical lab industry," urged Jeter. "We greatly encourage public comments about these proposals."

The proposals are needed to address what Jeter and Barlow said is a lack of data about the 1,500 or so MDTs and the thousands of LDTs for which labs daily ask Medicare contractors to pay.

"For many of these tests, there is a lack of publicly available data," commented Barlow. "As a payer, we don't know enough about these tests. Our Molecular Diagnostic Services Program is a way for us to categorize each test so the science that supports a specific test can be identified.

Direction For Referring Doc

"When the laboratory submits a code-stacked claim for payment, it uses a number of methodologic codes to produce a single result," Barlow explained. "That single result is intended to drive a specific clinical utilization or direction for the referring physician.

"We understand that the various procedures performed by the laboratory are designed to produce a single result," he continued, "and, in that way, an MDT is no different from any other test that delivers a score or a value that a clinician uses.

"The Medicare program requires an assessment of the clinical utility of laboratory tests and other procedures," observed Barlow, "But for an MDT's single result, there are a number of tests and we do not know the clinical utility behind those tests. When we don't know the science behind these tests, we have to draw a line, particularly for molecular diagnostic testing."

Palmetto Wants to Encourage Innovation And Support Medicare Coverage Guidelines

EXECUTIVES AT PALMETTO GBA, the nation's largest Medicare Administrative Contractor (MAC), told THE DARK REPORT that they have no desire to stifle innovation or impede good patient care.

Instead, two Palmetto executives, Medical Director Elaine Jeter, M.D., and Vice President Mike Barlow, said that they want to standardize how each molecular diagnostic test (MDT) and each laboratory-developed test (LDT) is reviewed and approved.

Handling Questions

"Recently, Palmetto GBA got a question involving thrombophilia (or abnormal blood coagulation)," recalled Jeter. "This test had two or three assays. We will not reject a thrombophilia test claim simply because it includes two or three assays. That's not our goal here.

"Most laboratories are doing the right thing," she added. "But problems occur when a lab submits a claim with the phrase 'comprehensive workup' on a test requisition and the lab does not define what 'comprehensive' means.

"Once the physician checks the box for comprehensive workup, it allows the lab to self-refer to itself, in essence, to make that determination," she added.

"In addition, Palmetto GBA sees numerous instances where, if the lab has a templated way to handle 'comprehensive workups' for some conditions, then unnecessary molecular, FISH, and other testing is being done," explained Jeter. "Although the requisition was submitted as a comprehensive test, the lab could have limited further testing when it had the flow cytometry results because the flow cytometry nailed the diagnosis. But the laboratory continued to do unnecessary testing."

Jeter and Barlow emphasized that most labs are careful to run only those tests that are appropriate. "There's a select and small subset of labs that will be most affected by these proposed policies," observed Jeter. "Palmetto GBA proposed these draft policies because it saw how this problem was growing as some laboratories were using this one avenue to maximize their revenue."

For many MDTs and other tests, labs use stacks of codes, meaning bills from labs show several tests are run to produce the one result. Such code stacking makes it impossible for Palmetto to evaluate the clinical utility of these tests.

"Because there's a lack of transparency, we had to define what the limitation would be," Barlow said. "We're simply telling the labs that, if you're in this environment: 1) you have to tell us what specific service is represented by the claim; and, 2) how you are billing us. This information will allow us to determine whether coverage should be applied. Absent that, coverage is not automatic.

"Basically, we are working in an unknown universe," he added. "For most routine lab tests, we have published science and clinical studies to evaluate the utility of tests. But for MDTs, clinical labs submitting claims have not shared how they developed these assays. Nor have they showed us the supporting science.

Using Code Stack For Claims

"When a code stack is involved, we have yet to see a single test that is wholly described, wholly analyzed, and that accurately describes the complete test," Barlow explained. "The variables of how code stacks are used are subject to interpretation by each clinical laboratory. The problem is that the test developers make decisions about what code stacks to use—irrespective of whether or not they are using accurate codes for all the tests that they include in that code stack.

"Also, many MDTs include algorithms that are not represented in the code stack. Yet it's the algorithms that produce the final results that are intended to be actionable by the referring physician," he said.

"Palmetto GBA's position is that, if there is one test, there should be one result," Barlow continued. "The lack of transparency on this point is demonstrated by the fact that the laboratory can't describe the test completely with the code stack it uses. Instead, it uses one of the NOC codes, meaning 'not otherwise classified.'

"For the past two and a half years, Palmetto GBA has advised labs to use NOC codes," he added. "But laboratories persist in using code stacks, and, I repeat, the number one problem with code stacks is Palmetto GBA does not know what test is represented by the claim. Therefore, Palmetto doesn't know what specific clinical service it is being asked to pay for."

The Medicare contractor has a similar problem with LDTs. There is ongoing growth in the number of unique laboratory-developed tests where the lab runs a number of tests to produce one result, Barlow and Jeter explained.

Science In Support Of Tests

"We issued the proposed LCD on non-standardized organ or disease-oriented panels because labs bundle tests together and bill Medicare for a series of tests under this construct, often using stacked codes," explained Jeter. "Yet for half of the tests in a specific code stack construct, the lab offers no science to support that part of the test to be run."

Another issue associated with test panels is how clinical laboratories organize the lab test requisition form they distribute to physicians. "Laboratories are using requisitions that ask physicians to check a box that represents a panel of tests," she noted. "This means a single check item is used on the test requisition form for a comprehensive test. The physician understands that, by checking this box, he or she is ordering a panel of tests.

"The physicians do get richer information from the panel of tests than if the lab ran each test individually," Jeter explained. "But some of these panels are used for risk assessment and screening, and CMS doesn't pay for risk assessment and screening.

"Palmetto GBA knows it is paying for risk assessment and screening," she continued. "But, in looking at a claim for one of these panels, it is impossible to sort out which tests are for diagnostic purposes and which tests are for screening.

"Palmetto GBA's position is that, if there is one test, there should be one result," Barlow continued. "The lack of transparency on this point is demonstrated by the fact that the laboratory can't describe the test completely with the code stack it uses. Instead, it uses one of the NOC codes, meaning 'not otherwise classified.'

"Palmetto GBA is asking laboratories to identify the clinical situations that support the physicians' use of these tests," stated Jeter. "If the laboratory can't identify the reasons for each test, then it's going to be noncovered."

Both Jeter and Barlow encouraged labs to comment on the draft proposed LCDs and the MolDx policy as well.

THE DARK REPORT observes that these policies have the potential to change the review and payment policies significantly for molecular, genetic, and other complex tests. That is an important reason why pathologists and lab administrators should take the time to review the proposals and submit comments to Palmetto GBA by December 5. TDR

—By Joseph Burns

Contact jib.policy@palmettogba.com to submit comments.

Palmetto GBA Announces Molecular Test Registry

Labs in California, Hawaii, and Nevada need to seek approval for each code-stacked test

CEO SUMMARY: Palmetto GBA, the nation's largest Medicare Administrative Contractor (MAC), is asking labs in the J1 jurisdiction to submit applications for each molecular test they run. Molecular assays will receive a unique five-digit alpha-numeric identifier (Z-code) that will be entered into the narrative/comment field on claims. A panel of subject matter experts will evaluate the analytical and clinical validity of the assays, and to determine the clinical utility of the assay.

SEEKING A CLEAR, EVIDENCE-BASED PROCESS to ensure the clinical quality of molecular diagnostic tests (MDTs), the **Centers for Medicare & Medicaid Services** (CMS) has asked its largest payment contractor to develop coding and reimbursement guidelines for these tests.

In an announcement issued on November 2, CMS said that **Palmetto GBA,** located in Columbia, South Carolina, should use its Molecular Diagnostic Services (MolDx) Program to establish a standardized test registration and coverage-determination process.

A Molecular Test Registry

In an interview with THE DARK REPORT, Palmetto Medical Director Elaine Jeter, M.D., and Vice President Mike Barlow explained the process Palmetto GBA will use to establish a registry of molecular tests and to review and approve molecular tests.

Currently, clinical laboratories and pathology groups use methodology-based code stacks for molecular assays that do not contain the information needed by Palmetto GBA and other payers to identify the assays actually performed. The methodology codes are analogous to baking—one measures the baking ingredients, uses an electric mixer to blend the ingredients, pours the mixture into a pan, bakes the product, and gets a baked good. But what was it? A cake, a pie, or cookies?

Similarly, Medicare and all other payers are paying for methodologic steps to perform an assay, but the payer does not know what assay was actually performed. Without this information, it is not possible to evaluate the services rendered for many molecular assays submitted for Medicare payment. For these reasons, Palmetto GBA has stated that is has no way to determine the medical necessity of laboratory-developed molecular diagnostic tests (MDT).

"The growing volume and complexity of these tests, combined with the practice of code stacking, made it necessary to develop the proposed policies," noted Jeter. "In the current coding construct, the methodology of code stacks precludes our knowing what we are paying for."

"Under the MolDx program, each lab will need to obtain a Z-Code for every molecular test it uses," explained Barlow. "The Z-Code will be unique to each lab test and the laboratory which performs that test.

Molecular Test Registries

"The process of establishing Z-Codes and a molecular test registry is an opportunity to bring transparency to molecular testing," Barlow explained. "It's an attempt to solve the identification problem and the registration of the test. The Z-Code simply says, 'Now we know who you are, and we know this is your test.'

"Keep in mind that registration has nothing to do with coverage," he added. "The registration application simply explains the steps that a lab follows to get a unique code. Thus, the test will have an identity.

"To that identity, we can attach a coverage assessment of the science and the clinical utility of that test that is provided by the laboratory," commented Barlow. "Palmetto GBA can publish that assessment so that physicians can make good clinical judgment about the utilization of that test.

"The Z-Code registration will be specific for each test from each lab," he added. "It's comparable to a National Drug Code (NDC) number that pharmaceutical companies use for generic drugs. Each generic drug from each different manufacturer has a different NDC number. Z-Codes are simply the lab industry's version of NDC numbers.

Developing An Online Tool

"To obtain a Z-Code, a lab simply needs to visit the website, download and complete the spreadsheet, then submit it to us," stated Barlow. "Palmetto GBA is developing an online tool that will replace the spreadsheet in the coming months.

"Expectations are that we will receive a large volume of requests for Z-Codes," he said. "A panel of subject-matter experts will review each application. *(See sidebar on page 9.)*

"In the meantime, we encourage laboratories to use the spreadsheet and start the process of getting the Z-Codes now," advised Barlow. "That way, they'll be ready by March 1. That is the date when every lab that runs molecular tests will need to have a Z-Code for each of its tests.

"Until March 1, Palmetto GBA will continue to pay for these tests while the science in support of that laboratory test is evaluated," observed Barlow. "Any laboratory that currently submits claims for a MDT to Palmetto GBA will need to submit the clinical justification for these tests. If you are in J1 and you bill Palmetto GBA with a stack code today, you will have to get a Z-Code.

Coverage Determination

"To be clear: any lab currently submitting molecular tests to Palmetto for reimbursement has to submit the clinical and scientific material for each test so that Palmetto GBA can make a coverage determination for that test," emphasized Barlow. "At the same time, we will not go back in time and penalize any laboratory that was benefiting from an ambiguous coding system. We were asked that question and we will not work retroactively, as some had speculated we would."

The situation will be different for laboratories that wish to submit claims for MDTs that have not previously been submitted to Palmetto GBA. "For any new assay that we have not seen before—and for any new laboratory opening now—the only point of entry is to register that assay to get a Z-Code," he said. "That creates a clear identity of that test and the laboratory that performs that test.

"Next, the laboratory will need to submit documentation about the science and the clinical utility of that test," stated Barlow. "Subject matter experts will review the supporting science for each

Palmetto Explains How Labs Can Register Molecular Dx Tests for Coverage Review

TO APPLY FOR A COVERAGE DETERMINATION, laboratories will first apply to get a Z-Code for each molecular diagnostic test (MDT) they perform, according to the proposal drafted by Palmetto GBA. Next, a panel of molecular diagnostics experts will review the clinical documentation that labs provide once they have a Z-Code for each of their MDTs.

Palmetto described the methodologies it will use in the coverage determination process. For each molecular test that a lab submits for review and approval, a specific value will be developed. Palmetto GBA said it is seeking to approve MDTs that are value- and market-based.

Requesting Z-Codes

It was on November 14 when Palmetto announced that providers could request Z-Codes via a downloaded template on the MolDx site. *(See "Jurisdiction 1, Part B, Z-Code Registration is Now Open," on the Palmetto website: http://tinyurl.com/786t9t8.)*

Palmetto GBA is asking laboratories to submit their test catalog for procedures/services that require or use more than one CPT code to identify the service; or that use the methodology-based "stacking CPT codes" (83890-83914), micro-array CPT codes (88384-88386), and cytogenetic CPT codes (88230-88291)."

There are several steps to the process. Each laboratory seeking a coverage determination for a molecular test must submit the required test information and supporting evidence to the McKesson Diagnostics Exchange Test Assessment Module. Palmetto GBA will send the non-confidential components of all completed coverage requests to a panel of subject matter experts who will assess the evidence using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) System to evaluate tests. The GRADE Working Group began in 2000 as an informal collaborative of healthcare experts from around the world who seek to address the shortcomings of grading systems in healthcare.

Following the evaluation, the subject matter experts will report their findings to Palmetto GBA. Once it reviews these findings, Palmetto GBA will publish a coverage determination in a policy or article and publish the corresponding tech assessment summary of the coverage determination on the Diagnostics Exchange. All proprietary test information will remain confidential.

In January, the McKesson Diagnostics Exchange Registry Module will be available online for laboratories to access their Z-Code assignments and to register new tests, Palmetto said.

Also in January, the voluntary, manual registration of MDTs will begin. This registration becomes mandatory on March 1. After March 1, all MDT and LDT claims without a Z-Code will be rejected. Also, from March 1 forward, Palmetto said that claims for MDTs will not be considered for adjudication unless the test has been submitted to the test registry for review and a Z-Code has been assigned to the test.

assay. Only then will a decision about coverage be made."

It will take considerable effort to work through the volume of applications that are expected, given the number of different MDTs that currently exist. "Currently, laboratories may be submitting code-stacked claims to Palmetto GBA for as many as 1,500 unique laboratory tests," observed Barlow.

"Laboratories want to know if Palmetto GBA can review and approve these tests between now and March 1," he commented. "The answer is, yes!

Resources are in place to accommodate this need and we are committed to the timeline. It will be a scramble for us over the next six months, but we expect to get the job done within the schedule we set out.

"Things should work like this," Barlow explained. "From the date a lab's application is accepted, a 90-day clock will run. If, at the end of that review cycle, the lab's supporting material is found wanting, it can reapply after an additional 180 days.

"Each laboratory is requested to put forward the best science it has for each test and we will accept a whole range of data," added Barlow. "Full details are explained on the MolDx site, which is *http://tinyurl.com/7qnlbzm*. Should a laboratory get a noncovered decision, it will also receive an explanation about why."

Assessing Test Utility

Some pathologists have raised the question about whether Palmetto GBA will recognize that certain molecular tests are useful for a small population of patients. For that reason, there may be limited clinical research and not much information available in the literature.

"We heard that question and we are aware of such possibilities," responded Barlow. "Palmetto GBA does not want to curb innovation. At the same time, it is necessary for us—and also for physicians—to understand the reason for the innovation.

"To be more specific, there is a concern that many molecular tests are for risk assessment or for screening," he continued. "Most pathologists and lab administrators understand that the Medicare program does not pay for assessment and screening."

Barlow and Jeter wanted to emphasize that the review panel would be part of the process only for establishing the technical assessment. "Remember that the panel of subject matter experts will be limited to an examination of the science and clinical utility in these applications," noted Jeter. "The review panel will not make a coverage determination. A coverage determination is a function of the contractor, Palmetto GBA.

Separate Calculation

"A component of the coverage determination is reimbursement," she continued. "That will be a separate calculation. The reimbursement equation will include a review of the clinical efficacy of each test and the financial cost of running the test."

Jeter also hopes that clinical lab professionals, physicians, and scientists will consider serving on the panel of subject-matter experts. "The names of these experts will be confidential," she said. "Each will be asked to sign confidentiality and nondisclosure agreements.

"We welcome any industry experts who want to step forward to serve on this panel," stated Jeter. "We have asked the industry associations to provide recommendations as well. Anyone interested in serving on this panel should send an email with a CV and a description of areas of expertise and knowledge of molecular testing. Such applications should be sent to *MolDx@palmettogba.com*."

Public Comments Invited

It has been about eight weeks since Palmetto GBA published its proposed two local coverage determinations. It later released details discussed here by Jeter and Barlow about the process that will be used to develop a molecular test registry. Palmetto GBA is keenly interested in public comment from the laboratory industry. It would be timely for pathologists and lab administrators to respond and offer their comments, as now is the time to influence the final processes that will be implemented in coming months. TDR

—Joseph Burns

Contact jib.policy@palmettogba.com to submit comments.

Rite Aid Offers Free Tests To Preferred Customers

National chain has pharmacists discuss lab test results with rewards program members

CEO SUMMARY: National pharmacy chain Rite Aid now offers free clinical laboratory tests to members of its customer-rewards program once they reach certain spending levels. After the customer's specimen is tested, the laboratory test results are sent directly to the customer's local Rite Aid pharmacist. Next, the pharmacist will discuss the lab test results with the consumer. This marketing program is the latest example of how pharmacies want to use lab testing as a way to generate more prescriptions.

ONE OF THE NATION'S MAJOR PHARMACY CHAINS now offers free clinical laboratory tests to members of its "frequent shopper" program. As part of this free offer, its pharmacists are sent copies of the laboratory test results so they can use this information to discuss prescriptions with the patients.

Rite Aid Corporation of Harrisburg, Pennsylvania, offers this program in New England and other regions to members of its customer rewards program, which is called "Wellness+." When a member achieves silver (500 or more points) or gold status, Rite Aid sends out a cover letter and a laboratory test requisition form.

The laboratory tests will be performed by **Quest Diagnostics Incorporated** and the lab test requisition form is signed by a physician associated with **Medivo**. The member/patient is asked for permission to release the laboratory test results to that customer's local Rite Aid pharmacist. Rite Aid then asks the member to call the pharmacy for the test results within two days.

Rite Aid has 4,671 stores in 31 states and the District of Columbia. Most of its stores are east of the Mississippi River. Rite Aid and Quest Diagnostics declined several requests to comment on this clinical lab testing program.

Once members of the Rite Aid Wellness+ program make enough store purchases and pick up enough prescriptions to achieve 500 points in the customer-loyalty program, they are eligible for free blood glucose and total cholesterol screening through a Quest Diagnostics laboratory.

Free Health Screenings

In one letter sent to members, Rite Aid President and CEO John Standley wrote, "Part of staying well is staying on top of your glucose and cholesterol levels. Unchecked, they can lead to diabetes and heart disease. Yet many people are unaware they are at risk."

Standley explained that one in five Americans is at risk of diabetes and one in three has borderline or high levels of cholesterol. He then urged Wellness+ members to take advantage of the free health screening.

To get the free clinical laboratory tests, members are instructed to follow three

instructions. *(See sidebar on facing page.)* After the specimen is collected, Quest Diagnostics will perform the tests and send the results to the Rite Aid store closest to the customer. This pharmacist will then contact the customer to discuss the laboratory test results with him or her.

Pharmacists Can Consult

It is not a surprise that Rite Aid recognizes the value of gaining access to the clinical laboratory test results of the customers who most frequently patronize their drug stores. With this knowledge, Rite Aid pharmacists can engage the customer in a consultation which can result in either a change in medication or a new prescription. It also creates the opportunity for the pharmacist to build a stronger personal relationship with a regular customer.

At a strategic level, Rite Aid's willingness to pay for free laboratory tests to screen its customers for glucose and cholesterol signals another threat and opportunity in the medical laboratory testing marketplace. For one thing, over the past two decades, in different states around the nation, the pharmacy industry has tried to get legislation passed that would expand the pharmacist's scope of practice to include laboratory testing.

Drug Stores And Lab Testing

Over these same years, the **College of American Pathologists** (CAP) and other laboratory medicine societies have opposed such bills, mostly with success. But the persistence of the pharmacy profession at introducing such bills demonstrates that it recognizes the clinical value and economic benefits of offering laboratory testing services to the customers who walk into their drug stores.

Thus, if Rite Aid's program of free lab testing proves successful, pathologists and lab administrators should expect to see Rite Aid expand the range of lab screening tests it offers to its Wellness+ members. That would allow its pharmacists to have discussions with customers about a greater number of medical conditions and the prescription drugs that would be used to treat these conditions.

As well, Rite Aid's competitors will be watching to see if this program is liked by consumers and generates a profitable volume of additional prescriptions. Both national and regional pharmacy chains will be ready to copy Rite Aid with their own free lab test screening programs.

For Quest Diagnostics, the Rite Aid relationship represents an opportunity to provide laboratory testing at more favorable prices than it gets from managed care plans. This business niche also comes with an added benefit: it is a client-bill arrangement and so collection costs will be minimal.

Free Tests And Inducement

Some pathologists and lab administrators may ask whether an offer of free lab testing to consumers might violate laws. Is there any inducement if the Medicare patient gets a free laboratory screening test and the pharmacy which paid for that free service then generates a prescription?

It must be assumed that the corporate legal departments at both Rite Aid and Quest Diagnostics took care to design this free lab testing program so that it fully complies with all applicable federal and state laws. As billion-dollar corporations with their respective Medicare licenses at stake, neither partner in this arrangement would want to run afoul of the various laws pertaining to anti-kickback and inducement.

What is true about the Rite Aid free lab testing screening service for its Wellness+ members is that it shows how alternate delivery channels for clinical lab testing are emerging. Other clever and never-before-seen arrangements by pharmacy companies that use lab testing as a hook to boost business are likely to follow.

Moreover, it is the changing dynamics in healthcare that encouraged Internet-based lab testing companies to spring up

Rite Aid's Wellness+ Members Can Get Free Laboratory Tests for Glucose and Cholesterol

FREE CLINICAL LABORATORY TESTS are offered to members of Wellness+, which is Rite Aid Corporation's consumer awards program, once they accumulate 500 points and achieve silver or gold status.

In the letter Rite Aid sends to members, they are asked to do the following steps. First, the letter said, visit Quest's website or call the toll-free number to find a local Quest lab or patient service center (PSC).

Second, Wellness+ members are to complete a consent form that is enclosed with the letter and told to bring it to the appointment at the Quest Diagnostics laboratory or PSC.

Third, the letter said, "Your health screening will be sent confidentially to your Rite Aid pharmacist within 48 hours. Simply give them a call to discuss or schedule a time to review in person."

Attached to the letter is a Quest Diagnostics requisition form. The requisition THE DARK REPORT saw includes the patient's name and unique patient identification number. The requisition is for:

- 483 Glucose;
- 334 Cholesterol, Total; and,
- 3259 Quest PSC Collection Fee.

On the Quest Diagnostics' website, 483 Glucose refers to CPT Code 82947, a glucose specimen; 334 Cholesterol, Total, refers to CPT Code 82465; and 3259 refers to CPT Code 36415, the draw fee at a PSC.

The form also instructs Wellness+ members to visit the Quest Diagnostics website and click on the "Make appointment" tab. There, under reason for testing, members should choose "Employer and wellness services," the requisition said.

Next, the requisition instructed members that, by signing the requisition, they are authorizing the release of their laboratory test results to a Rite Aid pharmacist "for the purposes of a consultation."

"I understand that by my voluntary participation in the Rite Aid sponsored wellness program, I am authorizing the release of my laboratory results in a confidential manner to a Rite Aid pharmacist for the purposes of consulting with me on those results."

Ordering Physicians

At the bottom of the requisition, just above the line designated for the patient's signature, the form lists four physicians under the heading "Ordering Physician." Each of the four physicians is listed as "a **Medivo** authorized physician."

One Medivo physician is for patients in California only, one is for patients in New York only, and one is for Pennsylvania only. The fourth physician is for patients in all other locations.

Medivo is a New York-based healthcare startup company that recently raised $7 million in funding led by **Safeguard Scientifics**, of Wayne, Pennsylvania, according to *BusinessInsider.com*. "It's a data and lab testing service company that connects patients to a network of physicians," said *BusinessInsider.com*.

"Medivo helps patients schedule everything from cholesterol to cancer tests," wrote *BusinessInsider.com*. "It gives patients easier access to lab testing services and breaks down the results in a way that's easy to understand. It was founded by doctors and entrepreneurs Sundeep Bhan, Destry Sulkes, M.D., and Jason Bhan, M.D."

and provide low-priced laboratory tests to the uninsured, the underinsured, and those individuals with high-deductible health plans who are motivated to save money. These are examples of how the pace of change in the laboratory testing marketplace is accelerating. **TDR**

—Joseph Burns

Book Review

New Lab Management Resource For Pathologists, Lab Leaders

"Laboratory Administration for Pathologists" offers comprehensive and up-to-date information

FOR PATHOLOGISTS AND OTHERS wanting to sharpen their skills in lab management and administration, there is a new resource. *Laboratory Administration for Pathologists* has just been published by the **CAP Press**.

It has been long-recognized within the pathology profession that university training emphasizes clinical knowledge and skills. Thus, most pathologists, as they finish their residency and fellowships, have not received the desired level of education in laboratory administration and management.

Three Authors

This new book is designed to help pathologists and others advance their understanding and skills in laboratory administration. This project is a direct result of the ongoing involvement of the three authors—each of whom is a pathologist—to teach pathology residents the essentials of laboratory management and administration. The three authors are:

- Elizabeth A. Wagar, M.D., Professor and Chair, Department of Laboratory Medicine at **University of Texas MD Anderson Cancer Center** in Houston, Texas;
- Richard E. Horowitz, M.D., Clinical Professor of Pathology at the **University of Southern California** in Los Angeles, California; and,
- Gene P. Siegal, M.D., Ph.D., Professor and Executive Vice Chair of Pathology at the **UAB Health System, University of Alabama at Birmingham**, in Birmingham, Alabama.

In the preface, the authors write that the purpose of the book is to provide pathologists and others "with an overview of the fundamentals of management and leadership" that are unique to medical laboratories. The book puts particular emphasis on the "specific role and responsibility of the pathologists in directing the laboratory."

The 14 sections of this book cover the range of responsibilities and activities required to manage a clinical laboratory. Seven other pathologists contributed to certain of these sections. The authors recognize the increased complexity of the modern laboratory. Not only is the technology utilized in lab testing more complex, but rapid advances in information technology and new management paradigms require a different administrative approach than what was common a decade ago.

Practical Knowledge

For pathologists and lab administrators wanting to advance their personal knowledge and skills, this book is organized as a practical and comprehensive guide. TDR

For more information about "Laboratory Administration for Pathologists" and to order this book, visit www.cap.org *and go to "CAP Press and Publications."*

Anatomic Path Insourcing Expected to Be Ongoing

Pathologists and lab executives surveyed affirm their belief that this trend will continue

CEO SUMMARY: Insourcing of anatomic pathology services by office-based physicians has been especially prevalent and is increasing among three specialties (gastroenterology, urology, and dermatology), according to a survey conducted last month. Survey respondents also indicated that the trend toward increased insourcing is so strong that it could spread to other specialty groups such as ob-gyns and oncologists. THE DARK REPORT and Blair & Company conducted the survey in October.

INSOURCING OF ANATOMIC PATHOLOGY by specialist physicians is a trend that is expected to increase during the next two years. That's one finding of a recent survey conducted jointly by THE DARK REPORT and **William Blair & Company, LLC**, of Chicago, Illinois.

This is not auspicious news for the nation's pathology laboratory companies. It also presents community hospital-based pathology group practices with a mixed market situation.

The findings of this national survey were published by **William Blair & Co.**, in a report authored by Amanda Murphy, CFA, and Sylvia Chao, and released on October 18, 2011. Earlier that same month, hospital-based and independent pathology/laboratory professionals were invited to participate in this survey. There were 212 total respondents and 124 fully-completed responses.

The trend of establishing in-office anatomic pathology (AP) laboratories is particularly strong among gastroenterologists, urologists, and dermatologists. This is due, in part, to a high volume of tissue specimens generated by these medical practices, as well as the relative ease of processing these types of specimens.

Murphy and Chao believe the trend toward increased insourcing is strong enough that it could spread to other specialty groups. "Most recently, we heard that some ob-gyn and oncology groups have looked to insource some testing, although it has not yet become as prevalent in these specialties because of the high volume of specimens necessary to make Pap smears profitable and the complex nature of oncology testing," they wrote.

In-Office Pathology Testing

"The overwhelming majority of survey respondents expect insourcing of anatomic pathology testing by office-based physicians to increase over the next two years," the report said. *(See figure 2 in sidebar on page 17.)* "This is the case across all three specialty areas: gastroenterology, urology, and dermatology."

The survey results show that 77% of the 124 respondents expect the trend to increase next year and 73% expect it to

increase in 2013. Of the 212 respondents to the survey, approximately 44% were independent laboratory organizations and 46% were hospital-based or hospital-associated laboratory organizations.

Murphy and Blair observed that, to benefit from AP testing-derived revenue, physician practices can build an in-house laboratory while still operating within the boundaries of the Stark self-referral law. The Stark law prevents physicians from referring healthcare services to providers or facilities in which the physician has a financial interest. An exception for in-office ancillary services allows physicians to offer such services as imaging, physical therapy, and medical lab testing in their own offices.

Leveraging Payment

Another approach for insourcing anatomic pathology testing services involves handling technical component (TC) and professional component (PC) in different ways. Physician practices can leverage payment structures whereby the physician group provides and bills for the professional component portion of the test (such as the slide reading) and has a laboratory perform the technical component, which is the actual cutting and staining of the tumor tissue.

One reason the trend of in-office anatomic pathology is expected to increase is that, across the nation, smaller physician practices are combining to form larger practices. The resulting larger groups are likely to develop their own in-office AP laboratories. Typically, a practice needs at least five or six physicians to justify the capital investment.

"Anecdotally, we are hearing about consolidation of smaller practices and a continued shift toward physicians actually building in-office laboratories (compared with just leveraging unique TC/PC payment models), particularly in dermatology," observed Murphy and Chao.

Insourcing is considered a major business threat by most of the laboratory industry. More than 30% of the survey respondents said physician insourcing was the biggest risk their laboratory organization will face over the next three years. In fact, these 30% of respondents rated the risk of insourcing by physicians to be greater than the risk of reduced payment from lower Medicare reimbursement.

The insourcing trend is so prevalent that it is affecting the nation's larger independent laboratory companies. While recent commentary from the two largest lab companies points to a moderation of insourcing in gastroenterology and urology, the survey results suggest insourcing is expected to continue in these medical specialty areas. It may be particularly strong in dermatology.

"The shift in AP test volumes to the physician office has weighed on independent lab volumes, particularly at **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**," wrote Murphy and Chao. "And recent commentary from the large labs suggests the rate of insourcing in gastroenterology and urology is beginning to slow, although most recently, there appears to be an increase in in-office laboratories within dermatology.

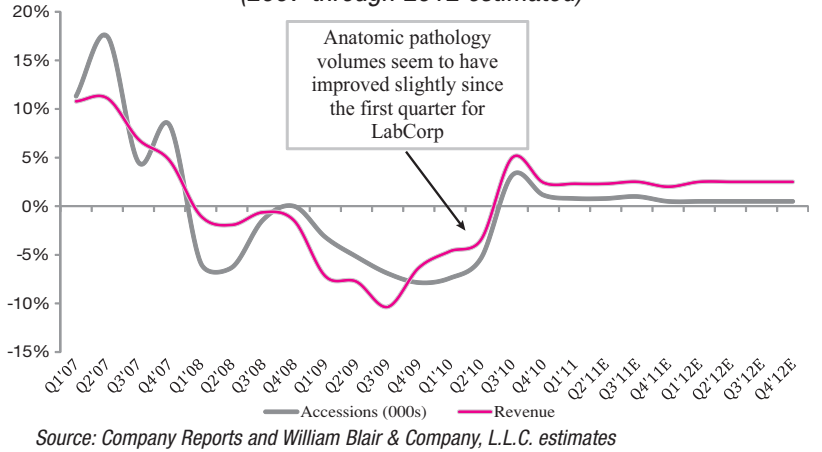
Labs See Decline in Volume

"Quest Diagnostics reported a 9% decline and LabCorp reported a 2% decline in anatomic pathology sales in 2010," continued the authors. "Consequently, we expect insourcing by physicians to weigh on lab volumes for the near future—particularly at Quest Diagnostics, which has higher exposure to anatomic pathology (at 14% of revenue for Quest versus 6% of revenue for LabCorp)."

In 2007 Quest Diagnostics acquired **AmeriPath, Inc.**, an anatomic pathology company that once held a substantial market share in dermatopathology. As a division of Quest Diagnostics, it now represents 14% of the parent company's revenue. Therefore, as the AP insourcing

Strong Belief in Lab Industry Survey that In-Office Pathology Trend Will Continue

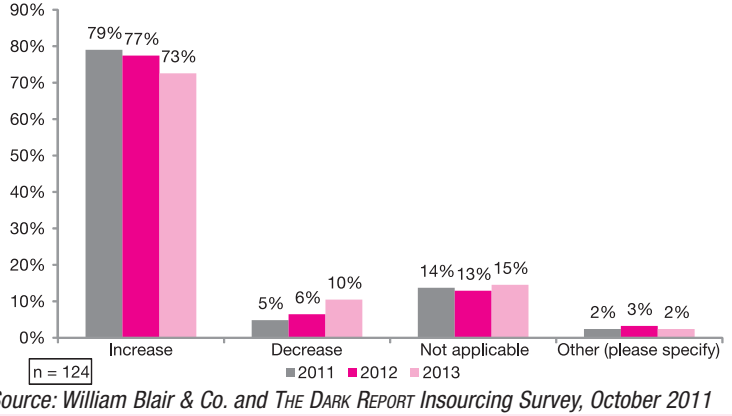
Figure 1: LabCorp's Histology Revenues and Volume Trends
(2007 through 2012 estimated)



Source: Company Reports and William Blair & Company, L.L.C. estimates

What may best summarize the findings of a recent survey of pathologists and lab industry managers are the two graphs presented here. Figure 1, above, shows the quarter-by-quarter increase/decrease in anatomic pathology accessions and revenue from 2007 through 2012 (estimated), as compiled by William Blair & Co. It is only in the past four quarters that LabCorp has seen a decline in AP specimens and revenue turn positive—but at annual growth levels under 5%. Figure 2, below, shows the expectations of the survey participants that office-based physicians will continue to insource anatomic pathology testing services. For the years 2011, 2012, and 2013, an overwhelming 79%, 77%, and 73%, respectively, of respondents believe this AP insourcing trend will continue.

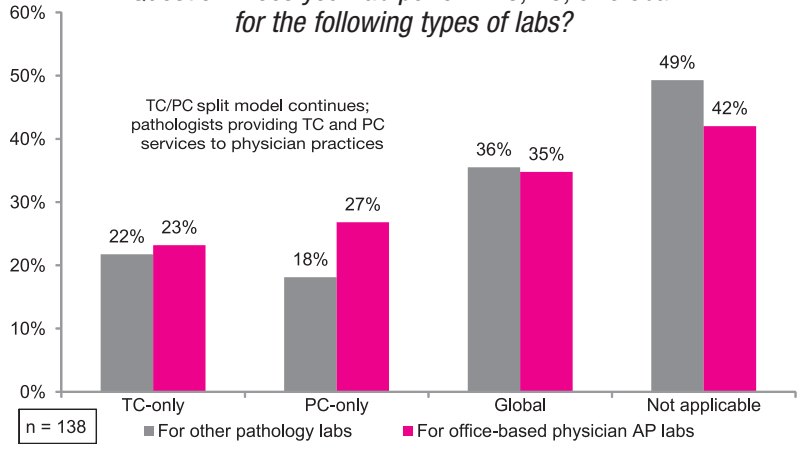
Figure 2: Anatomic Pathology Insourcing Survey
Question: How do you expect insourcing of AP testing by office-based physician practices to trend in the following years?



Source: William Blair & Co. and THE DARK REPORT Insourcing Survey, October 2011

TC/PC Arrangements May Be Widespread

Figure 3: Anatomic Pathology Insourcing Survey
Question: Does your lab perform TC, PC, or Global for the following types of labs?



Source: William Blair & Co. and THE DARK REPORT Insourcing Survey, October 2011

One finding of interest is that more pathology labs are willing to provide either or both TC and PC services to in-office anatomic pathology labs operated by specialist physicians. In THE DARK REPORT/Blair & Co. survey, 23% of the 130 respondents to this question indicated that they are willing to perform TC-only and 27% will provide PC-only services.

trend moves from gastroenterology and urology into dermatology, Murphy and Chao believe Quest Diagnostics could have a high portion of its existing AP revenue exposed to further insourcing.

"On its second-quarter earnings call, Quest indicated the company expects AP insourcing to continue to pressure volume through the remainder of the year," noted the authors. "Last year, Quest Diagnostics reported a 9% decline in AmeriPath revenue.

"While LabCorp stopped providing AP volumes data in the first quarter of 2011," they continued, "earlier quarterly data reports highlighted the negative impact that the shift in AP testing to the physician office has had on the company's volumes, predominantly in 2009 and early 2010.

"But then this year, LabCorp reported year-over-year growth in histology in the second quarter and appeared cautiously optimistic that the worst of physician AP insourcing could be over," added Murphy and Chao. *(See figure 1 in sidebar on page 17.)* "At some point, we believe the insourcing trend reaches a bottom (meaning all physician practices that have the capital and desire to insource will do so)."

Another significant finding of the survey involves how government health programs and private payers are reacting to the AP insourcing trend. While Medicare officials have scrutinized physician-owned anatomic pathology laboratories, more than 50% of survey respondents said they have seen no change in private payer reaction to stop or slow insourcing of anatomic pathology testing by specialty medical groups. TDR

Contact Amanda Murphy at 312-364-8951 or amurphy@williamblair.com; Sylvia Chao at schao@williamblair.com or 312-364-8654.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's an interesting window on the true uptake of telemedicine and Internet access. In Oklahoma, the cost of this subsidized service was $28 million in 2009. That cost climbed to $52 million in 2010. Of that total, $19 million was the cost of telemedicine. In Oklahoma City, *The Oklahoman* newspaper reported that the increase is blamed on the larger size of telemedicine files as they "changed from basic X-rays to more detailed MRIs, and large medical and laboratory reports." It was noted that even higher costs for this program are expected in 2012.

MORE ON: *Telemedicine*

Oklahoma state lawmakers are being asked to increase the amount of fees collected from telephone users that are used to subsidize this program that, among other things, funds free Internet access lines for public schools, libraries, and rural nonprofit medical facilities. The telemedicine links allow rural providers to access specialists and tertiary care centers so as to treat patients locally. Called the "Oklahoma Universal Service Fund," the program was authorized in 1997.

TRANSITIONS

• On December 1, Joseph Skrisson will become the Chief Operating Officer at **Dynacare Laboratories, Inc.**, in Milwaukee, Wisconsin. This Dynacare division is a laboratory joint venture that includes **Froedtert Hospital**, the **Medical College of Wisconsin**, and **Laboratory Corporation of America**. Skrisson has held excecutive positions at **Sparrow Health System**, **Piedmont Medical Laboratories**, and **Beaumont Reference Laboratories**.

• Pat Noland was appointed CEO of **StrataDx**, an anatomic pathology company located in Lexington, Massachusetts. Noland was formerly an executive with **Laboratory Corporation of America**, where, among other assignments, he served at **Dianon Systems, Inc.**

• **Ventana Medical Systems, Inc.**, announced that Gerardo (Jerry) Fernandez, M.D., is now the Medical Director for Ventana Digital Pathology. A pathologist, Fernandez has worked at **Aureon Biosciencs**, **Genzyme Genetics**, **St. Lukes-Roosevelt Hospital Center**, and **Beth Israel Medical Center**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 19, 2011.

Save the Date!

Executive War College

May 1-2, 2012 • Sheraton Hotel • New Orleans, Louisiana

for details, visit www.executivewarcollege.com

THE DARK REPORT

UPCOMING...

- ***Final Lab Companies Settle California Medi-Cal Whistleblower Lawsuit: What Comes Next?***
- ***America's Most Productive Health System Outreach Lab Program Shares Success Secrets.***
- ***Part Two of Interview with Aperio CEO Soenksen: Digital Pathology and the Myth of "Full Adoption."***

For more information, visit:

www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends