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Exclusive Coverage:
**Molecular Test Pricing Fiasco Means Many Labs Unpaid for Months!**
*Why payers weren't ready...*
*Best ways for your lab to respond...*

# 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

## Reimbursement System Fails Labs and Patients

There is confusion and disruption in the molecular testing sector of the clinical lab testing industry. That's because both government and private payers were not ready to process and reimburse for the 100+ new molecular CPT test codes on January 1, 2013.

That is the date when the Medicare program was supposed to be ready to handle these molecular test claims. As a result, many clinical labs and pathology groups across the nation have now gone as long as three full months without payment for these claims.

This is a major failure of the system and a situation that is unique in my memory. I cannot recall a time over the past 20 years when government and private payers have ceased to pay labs for an important range of CPT codes for a period now extending to 14 weeks!

Equally significant is the fact that both laboratory executives and lab billing experts do not have a clear understanding of the scale and scope of this situation. There is a vacuum of knowledge about this topic.

In fact, as you read the comments from lab professionals we interviewed for this issue, you will see for yourself that most of what they have to share is anecdotal. It is a combination of personal experience, hearsay, and conjecture.

Yet, this issue of THE DARK REPORT is believed to be the most comprehensive coverage yet published about the failure of both government and private health programs to pay laboratories on a timely, accurate, and fair basis for those molecular test claims covered by the new molecular CPT codes. Once again, THE DARK REPORT has stepped up in a unique way to provide you with valuable business intelligence you can use to protect the clinical and financial integrity of your laboratory until this crisis passes.

I'd also like to offer you a piece of advice. There is no better time to contact your elected officials in Washington, DC, than now—a moment in time when the **Department of Health and Human Services** and the federal **Centers for Medicare & Medicaid Services** each cannot deny nor explain away the consequences of its failure to properly implement the new molecular CPT test codes. Your elected officials need to hear directly from you about the negative consequences to patient care and the destabilizing effects to the nation's labs because of the bureaucracy's gross mishandling of this situation. TDR

# Payers Bollix MDx Codes, Labs Unpaid for Months

## Medicare contractors slow to create processes to reimburse for new molecular/genetic CPT codes

***CEO SUMMARY: Clinical laboratories complain that implementation of a new payment system for molecular tests has been a disaster since January 1. Most contractors for the federal Centers for Medicare & Medicaid Services have not paid labs for molecular tests billed this year. Billing experts indicate that many commercial plans are not paying either. Groups representing labs have asked CMS to make changes to the new payment system to smooth implementation and make it more transparent.***

CLINICAL LABS ACROSS THE UNITED STATES are facing a situation without precedent. They have now gone three full months into 2013 without payment from most federal contractors and commercial health plans for many types of molecular tests.

Blame it on the slow response by payers to the 100+ new molecular test CPT codes. Most contractors for the federal **Centers for Medicare & Medicaid Services** (CMS) have not paid labs for all these tests on invoices submitted this year, according to billing experts.

Because private payers typically follow Medicare's lead on payment issues, when the Medicare contractors stopped paying for molecular tests after December 31, some commercial plans stopped paying labs as well. That has left a large number of clinical labs and pathology groups without reimbursement for claims submitted since January 1, 2013.

CMS has heard complaints about this situation from the **California Clinical Laboratory Association** and the **American Clinical Laboratory Association**, among other groups representing labs. These lab industry groups have excoriated CMS about its failure to adopt a new payment system in time to implement reimbursement codes, thereby causing the three-month interruption in reimbursement to labs for these molecular CPT codes.

As this issue of THE DARK REPORT went to press, there was no news of a satisfactory resolution to this situation. Executives at several national billing companies say that labs may not see payment for these tests until next month, at the earliest.

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Faced with lower rates of reimbursement, one lab director said he laid off several staff members from his lab's staff and that —as a result of not being paid by Medicare contractors—had experienced a revenue shortfall of about $900,000 since January 1. His lab company had expected to receive about $1.5 million in revenue for its molecular tests during this period, but so far has received only about $600,000, he said.

## Complete Payment Stoppage

It is reported that a few Medicare contractors have made some payments for a few of the molecular CPT codes. But many clinical labs and pathology groups are reporting a complete stoppage of payments for these CPT codes.

One good source of market intelligence concerning this situation are the national pathology and laboratory billing companies. At **McKesson Corporation**, billing experts there say that April may be the earliest that pathology practices and labs can expect to see payments restarted for these molecular tests—but there are circumstances that may delay that event. McKesson serves hospital-based pathology and laboratory clients nationwide, so it has a broad perspective on this matter.

"Across all our clients, there have been only a few payments since the first of the year," observed Stephanie Denham, Client Services Director for McKesson. "Medicare contractors are not paying for molecular tests covered by the new CPT codes."

## Specific Contract Language

"One of our clients has a contract with one of the large private payers and that lab has been paid," she added. "But this contract has specific language stating that when a new code is used, the lab will be paid a certain percentage of the allowed amount. However, that is one of the few situations where a lab has been paid. We have not seen reimbursement from any of the Medicare contractors remitted to our lab clients."

"Each Medicare contractor is acting independently, and we believe they are trying to determine an appropriate payment amount for each test," explained Laura Edgeworth, CPC, Coding Compliance Director for McKesson. "But to date, we haven't seen real movement from any of the contractors to set fees for these tests or to make payments."

"Keep in mind that running molecular tests is costly for labs because they have to pay for staff, equipment, and reagent rentals," stated Leigh Polk, Business Support Services Director for McKesson. "Some labs refer these tests out to other labs, meaning they incur costs without getting any reimbursement. Labs continue to provide these molecular tests because of the need to support appropriate patient care."

## Rates Less Than Lab Costs

Earlier this year, the largest Medicare contractor, **Palmetto GBA**, was criticized for posting reimbursement rates for molecular rates that lab directors and pathologists said did not cover the costs of running the tests. Palmetto is the Medicare contractor serving the states of California, Hawaii, Nevada, North Carolina, South Carolina, Virginia, and West Virginia. *(See TDR, February 11, 2013.)*

Currently, Palmetto is asking labs to use what it calls a gap-filling process when submitting bills. The lab industry is critical of this process, claiming it to be confusing and time-consuming. On page 15, a Palmetto official comments on the current situation.

In a letter to CMS, ACLA President Alan Mertz said the new pathology codes were added to the CPT Manual last year but CMS waited a year to implement them, a factor that led to the problems affecting labs now. In that time, ACLA suggested that CMS should use the simpler and more transparent cross-walking method to set prices for the new molecular codes, but CMS rejected this suggestion, Mertz wrote. *(See sidebar on next page.)*

Now, pathologists are reporting that the low rates could put some labs out of

# ACLA Claims that Current Gap-Filling Process Used by Medicare Is Flawed in Significant Ways

**SERIOUS FLAWS EXIST IN A NEW GAP-FILLING** method used by Medicare contractors to set prices for more than 100 recently-adopted molecular CPT codes, according to a letter written by the American Clinical Laboratory Association (ACLA) to the federal Centers for Medicare & Medicaid Services (CMS).

Previously ACLA has expressed its concerns about the fairness and transparency of the gap-filling method, wrote ACLA President Alan Mertz, in a letter sent on March 27 to Marc Hartstein, Director of CMS' Hospital and Ambulatory Policy Group. Mertz stated:

*It now has been five months since the decision to use gap-filling for the new [molecular] codes was announced. Based on our interactions with the [Medicare] contractors who are pricing the tests, we continue to have the same concerns about the fairness and transparency of the process.*

Specifically, Mertz said CMS should instruct all Medicare contractors to release their data and methodologies to the public to show how they arrived at their pricing determinations. ACLA also suggested that CMS should convene an open forum to review the price-setting process for the remainder of the year, as well as respond to the many questions about gap-filling recently asked by lab directors and pathologists. The letter stated:

*As you will recall, the new pathology codes were added to the CPT Manual for 2012, but CMS delayed their implementation for a year so that it would have time to determine how best to implement them. During that process, ACLA urged CMS to use a cross-walking process to establish prices for the new molecular pathology codes, largely because it is the simplest and most transparent method for pricing the new codes and because these new codes represent existing well-established tests. However, in its November Notice of Final Payment Determinations, CMS determined that it would use the gap-filling process to price the new codes.*

*At that time, ACLA expressed concern about the significant workload involved in this task, the short time in which contractors had to price the new codes, the relative inexperience of most contractors with gap-filling and molecular pathology, and the potential for a negative impact on patient care.*

*This far into the process, it is increasingly clear that there are major problems with how gap-filling is proceeding. Even though we are less than a week away from when prices must be reported to CMS—and almost two years from the time when the codes were first announced—the process is still far from complete, and significant questions persist about how contractors arrived at the prices that they have posted.*

As of this date, CMS has not issued a public statement in response to lab industry comments about this situation.

business and that the gap-filling process is confusing and not transparent.

To help clinical labs and pathology groups understand the scope of this problem, THE DARK REPORT has interviewed a wide range of experts and lab executives on this matter. This entire issue provides the lab industry's first detailed coverage of this important and still-unfolding story. **TDR**

*—Joseph Burns*

*Contact Sandy Laudenslayer at Sandy.Laudenslayer@McKesson.com or 770-237-7820; Alan Mertz at 202-637-9466 or amertz@acla.*

# One Lab's Revenue Loss Due to CMS' Slow Process

## ➤Some private payers continue to reimburse for lab's molecular tests, while CMS pays nothing

***➤➤CEO SUMMARY: How is it that some commercial payers for one lab running molecular tests have continued to pay the lab for tests it has run this year, but contractors for CMS have so far failed to pay? That's the question one lab CEO is asking. Both the commercial payers and the CMS contractors are introducing new codes for molecular tests, this year. Yet some Medicare contractors have not paid for one test yet this year, the CEO said, while some of his lab's commercial payers have continued to pay on time.***

WHEN GOVERNMENT AND PRIVATE HEALTH PLANS cease paying for clinically-useful molecular diagnostic tests because of bureaucratic snafus, should clinical laboratories continue performing these tests in support of patient care?

Across the nation, many laboratories are asking this same question. At **Genelex Corporation** in Seattle, Washington, CEO Howard Coleman answered that question by continuing to serve client physicians who send patients' samples to Genelex because the test results are essential to patient care.

But then he paused to think about the question again. "Continuing to operate without income is a challenge," observed Coleman. "Every lab company has a responsibility to ensure accurate results and high quality service.

"At the same time, there are equally significant issues that must be considered," he added. "Is it appropriate to continue to offer the three molecular tests Genelex performs without reimbursement? Genelex has a staff of 60 employees and just this year we've laid off three staff members because Medicare stopped paying. These are real human issues and the fiscal solvency of some laboratory companies are likely at stake."

This situation exists because the federal **Centers for Medicare & Medicaid Services** was not prepared to handle claims for tests covered by the new molecular CPT codes on the effective date of January 1, 2013. This has affected every clinical lab and pathology group across the United States that performs molecular tests covered by these CPT codes.

### ➤Financial Pain For Labs

In some cases, the financial pain to certain clinical labs has been substantial. Lab employees have been laid off or terminated. With expected revenue—legally due the labs for the claims they have submitted—going unpaid for more than three full months, there is also the question as to whether some labs can survive until CMS begins issuing reimbursement for this already-sizeable and still-growing backlog of molecular test claims.

# Genelex CEO Recommends Lab Leaders Take Direct Action to Correct Current Situation

**WHAT TO DO ABOUT THE MESS** associated with pricing for the new molecular CPT codes? That may be the most pressing question now facing pathologists and lab executives in lab organizations throughout the United States.

Labs offering these molecular tests have now gone more than three months into the current year without payment from the Medicare program. For some, this lack of payment has placed their labs in financial jeopardy.

"This is a crisis, particularly for labs like ours that only offer molecular assays defined by the new CPT codes," declared Howard Coleman, CEO of Genelex Corporation in Seattle, Washington. "This is a time for lab directors and senior corporate leaders to get involved in addressing this situation and work toward a positive and speedy resolution.

"The first step is for lab directors and managers to engage with our industry trade associations to understand the issues and press for answers," Coleman suggested. "Many lab executives are not familiar with the political process and how to go about working for change.

"As a laboratory executive, you have to get in the trenches, make noise, and communicate directly with the officials involved," he continued. "Doing so can be a cost-effective way to deal with similar situations. You don't do this work by choice, but when you have to save your company, there is no one else you can trust to be as thorough and persistent as you will be."

Over the years, Coleman has gained valuable experience in government relations on behalf of Genelex, the **Washington Biotechnology and Biomedical Association**, and other organizations.

"Once it became clear in early January that this was going to be a problem, I've been as active as anyone–particularly at the CEO level–in providing leadership to deal with this," he explained. "I also organized a small coalition of labs concerned with molecular CPT codes that were hit the hardest."

Coleman has informed members of the state's congressional delegation about the problems labs face. He is working with trade associations such as the **American Clinical Laboratory Association**.

"I also wrote a letter to acting CMS administrator Marilyn Tavenner to explain the problem from the lab industry's perspective," noted Coleman. Later this month, he plans to meet with CMS officials in Baltimore. "I'd like to find out how this is going to be handled going forward because there are many questions as to how this is going to play out over the rest of this year," concluded Coleman.

At Genelex, the last payment it received from CMS was back in January. That is when CMS paid the last of the claims from the molecular tests that Genelex had submitted through the end of 2012. Since January 1, CMS has not paid Genelex for any of the almost 2,000 claims it has submitted this year.

"It would be easy to stop doing these tests because Medicare isn't paying us," explained Coleman. "But our management team here recognizes that this is really about patient care. The results of these molecular tests are too important to patients and physicians. We want to continue providing these tests in support of more accurate diagnoses.

"We started this business in 2000 and only reached break-even in the past three years," he noted. "We've stayed with it this

long because these tests contribute greatly to patient care, especially for older, sicker patients who are on a lot of medications.

## Testing To Improve Health

"By identifying what is going on with people's medications, it is possible to change their lives for the better," stated Coleman. "We have the most advanced diagnostic technologies for doing that.

"Our services include sophisticated medication management software and staff pharmacists to assist doctors with their interpretations," he continued. "Our test menu is made up of just these three Cytochrome P450 tests.

"Labs like ours are being hit in two ways," he added. "Not only is CMS reducing what it pays in 2013, it is also taking a very long time to revise its bill-paying procedures. Effectively, that means Genelex has no revenue from CMS for the year-to-date.

"By contrast, some commercial health plans are paying our claims," he noted. "Several payers asked Genelex to resubmit some bills because the health plans are working with new CPT codes required by the **American Medical Association (AMA).**

***"Labs like ours are being hit in two ways," he added. "Not only is CMS reducing what it pays in 2013, it is also taking a very long time to revise its bill-paying procedures. Effectively, that means Genelex has no revenue from CMS for the year-to-date."***

"Payers required use of these new codes this year. That's fine with us," said Coleman. "We understand why they would do that. We also understand that—when there are new codes—there is sometimes a period of adjustment. So, when we were requested to resubmit some claims, we did that. The commercial health plans have eventually paid most of those bills.

"But the Medicare contractors have paid nothing for our three molecular tests," he said. "Our testing is limited to only three Cytochrome P450 tests. They are CYP2C19 (CPT code 81225), CYP2D6 (CPT code 81226), and CYP2C9 (CPT code 81227).

"When we inquired about when we would be paid, it took a while and we didn't get a straight answer at first," he said. "Our billing department is very thorough and had been communicating with our contacts at **Noridian**, which is our Medicare contractor. But they had no success.

"It took a call from our attorney to officials at CMS to find out what was happening," explained Coleman. "Originally, Noridian told us it was a software glitch with no information as to when they would be paying. After our attorney called CMS, we learned Noridian had never intended to pay until April 1 and that doesn't seem like a software glitch at all.

## May See Payments In April

"It turns out there was a problem setting prices for the new molecular costs. Now that they are about to announce new prices, we expect to get paid sometime this month [April]," he stated. "We have already resubmitted all of our CMS claims, almost 2,000 of of them. Typically claims get paid in a couple of weeks. So we are hopeful we should be paid by the end of the month. We'll see."

Since several commercial health plans have used new codes and paid most of Genelex's claims this year, Coleman draws a distinction between how CMS has responded to the introduction of new codes and the way private payers have responded.

"Most of our private insurers have paid our lab test claims without interruption—although our appeals have gone up because of the new codes," stated Coleman. "But that's to be expected. The

appeals slow down cash flow a bit, but we have a good process for appeals and we follow up on each one.

"On the other hand, CMS has made a hash of it," noted Coleman. "In May 2012, CMS announced in the *Federal Register* that it would announce new prices in September, 2012. That announcement was never made.

"In November 2012, CMS ordered their Medicare contractors to use the gap-filling process for the 100+ new molecular codes," he stated. "Gap-filling is almost never used because it's so difficult. Also, the process is opaque and that makes it impossible to know how CMS determined what it should pay for each of these CPT codes and be able to comment meaningfully.

## Straightforward Test Pricing

"The process to identify the proper price for each test could be relatively straightforward," he explained. "What's needed is someone familiar with molecular diagnostics and a couple of good cost accountants. Next, have labs complete a form or an application that explains how each lab does its cost accounting for each molecular test.

"That would not be difficult to do and it would be transparent, allowing lab directors and pathologists to comment," he said. "Since there are only 104 new molecular CPT codes currently on the clinical lab fee schedule, a process like this would simply take time and effort."

## Painful Consequences

The experience of Genelex in not getting paid by Medicare contractors since January 1, 2013, demonstrates the disruption that labs are suffering because the Medicare program was not prepared to implement payment for the new molecular CPT codes as of that date. This is a case study of the painful consequences that laboratory providers are enduring as a result of this situation.

At this point, it should be noted that CMS officials and the Medicare contractors are scrambling to resolve this situation. In the days before publication, Coleman notified us that some Medicare contractors had posted revised prices on or after April 1, and that these prices were much closer to the prices paid for code-stacked claims during 2012. TDR

*—Joseph Burns*

*Contact Howard Coleman at 206 826-1970 or hcoleman@genelex.com.*

## CMS Contractors Slashed Prices for Certain Codes

**IN FEBRUARY AND MARCH,** several Medicare contractors announced pricing for molecular test costs for this year. The level of reimbursement caused concerns throughout the clinical lab industry.

The table below shows the 2012 Medicare Code Stack Reimbursement for several cytochrome P450 tests. Labs were paid at that level during 2012.

Next are presented the 2013 pricing for these same molecular CPT codes by three different Medicare contractors, as first posted by each contractor earlier this year. In recent weeks, the three Medicare contractors have posted different prices that, in most cases, are about 80% to 90% of the 2012 code stack reimbursement.

These three molecular assays are relatively high volume tests for the laboratories which offer them to physicians.

### Examples of First Prices Posted by Three Medicare Contractors

| CPT CODE: | 81225 | 81226 | 81227 |
|---|---|---|---|
| ASSAY: | CYP2C19 | CYP2D6 | CYP2C9 |
| *2012 Median Code Stack Price* | **$379** | **$563** | **$344** |
| *Noridian* | $121 | $132 | $87 |
| *Palmetto* | $135 | $148 | $50 |
| *Cahaba* | $305 | $50 | $50 |

*Source: CodeMap, LLC, Schaumburg, IL*

# How CMS 'Mismanaged' Pricing of Molecular Tests

## ➤Critic says actions by CMS and its contractors are harming smaller labs that run molecular tests

***➤➤CEO SUMMARY: CMS and its contractors had ample opportunity to implement a new reimbursement system but failed to act in a timely manner, stated an expert familiar with the problem. The result is that laboratories, particularly those that have one or two proprietary molecular tests, are being harmed needlessly, he said. Without regular payments for molecular test claims, some smaller lab testing organizations may end up in such deep financial holes that they cannot recover, even when back claims are paid.***

WHY HAVE THE FEDERAL GOVERNMENT'S efforts to revise molecular test payments failed this year? The answer, according to a former federal health policy official, is simple: bureaucratic mismanagement.

That's the opinion of Scott Gottlieb, M.D., a former senior policy advisor for the federal **Centers for Medicare & Medicaid Services** (CMS) and a Clinical Assistant Professor of Medicine at **New York University School of Medicine**. Gottlieb made these comments in his column for *Forbes Magazine* titled: "Medicare Has Stopped Paying Bills for Medical Diagnostic Tests. Patients Will Feel the Effects." *Forbes* published this column on April 1.

In his Forbes column, Gottlieb wrote about how CMS has mismanaged the introduction of a new lab test reimbursement system. In so doing, it is harming diagnostic laboratories, particularly those running only one or two molecular tests.

Gottlieb then explained how CMS and Medicare contractors have not paid labs for molecular tests since January 1, 2013, and that this failure has nothing to do with automatic budget cuts under the sequester that Congress and President Obama agreed to last year.

Gottlieb can speak knowledgeably on this subject because he has worked on both sides of the table. Currently, he is a practicing physician of internal medicine and a board member for two lab companies. In past years, Gottlieb served in various positions at the **Food & Drug Administration**.

### ➤A Positive Reaction

When his comments were published, experts in clinical laboratory reimbursement generally hailed the article for explaining the problems to a wide audience. "Bravo to Dr. Gottlieb for so clearly describing the issue and its effect, and for pointing out the MoPath repricing not only affects labs, it also impacts patients," said Lâle White, Executive Chairman and CEO of **XIFIN, Inc.**, a company that specializes in revenue cycle management for diagnostic laboratories. *(See pages 12-14 for all of White's comments on this situation.)*

In an interview with THE DARK REPORT, Gottlieb described the disruption

this situation is causing to a large number of clinical laboratory organizations. "Labs are getting squeezed, particularly those labs that have maybe one or two proprietary tests that they're billing under some new codes that aren't getting reimbursed yet," explained Gottlieb.

"The problem for these labs is they can't bridge themselves—meaning to obtain a short term or bridge loan," he continued. "A big laboratory company, like **Quest Diagnostics** or **LabCorp**, can bridge itself. But those labs that perform a limited menu of molecular tests and need a six-month loan, might not be able to do so.

"The issue is that all of this was entirely unnecessary," Gottlieb said of the problems CMS created. "Whatever you want to argue about the reimbursement scheme under code stacking, CMS had ample time to get a new reimbursement structure in place for the molecular tests that had been billed using code stacks."

As a member of the board of directors of both **Combimatrix, Inc.**, and **American Laboratory Partners**, Gottlieb fully understands how the clinical laboratory industry works. Yet, like most observers, he has only anecdotal evidence as to how that lack of payment for molecular tests is hurting labs.

## Uncertainty for Small Labs

"Those labs that have only a few molecular tests may be unprofitable," he noted. "But now they face increased financial instability because they have no revenue as well. That also has some venture capital companies worried about their investments in diagnostics.

"If a professional investor has invested in unprofitable diagnostic testing companies that haven't had any revenue for three months, how does he or she make that up?" asked Gottlieb. "That investor would neet to tap his/her venture capital syndicate or get a bridge loan if one is available.

"But the cost of capital is exceedingly high," continued Gottlieb. "Even if those lab testing companies continue to be going concerns, they have no capacity to invest in new technology right now.

"Almost every venture firm has at least one of the molecular diagnostic companies in its portfolio that is experiencing this problem," he said. "However, what investor would make a new investment in this environment? There's too much uncertainty and that uncertainty probably will not be resolved for a while. If there is no certain date for when these billing issues will be settled, that could be the worst possible outcome because it creates more uncertainty.

## No Tolerance for No Payment

"To a certain degree, the market for investments in diagnostic testing companies can tolerate reduced reimbursement,' stated Gottlieb. "But the market can't tolerate the fact that these companies are not getting paid at all!"

While CMS played a significant role in creating these problems, commercial health plans also contributed—as did clinical labs themselves, to a degree. That's because use of stack codes made it difficult for public and private payers to know exactly what type of molecular test they being asked to pay for.

"Some laboratories were more adept than others at gaming the code-stacking process," Gottlieb conceded. "But it's hard to be sympathetic to the payers who complained that they didn't have any transparency about what they were paying for. They certainly had enough leverage to demand more information from labs and yet they didn't do that. Instead, commercial payers sat on their hands waiting for CMS to implement a new reimbursement scheme. Now they'll piggyback on what CMS does." TDR

*—Joseph Burns*

*Contact Scott Gottlieb, M.D., at Scott.Gottlieb@gmail.com or 202-270-1991.*

## Letter to the Editor

# Medicare Taken To Task about Molecular Test Pricing Method

**EDITOR'S NOTE:** Submitted by Lâle White, CEO of **XIFIN, Inc.**, of Carlsbad, California, this letter describes the problems caused by the Medicare program's failure, as of January 1, 2013, to be ready to process and reimburse lab test claims for more than 100 new molecular diagnostic CPT codes.

***Dear Editor:***

*Everyone should read Scott Gottlieb, M.D.'s* Forbes *article published on March 27, 2013, and titled: "Medicare Has Stopped Paying Bills for Medical Diagnostic Tests. Patients Will Feel the Effects." I can only say, "Well put!"*

*Bravo to Dr. Gottlieb for so clearly describing the issue and its effect. He points out how the Medicare program's current struggles to properly handle repricing of the new molecular diagnostic test CPT codes not only affect labs, but it also impacts patients.*

*What strikes me most about the entire "process" now in use by the Medicare program is the lack of transparency and the feelings of poor faith that blanket the proceedings.* ***Palmetto GBA*** *took the lead on the pricing front and asked for laboratory input and feedback about its pricing. It then proved reluctant to engage in any conversations about its methodologies or how laboratories have been coding their tests.*

*When the* ***California Clinical Laboratory Association*** *(CCLA) issued a press release warning that the molecular diagnostic test prices first announced by Palmetto could bankrupt California genetic labs, Palmetto directors responded with hurt and surprise.* [See TDR, February 13, 2013.]

*Again, at this time, Palmetto officials asked CCLA and clinical laboratories to work with them to sort out the pricing. Yet when CCLA members responded with the test pricing and cost data that Palmetto requested, Palmetto "went to ground" and failed to respond to repeated requests to discuss the data and findings.*

*Instead, Palmetto issued notice that it would provide new fee schedule updates by April 1st. On April 3rd, when prices were finally released, there was some improvement, but the top volume tests continue to be below expectations and—in some cases—below cost.*

*Once the revised rates were released, Palmetto pushed back to subsequent industry requests for dialogue under the premise that future comments should be directed at CMS. However, Palmetto had previously agreed to continue their review and discussion about industry-submitted data through the month of April and until the deadline when CMS requires it to publish pricing as a precursor to the CMS comment period.*

*CMS and contractors are demanding transparency to molecular services for which payment is being sought. But they seem unwilling to reciprocate regarding their processes or how they evaluate and pay for these services.*

*It was this very problem within government programs that resulted in the establishment of negotiated rule-making guidelines which finally provided industry with transparency and government programs with accountability. It would be a disservice to healthcare and the general public good to take a step backwards at this critical time in a transitioning healthcare delivery model.*

*The gap-fill process requires a level of interaction with providers to analyze data needed to adequately conduct the exercise. The truth is that gap-filling is a technique for establishing prices that is data intensive and time consuming. It requires significant collaboration between parties,*

*both payers and providers, to make sure all data is properly submitted—and more importantly—properly vetted and interpreted.*

*Palmetto knew and understood that it was not feasible to properly complete the gap-filling process in a timely manner for over 100 tests, Palmetto defaulted to a cross-walking process and led labs to believe it was following the proposed recommendations of the* ***American Clinical Laboratory Association*** *(ACLA).*

*Palmetto then cross-walked primarily the highest volume tests. But Palmetto officials failed to disclose that their starting point for the cross-walk was an internal, unjustifiable, and arbitrary down-coding of the previously submitted stacking codes in a manner that was neither disclosed to labs nor supported by coding experts.*

*Once labs were informed of this—albeit with no details—they provided methodology and justification for their prior coding, vetted the coding through premier industry coding experts, and provided cost information to Palmetto. In return, the collective lab industry asked only for collaboration and transparency.*

*Instead, Palmetto released prices on April 3rd that only continued to reflect the contractor's bias for using the pricing exercise to cut reimbursement on these critical services. This sentiment has been expressed by Elaine Jeter, M.D., Palmetto's Medical Director, in numerous presentations where she has asserted that technology advances have reduced the cost of performing these tests. This same sentiment was repeated by Marc Hartstein, Director, Hospital & Ambulatory Policy for CMS at an ACLA conference on April 3rd.*

*While there continues to be technology improvements in molecular diagnostics and genetic testing, these advances do not all represent testing with superior clinical specificity. Nor are 100% of these technology improvements commercially accepted.*

*This is evidenced by the cost data provided by labs performing the services to Palmetto. If labs could have adopted less costly methodologies even while obtaining higher reimbursement, they surely would have done so if quality of services was not at stake.*

*Both Palmetto and Marc Hartstein publicly blamed labs for not providing data, knowing there was an impending pricing exercise. However, exactly the opposite was the case, because those labs in Palmetto's jurisdiction who meet with the contractor quarterly have provided a high level of data though Palmetto's MolDx program.* [See TDR, November 28, 2011.]

*Since mid-2012, these same labs have regularly asked what additional data would be needed for gap-fill. They have also asked how they could work with Palmetto, only to be told by Palmetto that the contractor possesses the necessary data to adequately complete the exercise.*

*Next, the consistencies in messaging between Palmetto and CMS appear to reflect a more coordinated effort to reduce rates then either party is willing to admit. However, regulatory guidelines do not support this approach to cutting costs. In the end, the laboratory testing industry will need to assert its rights under established rules in order to obtain equity.*

*With so much at stake, it is in all our interests to keep lines of communication open to create a fee schedule that makes sense and has a defensible methodology behind it. As we explained in our blog* [http://www.xifin.com/resources/blogs], *Congress requires CMS to explain its rationale for payment amounts; this requirement for transparency is needed at the contractor level to allow advice and comment by stakeholders.*

*Because laboratories,* in vitro *diagnostics manufacturers, and diagnostic industry advocates are unable to replicate any of the price points established by Medicare contractors to date, the lack of a transparent and thoughtful process is likely to create more stonewalling. That is, at least until CMS or the contractors are forced to begin communicating more openly as required by section 1833(h)(B)(iv) of the Social Security Act.*

*This is an issue with serious consequences, starting with patients who may lose access to essential and unique molecular diagnostic tests. It*

# Estimated 2013 Prices Based on Gap-fill Rates For Selected New Molecular Test CPT Codes

This table shows how 2013 reimbursement is on track to be significantly less than 2012 reimbursement for the new molecular CPT codes. The data for Quest Diagnostics and LabCorp represent estimates of what these companies were paid under 2012 stack codes. The other columns show prices posted by Medicare contractors since January 1, 2013. The notes below the table explain sources and other relevant information. Among other things, this table demonstrates how Medicare contractors are reducing 2013 prices relative to estimates of 2012 stack-code pricing.

| CPT Code | Test | Quest[1] (Stack) 2012 | LabCorp[1] (Stack) 2012 | Cahaba[2] 2013 | Palmetto[2] 2013 | Noridian[2] 2013 | CodeMap National Average |
|---|---|---|---|---|---|---|---|
| 81210 | BRAF | $259.10 | $53.00 | $123.00 | $57.51 | $51.47 | $63.43 |
| 81220 | CFTR | 1,132.82 | 1,174.62 | 1,200.00 | N/A | N/A | 1,200.00 |
| 81225 | CYP2C19 | 75.88 | 349.40 | 305.00 | 135.26 | 121.06 | 151.23 |
| 81235 | EGFR | 301.92 | 533.48 | 123.00 | 116.25 | 104.04 | 112.61 |
| 81243 | FMR1 | 348.50 | 637.49 | 123.00 | 60.51 | N/A | 77.55 |
| 81255 | HEXA | 378.82 | 349.40 | 123.00 | 93.90 | N/A | 93.36 |
| 81257 | HBA1/HBA2 | 183.22 | 230.70 | 235.00 | 183.22 | 163.98 | 181.61 |
| 81261 | IGH | 153.80 | 248.76 | 305.00 | 148.12 | 132.57 | 159.38 |
| 81275 | KRAS | 212.64 | 265.64 | 235.00 | 225.88 | 202.16 | 207.40 |
| 81292 | MLH1 | 930.52 | 2,147.96 | 650.00 | 803.28 | 718.94 | 746.62 |

*Sources: "2013 Medicare Gap-filling for Molecular Pathology (MoPath) Codes: Cahaba GBA and Palmetto GBA Fee Schedule Amounts Released," Quorum Consulting, San Francisco, February 1, 2013; and CodeMap LLC, Schaumburg, Illinois.*

**Note 1:** Amounts for Quest Diagnostics and LabCorp in 2012 represent estimates only of what these lab companies received from Medicare contractors based on the CPT code stacks used to bill for each test in 2012 and the National Limitation Amounts (NLAs) for each code on Medicare's 2012 Clinical Lab Fee Schedule. These amounts may not represent the actual payment amounts Quest and LabCorp received in 2012.

**Note 2:** Prices are estimated payments based on gap-fill rates posted by Cahaba and Palmetto and are from Quorum Consulting February. 1, 2013, and from Noridian on April 12, 2013. CodeMap national averages were collected from *www.codemap.com* on April 12, 2013.

*also includes physicians who find themselves unable to order and use these diagnostic assays to improve patient outcomes and to reduce the cost of healthcare. The current coding and rate structure also discourages the enhancement of these assays through the addition of variants that increase their clinical utility.*

*For medical laboratories across the country, the request for relief is simple. So long as labs continue to struggle with inconsistent feedback from individual Medicare contractors, and so long as CMS remains mute on the issue of dramatically reduced fee schedules, unpublished pricing, and even software glitches that prevent claims from adjudicating, the threshold for how long molecular diagnostic providers can survive with severely reduced cash flow is being callously tested.*

*Our advice to impacted laboratories is to remain vocal in your appeals, and to stay active in laboratory associations like CCLA and ACLA.*

*Yours truly,*
*Lâle White, CEO, XIFIN, Inc.*

**EDITOR:** An expert in laboratory coding, billing, and collections, over the past two decades, Lâle White has participated in a number of national advisory committees and panels.

MoPath Pricing Update

# Palmetto: 'We Are Processing & Paying Clean Claims Without Undue Delay'

*Medicare contractor says it established gap-fill pricing on January 31 and any delay to labs 'was minimal'*

SEEING THAT **PALMETTO, GBA**, the nation's largest Medicare Administration Contractor, seems to be at the center of the controversy over how Medicare is to pay for molecular pathology (MoPath) tests, THE DARK REPORT sent a list of questions to Palmetto Vice President Mike Barlow. Here are the questions and his answers.

**Q:** *Is it true that Palmetto has not paid any labs for molecular tests on invoices submitted this year?*

**A:** As of January 31, we established the gap-fill pricing for the majority of MoPath codes and have been processing claims. As these new codes and their pricing were effective for DOS 1/1/2013 and later, the delay to the labs was minimal. Some Tier II codes affecting a smaller sub-set of claims were manually priced until the gap-fill analysis was completed.

**Q:** *If no payments have been made, what is the reason for the delay?*

**A:** This isn't applicable to us, but all Medicare contractors had to establish gap-fill pricing in order to process the new MoPath Tier I and Tier II codes.

**Q:** *Is there a law that says MACs must pay all clean claims within 30 days?*

**A:** It is a performance requirement to process clean claims timely, but not a law. Any clean claim paid after 30 days includes interest payments.

**Q:** *What percentage of the total invoices submitted to Palmetto for molecular tests since January 1 have been paid to date?*

**A:** Unfortunately, we're unable to provide that level of detail. But, we can share that Palmetto is processing and paying clean claims without undue delay.

**Q:** *When can labs expect to be paid in full for molecular test invoices submitted since January 1?*

**A:** Again, not applicable to us as we're processing and paying clean claims without undue delay.

**Q:** *Has Palmetto posted all prices for molecular tests?*

**A:** We've priced and published all Tier I/II codes with claims in our processing jurisdictions. Some unique 'panels' and other combinations, which will need to be submitted using NOC codes, are being finalized this week. We're in direct communication with those laboratories.

**Q:** *Will Palmetto revise prices posted so far or are they final for the year?*

**A:** The gap-fill process includes a CMS posting for comment and we will review the comments. Any data submitted that might require reconsideration could result in revised pricing.

**Q:** *Is Palmetto setting prices for all the MACs nationwide?*

**A:** We're only responsible for establishing gap-fill pricing for our jurisdiction. We've used the data available through our MolDX program to facilitate our review. We've also shared our pricing with the other MACs. But, it's important to remember that each MAC is to conduct its own review process and submit to CMS for consolidation. TDR

# Experts Say Labs May Start to Receive MDx Payments

## At least seven Medicare contractors have posted prices for molecular CPT codes online

***CEO SUMMARY: In the fourth month of the current year, there is plenty of confusion and uncertainty over how the Medicare program will establish prices for the new molecular CPT codes and when both government and private payers will begin to regularly reimburse laboratories. As of this date, even lab billing experts and lawyers are forced to rely on anecdotal evidence as to the current state of affairs. That leaves most clinical laboratories and pathology groups with few options, except to "sit, watch, and wait."***

At the moment, all across the country, clinical laboratories and pathology groups are in a state of uncertainty as to both the level of reimbursement that will be paid for each of the new molecular CPT codes and when payments for these claims will begin.

Since January 1, the nation's Medicare Administrative Contractors (MACs) have been trying to determine how much to pay for the molecular assays that fall under the 100+ new molecular test CPT codes assigned to them this year. Seven MACs (**Cahaba GBA**, **Cigna Government Services**, **Noridian Administrative Services**, **NGS**, **NHIC Corp.**, **Novitas Solutions**, and **Palmetto GBA**) have posted prices on the web for some of the 104 tests, one expert said.

### MACs Still Posting Prices

When it comes to posting prices, the MACs seem to fall into two categories. One group of MACs has yet to post a single price for any of the new molecular CPT codes. Another group of MACs has posted prices for at least some of the new molecular codes. Lab billing experts were aware of only one MAC (Cahaba) that had posted prices for all of the new molecular CPT codes, as of this date.

As a result of posting these prices, it is believed that those MACs are making payments now or will do so soon, perhaps by April 30, some billing experts told The Dark Report.

### Uncertainty Over Payment

Yet, most clinical labs that provide molecular testing services have no certainty about when or how much they will be paid. Some labs are being paid for some tests but not for other tests. Some labs are not being paid. Some labs are being paid, but they're getting less than they expected. Many labs do not know when they will be paid for molecular tests run this year.

Most laboratories and organizations that represent labs are unsure about when clinical laboratories and pathology groups can expect to be paid for molecular diagnostic tests. It's almost as if luck—either good or bad—is playing a big role in whether or not an individual lab organization is getting payments for its molecular test claims.

# Labs Can Use CodeMap Site to Post Rates And See What Other Labs Have Been Paid

**ONE PERSON WHO MAY HAVE THE BEST VIEW** of what's happening in each Medicare jurisdiction is Gregory Root, Chief Operating Officer and General Counsel of **CodeMap, LLC**. CodeMap is a company in Schaumburg, Illinois, that posts lab test payments online. The site is: *www.codemap.com*.

Labs that have been paid can go to the web site and post the rates they have received. CodeMap then computes an average rate for each test. As of last week, CodeMap had posted rates from four MACs: Cahaba, Noridian, Palmetto, and CGS, stated Root. CGS serves Kentucky and Ohio.

"From what we've heard, those clinical labs that only do molecular testing are getting hit pretty hard," observed Root. "But it's important to emphasize that no Medicare contractor has said that labs won't be paid. It's just that they haven't been paid yet.

"As of last week (April 12) three clinical lab organizations had posted the molecular test fees that they had been paid on the CodeMap site," reported Root. "As more Medicare contractors pay molecular test claims, labs will have a chance to update the site and thus help answer many of the questions that are going unanswered now."

"What we've heard is that not all labs are being paid," said Genevieve Tang, Associate Director, Strategic Product Planning, at **Quorum Consulting**, a strategic pricing, reimbursement, and health economics firm in San Francisco, California. "Overall, the view is murky right now.

"Until we get more definitive information, it will be hard to say which MACs have been paying and which haven't been paying," she added. "In general, we're finding that the majority of the MACs are not paying for molecular tests.

"In fact, as of this date, only three MACs—Cahaba, Noridian, and Palmetto—have released payment rates for all or most of the new molecular codes," she said. "The other MACs have released rates for only a handful of codes.

## New Process for New Codes

"Both Cahaba and Noridian have communicated to laboratories that they will pay for molecular pathology tests by the end of the month," she commented. "However, I don't believe any laboratories have yet to receive reimbursement checks from Cahaba or Noridian."

Cahaba serves Alabama, Georgia and Tennessee. Noridian serves Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming. Palmetto is the largest MAC and serves California, Hawaii, Nevada, North Carolina, South Carolina, Virginia, and West Virginia.

## Billing For Molecular Tests

"Palmetto has instructed labs not to bill for tests that are not yet priced," Tang added. "So far, Palmetto has priced only about 85% of the Tier I codes and Tier II analytes, and I believe some labs are billing for them. At this time, however, we are unsure if Palmetto has paid many claims.

"Of all the MACs, Palmetto was the first one to release payment rates, and so it could be sending out payments now," she added.

"One lab reported in February that **National Government Services** (NGS), the MAC serving New York and Connecticut, was holding all claims until it released a fee schedule," stated Tang. "In mid-March, NGS released a fee schedule that listed nine codes. Since then, it's not clear if NGS has been paying labs for those nine codes.

"At the 2013 **American College of Medical Genetics and Genomics** (ACMG) meeting in mid-March, some labs reported that they had stopped billing Medicare contractors because they didn't see the point," Tang said.

Like Tang, Jane Pine Wood, an attorney with the national law firm of **McDonald Hopkins**, has only anecdotal evidence about the existing situation. She acknowledges that Medicare contractors have struggled since January 1 to post the rates they expect to pay for these new tests.

## Many Contractors Not Paying

"It's all across the board," Wood said of the situation nationally. "Even though many contractors are not paying because they don't have rates yet, I've heard from some clients that a few payments are starting to trickle in. But there's no way to quantify what's happening—at least not yet. So far, it's all word of mouth.

"Some Medicare contractors have issued fee schedules and there would be no reason not to pay labs once these contractors have a fee schedule," she added.

Wood recommends that any lab provider can take the step of contacting its elected officials and educating them about the situation. "We have lab clients who are talking to their legislators," observed Wood. "That's something every laboratory provider can do.

"When you call your legislator, it makes perfect sense to explain that your lab is an employer and a taxpayer and that it is providing clinical services to Medicare beneficiaries as a laboratory contracting with a federal government program," she continued. "Elected officials need to know that when a government program is not paying on a timely basis, it affects the lab's ability to remain in business, employ people in the community, and deliver clinical services to Medicare beneficiaries.

"Outside of that, there is no blanket advice that would apply to all labs," noted Wood. "Labs need to get advice from their advisers that is based on who the payer is and the applicable federal and state laws affecting that particular laboratory.

"For many reasons, it's a very individualized discussion," she noted. "When we get this question from a lab, it takes a while to develop a plan because each case is specific to unique facts.

"Every one of our lab clients has a different approach, depending on the situation," continued Wood. "Many of our lab clients have patients who pay for the testing. Some client labs include the test charges on a physician bill.

"To handle the lack of payment for these molecular claims, we see some clients looking at drawing down lines of credit," observed Wood. "Still other labs are looking at cooperative arrangements with labs that have a more diverse testing base or a stronger financial reach.

"These cooperative arrangements depend on the test and the payers involved," she explained. "Perhaps one lab bills the other lab, or maybe one lab performs the test for another lab. These arrangements are based on who the payer is, what the contract states, and what the state law says. And, if it's a federal payer, these arrangements depend on what the federal law says.

## Cash Flow Issues For Labs

"Depending on their mix of work, some labs can wait for the Medicare contractors to start paying while they are getting paid by commercial payers," she said. "But there can be cash flow issues for labs that run only molecular tests for Medicare patients or get very low rates. We have lab clients now getting extremely low rates and these labs are considering whether they can stay in business or whether they should stop offering these molecular tests." TDR

*—Joseph Burns*

*Contact Genevieve Tang at 415-835-0190 or Genevieve.tang@quorumconsulting.com; Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com; Gregory Root at gbroot@codemap.com or 847-381-5465.*

# INTELLIGENCE

## LATE & LATENT

*Items too late to print, too early to report*

**Geisinger Health System** broke ground last month on construction of a new $52 million medical laboratory facility. It will be 115,000 square feet and will be located at the site of the **Geisinger Medical Center** in Danville, Pennsylvania.

### LAB COMPANY COMPLETES IPO

**Cancer Genetics, Inc.**, of Rutherford, New Jersey, completed an initial public offering (IPO) and raised $6 million. It will trade on NASDAQ with the symbol: CGIX. It calls itself an early stage company with proprietary tests to detect difficult-to-diagnose cancers and predict treatment outcomes.

### ISO 15189 ADVANCES IN CANADA

Last month, the **Standards Council of Canada** (SCC) and **Accreditation Canada** declared that they would work together and "offer Canada's health care and medical laboratory communities accreditation to ISO 15189." SCC is a signatory and full member of **the International Laboratory Accreditation Cooperation** (ILAC).

### TRANSITIONS

• Clarissa A. Willett was named as the new Chief Financial Officer for **Pathology Associates Medical Laboratories, LLC** (PAML), based in Spokane, Washington. Willet was formerly an executive for **Quest Diagnostics Incorporated** and **Meritan Health**.

• Amber R. Phipps, Ph.D., is the new Vice President and Chief Operations Officer for **American Esoteric Laboratories** (AEL), a division of **Sonic Healthcare Ltd**. Phipps came to AEL after serving in the U.S. Army Reserves as a Medical Operations Officer at Fort Sam Houston, Texas.

• David A. Mongillo, retired from the **American Clinical Laboratory Association** (ACLA), died on February 18. He was 64 and suffered from Lou Gehrig's disease. Mongillo had a long career working for professional associations, including ACLA, the **College of American Pathologists**, The **American Petroleum Institute**, and **Washington Occupational Health Associates**.

• **bioTheranostics, Inc.**, of San Diego, California, named Michael C. Dugan, M.D., as Chief Medical Officer. Dugan was formerly CMO at **Roche Molecular Systems, Inc.**, and has held positions with **Genzyme Genetics** and **Specialty Laboratories**, as well as pathology professorships at **UCLA** and **Wayne State University**.

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### DARK DAILY UPDATE

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... new insights into the "dark matter" (non-coding) sequences of human DNA that may lead to new diagnostic lab tests. The work was done by scientists at Vienna's **Research Institute of Molecular Pathology** (IMP).

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***That's all the insider intelligence for this report. Look for the next briefing on Monday, May 6, 2013.***

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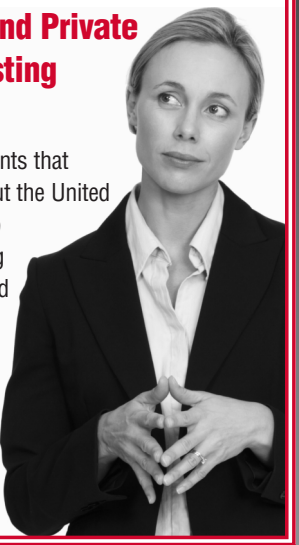

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