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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Why a Divided Lab Industry May Soon Fall

OVER THE PAST TWO DECADES, it has often been remarked on these pages and by many others that the divided nature of the laboratory medicine profession will prove to be its ultimate Achilles heel. These divisions center around different scientific disciplines within pathology and lab medicine as well as the competing economic interests of the different sectors of the lab testing industry.

Since the passage of the Affordable Care Act in 2010, a growing host of market forces and government funding shortfalls are collectively moving the lab and pathology testing industry toward what may be a financial breaking point. The status quo for most every sector of lab testing will not stand. It is this observer's opinion that the question is not "If?" but "When?"

For example, we are seeing the status quo disrupted in molecular and genetic testing. Payers—both government and private—have seized the introduction of new molecular test CPT codes as an opportunity to reshape this sector of lab testing to their own preferences. Most of this issue of THE DARK REPORT is devoted to original reporting of developments in payment and coverage guidelines for these 114 molecular CPT codes.

For my part, the fact that virtually all payers in the United States allowed labs to go unpaid since January 1 is a sign that they believe they have the power to dictate—despite the clear and obvious restriction of patient access to any number of life-changing molecular and genetic tests. Yes, there are many molecular assays that lack clinical utility or are overpriced. But the payers' actions to treat all molecular assays covered by the 114 new molecular CPT codes almost equally is a signal that should not be ignored by pathologists and lab executives.

With that as background, I next offer the breaking news that the **Office of the Inspector General** has delivered a report to the **Department of Health and Human Services** that includes a finding that the Medicare program could cut what it spends on Part C clinical lab testing by $910 million per year—if it adopted the lowest price for each assay paid by any of the 50 Medicaid programs in the United States! Oh, by the way... the study includes a recommendation that patient co-pays should be evaluated for implementation.

Would this disrupt the status quo in the clinical lab sector? You bet! Now you understand why I think it is time for all sectors, scientific disciplines, and different economic interests in lab medicine to come together and speak to lawmakers with a united voice. Our profession's future and patient care depends on it. TDR

Big Lab Industry Stories Reveal Trouble Ahead

Labs still looking for payment for MolDx tests, CMS told it could save $1 billion with lower prices

CEO SUMMARY: One after another, a series of breaking news stories points to more rough waters ahead for the entire clinical lab industry. Of greatest interest is the ongoing questions about when clinical labs and pathology groups will get paid for the molecular test claims they have submitted to government and private payers since January 1, 2013. However, last week saw its own surprise news event: a federal government report that says Medicare could save $910 billion annually by repricing lab tests.

BIG NEWS STORIES HAVE HIT the laboratory industry with regularity in recent weeks. Unfortunately, not all the news is good and the entire lab industry will need to prepare for severe challenges, particularly in how labs are paid for testing services.

This intelligence briefing summarizes current events and provides you with a road map of the topics presented in this issue of THE DARK REPORT.

For many clinical laboratories and pathology groups, the number one story is Medicare's non-payment of claims for the 114 Tier 1 and Tier 2 molecular test CPT codes that took effect on January 1, 2013. Across the nation, many labs continue to wait for the various Medicare contractors to issue payment for these claims. *(See TDR, April 15, 2013.)*

The big development was that, in the month of April, nearly all the Medicare Administrative Contractors finally posted prices in response to a directive from the federal **Centers for Medicare & Medicaid Services**. However, as we reported, near the end of last month, few Medicare contracts had posted prices for all 114 new Tier 1 and Tier 2 molecular test CPT codes.

Further, in a significant number of cases, the Medicare contractor listed prices that were substantially below the reimbursement level paid for code-stacked claims during 2012. *(See TDR, May 28, 2013.)*

And there is more bad news! Several Medicare contractors made comments to individual labs that the reason they had not posted prices for certain of the molecular CPT codes is because they considered those tests as medically unnecessary.

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

Of course, Medicaid and private payers are equally behind the curve in paying for molecular test claims. Private health insurers tend to wait for Medicare to establish coverage guidelines and reimbursement. They will then base their own policies and prices on what Medicare has done.

Two Big Concerns For Labs

Thus, the current situation carries two major concerns for clinical labs and pathology groups. First, if Medicare carriers are setting molecular test prices at levels 40% or more less than what was paid during 2012, this means labs are likely to see private payers set their own prices at similarly low levels.

Second, if, as noted above, certain of the Medicare contractors are deciding not to post prices for some of the new 114 molecular test CPT codes because they consider these tests to be medically unnecessary, then that is an unexpected development and it will create an entirely new set of challenges for labs that perform molecular and genetic tests affected by these determinations.

Both of these developments have the potential to negatively impact the financial stability of those labs which perform a large volume of the affected molecular CPT codes. Moreover, not all of these labs will have the staying power to work through the process of submitting documentation and appealing decisions made by the Medicare contractors and CMS.

Are Labs Getting Payments?

That brings up the next question: are labs now getting regular payment for molecular tests, given the fact that Medicare contractors did post prices in April?

The surprising answer is: "No one knows for sure." THE DARK REPORT has been in regular contact with a number of lab billing companies and individual lab organizations. As recently as last week, most could not positively confirm that they were seeing a regular flow of payments for molecular claims submitted since January 1. Our report on this situation is found on pages 5-7.

Another related and important story is how laboratories are surviving almost six months without payment for these molecular tests. On pages 8-10, you can read what THE DARK REPORT is learning about the negative financial impact that nonpayment of molecular test claims is having on labs. Among other things, we have identified one lab company that closed its doors in recent weeks because it cannot get payment for its molecular test—despite the fact that Medicare contractors reimbursed for this assay in past years.

New Molecular Coalition

What will be important news for many readers is that some clinical lab companies have come together to form a new association to advocate their position. It is called the **Coalition to Strengthen the Future of Molecular Diagnostics**. *(See pages 11-12.)*

Certainly this group would welcome new members and contributions of money so that it can educate members of Congress about the unprecedented situation of Medicare's inability (and unpreparedness) to properly and timely pay labs for molecular tests covered by the 114 new CPT codes.

As if these ongoing events, now lasting almost six full months, were not enough bad news for the lab industry, last week saw another bombshell development. Some of you may have learned about it.

On Tuesday, June 11, *The Wall Street Journal* was the first national news outlet to report that the Office of the Inspector General (OIG) had delivered a report to CMS that claimed that the Medicare program could save $910 billion per year. We provide useful analysis of this development for you on pages 17-18.

Collectively, these events demonstrate how tough it will be for labs to maintain financial stability, and that's with more budget cuts expected in 2014! TDR

Labs Have New Hurdles As Some Payments Start

Commercial and Medicaid plans demanding documentation for molecular pathology tests

CEO SUMMARY: Some payments are beginning to flow for claims submitted under the new molecular test CPT codes. But there is a new issue. Medicare contractors, Medicaid programs, and private health insurers are deeming certain molecular tests to be medically unnecessary. These payers are requesting that labs submit more documentation before they will pay for the molecular test claims. This new burden is another financial blow to labs. "It's a nightmare," said one lab billing expert.

PATHOLOGISTS AND CLINICAL laboratories may be entering a new phase in their quest for payment from Medicare contractors for molecular pathology testing.

Although some labs have started to receive payments for invoices for molecular tests submitted since January 1, not all labs have been paid. At least two labs have closed, some labs are discontinuing testing for some patients, and other labs are laying off staff and downsizing operations.

Delays in payment by the nation's Medicare Administrative Contractors (MACs) dragged on since January 1 while the MACs were setting prices for 114 new molecular test CPT codes that were added to the clinical laboratory fee schedule this year. The MACs took until April to set prices for some but not all of the 114 tests.

Now, in the past few weeks, THE DARK REPORT has learned that labs in Illinois, New Jersey, New York, and Texas are starting to see payments from MACs, according to Larry Siedlick, CEO of the **ARx Group**, a lab billing company in Long Island, New York.

"Our lab clients are getting paid from Medicare for the new molecular codes," Siedlick added. "However, we are seeing more requests for medical necessity documentation from the Medicare contractors and private payers.

"Also, a number of molecular tests are being considered not medically necessary," he noted. "Another thing we see is that many tests are being billed under the unlisted code 81479, which generally requires additional documentation and rarely results in payment."

Demand For Documentation

Medicare contractors are asking clinical laboratories and pathology groups to submit additional documentation to support the labs' requests for payment for these molecular diagnostic tests. Laboratory billing experts tell THE DARK REPORT that this new phase requires gathering and submitting a considerable volume of data to support the contractors' requests for reimbursement.

"We are aware of two laboratory companies that have closed their doors due to

Labs Now Must Confront New Billing Challenges

BILLING FOR MOLECULAR PATHOLOGY TESTS covered by the new molecular test CPT codes has become a nightmare, stated Mark Edwards, Vice President, Chief Information Officer for Kellison & Company, a billing company based in Cleveland, Ohio.

"The entire billing process is now dominated by the need to submit reams of documentation to support each individual claim," noted Edwards. "The plans are asking for signed letters from physicians, clinical documentation for the tests, and the complete medical and physical histories of patients.

"Responding to these requests is challenging because they are resource-intense," he continued. "As a billing company, we put so much time and effort into gathering and submitting the documentation that it's not profitable for us and it's certainly not profitable for our client labs.

"Some Medicare contractors have made promises to us because they posted prices at the end of April," added Edwards. "But at least one Medicare contractor says it doesn't recognize the new codes. "Each time we call, they say they're working on it. But we still have no payment.

"Instead, Medicare contractors and private health plans are asking for more documentation and going through a review process," he noted. "We continue to submit claims, but they immediately become subject to a long review process."

lack of investor confidence over the coverage and reimbursement landscape," commented Lâle White, Executive Chairman and CEO of **XIFIN, Inc.**, a lab revenue management company in San Diego, California. "One company is **Pathwork Diagnostics** and the other is **Predictive Biosciences**. I am aware of another lab company in Southern California that laid off 25% of its staff."

THE DARK REPORT reported earlier on what happened with Pathwork Diagnostics. *(See "Why One Molecular Diagnostics Company Closed Its Doors," TDR, May 28, 2013.)* In a coming issue, we will cover the issues that led Predictive Biosciences to cease lab testing and business operations.

"Some labs have reduced their offering of tests or defaulted to less effective FDA-approved versions of tests," noted White. "They did this because reimbursement or coverage decisions did not support the laboratory-developed test (LDT) that was more medically appropriate.

"We also hear that some doctors have complained about losing access to molecular tests that previously they provided to their patients," White said.

While **Palmetto GBA**, the nation's largest MAC, has been making payments for molecular pathology testing, all MACs have increased the number of non-coverage decisions, including—in the case of Palmetto—not covering the LDT versions of common tests, she added.

Non-Coverage Decisions

An increase in non-coverage decisions may be one reason many labs do not want to discuss these reimbursement challenges, said Michael Arnold, Executive Director of the **California Clinical Laboratory Association**. "Specific information is difficult to obtain and that may be due to concerns lab executives have that such developments will prove worrisome to investors and shareholders."

Another problem labs face is that health plans generally follow the lead of Medicare, which is just what's happening now, said Mark Edwards, Vice President and Chief Information Officer for **Kellison & Company**, a multi-specialty billing company in Cleveland, Ohio.

"The biggest issue we see now is that both commercial and Medicaid plans are not paying for some molecular pathology

tests, especially those defined by Tier 2 codes and the new miscellaneous code, CPT 81479," he said. "Much of the Medicaid HMO business is handled by commercial payers, and we're having problems with all of these plans. They say they can't pay or now require pre-authorization because the new tests are not on the Medicaid fee schedule, or are 'manually priced.'

Few Tier 2 Codes Are Priced

"Even though many prices for the new molecular test CPT codes were released, most of the Medicare contractors priced only the Tier 1 codes," Edwards explained. "Further, only two Medicare contractors have priced any of the Tier 2 codes.

"We see that the biggest problems are now with the commercial plans," he continued. "None of these health plans have established fees for these molecular codes.

"At the same time, both the commercial and Medicaid plans are asking for increased documentation," noted Edwards. "Lack of an established fee schedule for these codes has led to numerous requests for medical records and documentation to support medical necessity for tests that were previously paid without question under the old code stacks.

"Because AMA deleted the old molecular stacked codes 83898 to 83914 from the CPT book in 2013, all of these plans deleted the stacked codes," he said. "Many payers don't have the new molecular test CPT codes loaded into their fee schedules nor have they integrated these codes into their medical policy documents yet.

"This situation means labs are unable to bill under the codes they used last year," noted Edwards. "Instead, they get denials and must undergo a long manual appeals process when billing with the new codes.

"Basically none of the molecular laboratories we service have gotten paid this year by any Medicaid plan," concluded Edwards. "Further, our client labs tell us they cannot see a clear end to this situation." TDR

One CPT Code Generates Many Payer Questions

CLINICAL LABORATORIES are finding that claims coded to one particular new CPT code can be particularly troublesome. Use of CPT code 81479 under the new molecular pathology codes automatically generates requests from Medicare Administrative Contractors (MACs) for more documentation.

When it established the procedures for the 114 new molecular test codes in Tier 1 and Tier 2, the **American Medical Association** (AMA) also established CPT code 81479, stated Mark S. Synovec, M.D., of the **College of American Pathologists**. He is a member of the AMA's CPT Editorial Panel.

Synovec explained the new codes during a presentation last fall. He said that CPT code 81479 was established for labs that had an unlisted molecular pathology procedure—meaning it would be used for analyses not captured in Tiers 1 or 2.

In a publication explaining the new codes, **McKesson** describes CPT code 81479 as follows: "Molecular pathology procedures that are not specified in Tier 1 category should be reported using the appropriate Tier 2 code. In the event the assay performed is not specifically listed in the Tier 1 or Tier 2 category, AMA states to use the unlisted nonspecific CPT code 81479. The AMA states that you may not add a molecular pathology assay to either the Tier 1 or Tier 2 category that is not specifically listed. Therefore, if the molecular test (e.g., the gene(s) being tested) in question is not specifically listed under either the Tier 1 or Tier 2 category codes, then those must be coded with the CPT 81479."

—Joseph Burns

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Labs Face Consequences From MolDx Test 'Mess'

➤Decisions threaten laboratory viability and steady progress toward personalized medicine

➤➤CEO SUMMARY: Non-payment of molecular test claims for the first five months of 2013 is not the only financial disruption for labs that perform these tests. Reports are coming in about how Medicare contractors, Medicaid programs, and private payers are declining to pay claims based on rulings that the molecular tests fail to meet medical necessity criteria. Labs were unprepared to respond to requests for extensive documentation to support claims for the same molecular tests that were covered in 2012.

UNEXPECTED DEVELOPMENTS HAVE SURFACED AS A CONSEQUENCE of Medicare's botched implementation of the molecular test CPT codes. These developments are a totally new threat and new challenge to laboratories performing molecular diagnostic testing.

The primary issue—that of non-payment of molecular test claims submitted by labs since January 1, 2013—has gotten the most attention. In fact, in recent weeks, some labs have reported that they are now receiving payments.

However, much uncertainty still surrounds this situation. Executives at laboratory billing companies say that they can not state definitely that all Medicare Administrative Contractors (MACs) and private payers have resumed sending payments for these molecular test claims in May and June.

Meanwhile, the harm that many laboratory organizations have experienced—and continue to experience—has become visible. This harm is a direct result of the non-payment of molecular test claims for a period now extending into the sixth month of the year.

In its discussions with lab billing experts and lab leaders, THE DARK REPORT learned that labs are dealing with at least five troubling effects from this avoidable situation. First, some labs have stopped offering the molecular tests coded to the new molecular CPT codes.

Second, labs have laid off staff and downsized operations in response to non-payment. Third, THE DARK REPORT can identify lab companies that have been forced to close their doors because of the months of non-payment for these molecular tests.

➤Not Medically Necessary

Fourth is the new threat that all types of payers—Medicare, Medicaid, and private health insurers—are declaring some molecular tests to be medically unnecessary. Payers taking this stance are demanding that labs submit voluminous documentation to support the medical necessity of these molecular tests.

Fifth, and be no means the last type of consequence experienced by labs, they are being paid much less for many molecular tests compared with what they were paid

last year. Of course, in many cases they are not being paid at all.

"Just about every lab that performs the frequently-used and well-established molecular tests—such as EGFR, KRAS, and BRAF—have been affected negatively by decisions of the MACs," said a spokesperson for the newly-formed **Coalition to Strengthen the Future of Molecular Diagnostics**. *(See story on pages 11-12.)* "We estimate that it could be well over 100 laboratories, including hospital labs, that are affected negatively.

"In addition, MACs seem to have suddenly decided that many molecular tests are investigational, for screening, or not medically necessary," continued the spokesperson. "As a result, labs that run these tests are not getting paid and are in dire financial straits. This is particularly true for labs that specialize in running one or two molecular diagnostic tests and are now being sent reimbursement that is below the cost to perform this testing."

Documentation Required

This statement is consistent with the newest development identified by THE DARK REPORT. In recent weeks, labs have disclosed that certain MACs are demanding extensive documentation to support the medical necessity of molecular test claims.

These negative coverage decisions have hit some labs hard. In Lexington, Massachusetts, **Predictive Biosciences** has gone out of business. *(See sidebar at right.)* Another lab firm, **Genomas LLC** of Hartford, Connecticut, is being paid less than it received last year and needs to submit additional documentation about the utility of its molecular tests.

In an interview with THE DARK REPORT, Gualberto Ruaño, M.D., Ph.D., President and CEO of Genomas, explained that the Medicare contractor made problematic determinations for each of the company's three molecular assays.

In the case of the two CYP450 assays used to assess a patient's functional status for isoenzymes CYP2D6 and CYP2C9, the Medicare contractor posted no prices for those molecular CPT codes.

The Medicare carrier did post a price for CYP2C19. That is the third molecular test offered by Genomas. But, Ruaño said, the posted price is below production costs to perform the test. He added that these isoenzymes affect the metabolism of neuro-psychiatric and cardio-metabolic drugs.

Investors Close Laboratory After MAC's Decision

AT THE END OF MAY, venture capital investors for **Predictive Biosciences** (PB) of Lexington, Massachusetts, decided not to continue funding the molecular testing lab. The laboratory company ceased testing operations and closed its doors, said Pierre Cassigneul, PB's CEO.

This action came after PB's Medicare Administrative Contractor (MAC), CGS Administrators, in Nashville, Tennessee, deemed the company's tests to be not medically necessary. It would not alter this determination unless additional clinical utility studies were published about the tests in the *New England Journal of Medicine* or the *Journal of the American Medical Association* and the tests were included in published clinical guidelines.

Cassigneul said that CGS simply posted no prices for the molecular CPT codes that would cover PB's three molecular tests. These are the CertNDx Bladder Cancer Assays and are used for the detection, diagnosis, and management of bladder cancer.

Given this negative coverage decision by the Medicare contractor, Cassigneul stated that the company's venture capital investors decided to close the company. That threw 90 employees out of work. THE DARK REPORT will provide detailed coverage of this development in an upcoming issue.

The MAC for Medicare Part B providers in Connecticut and New York is **National Government Services, Inc.** (NGS). "NGS has not issued a formal coverage determination." stated Ruaño. "Instead, NGS has left those prices blank. Because of this, our claims are coming back to us with requests for medical necessity and documentation.

"To respond, we must obtain the patients' medical records to document the medical necessity," he continued. "NGS wants to know the names of the tests, the resources used to do the test, and how the test results were interpreted.

Doctors' Clinic Notes

"NGS also requires the clinical notes from the referring physicians as they relate to medical necessity, which is burdensome on clinicians," added Ruaño. "Along with this information, NGS asks us for a dossier of our peer-reviewed publications, which we are happy to provide.

"Since January 1, our lab has been underpaid for CYP2C19 and not paid for CYP2D6 or CYP2C9," he declared. "Now, instead of a price decision, we get the claims sent back to us this month along with demands for more information!

"We see most private health insurers following Medicare and questioning the coverage of this test as well," said Ruaño. "Only some private payers are paying now.

"The NGS decision has put us at a competitive disadvantage with labs in other parts of the country," observed Ruaño. "Those labs are getting paid for these tests. This situation is bad for our patients and for physicians too."

THE DARK REPORT invites other laboratories experiencing similar situations who are willing to share their stories to contact our offices. Without documentation of these situations, elected officials cannot act to correct the problems caused by Medicare and Medicaid program administrators. TDR

—Joseph Burns

Contact Gualberto Ruaño, M.D., at 860-545-3773 or G.Ruano@genomas.net.

Genomas's Tests Provide Info about Drug Effects

ONE LAB IN CONNECTICUT was surprised that its primary Medicare contractor did not post prices for the specific molecular test CPT codes it uses for its proprietary assays.

"This decision by National Government Services, Inc. (NGS)—the MAC for Medicare Part B providers in Connecticut and New York—has meant non-payment for two of our lab tests and payment below our production costs for a third," stated Gualberto Ruaño, M.D., Ph.D., President and CEO of Genomas LLC. "Private payers are following this Medicare contractor's lead and are also not paying our claims."

This currently affects patient access to the molecular tests offered by Genomas. "We continue to serve patients, but primarily those patients who can pay out-of-pocket for these tests," explained Ruaño. "They can afford the testing and see the value. Recognizing the value is what Medicare, Medicaid, and commercial insurers are supposed to do. But members of these plans are being deprived of personalized medicine!

"Doctors use these tests because many Medicare patients have multiple chronic conditions and are on multiple medications," he added. "Our studies show that about 75% of people on Medicare take more than two medications because they have diabetes, high blood pressure, a thyroid condition, or some other chronic illness.

"These patients are at very high risk for drug interactions," explained Ruaño. "We have demonstrated that the risk of drug interactions is genetically determined.

"People who have deficiencies of different pathways of drug metabolism are at higher risk of drug interactions than people who have normal activity," observed Ruaño. "So this is definitely a population in great need of this testing. Unfortunately, they are not getting it now because of decisions made by the Medicare contractors."

New MoPath Lab Coalition Takes Its Case to Congress

Low rates for molecular diagnostic tests will jeopardize patient access, coalition says

CEO SUMMARY: Prices recently established for molecular diagnostic tests are so low that they put patient access in jeopardy, declared a new lab industry coalition in a statement delivered to members of Congress. Called the Coalition to Strengthen the Future of Molecular Diagnostics, the organization also told members of Congress that—not only are the prices too low—but many laboratories continue to await payment for molecular test claims submitted since January 1, 2013.

THERE'S A NEW VOICE within the laboratory medicine profession and it is called the **Coalition to Strengthen the Future of Molecular Diagnostics**. This group has come together in response to the problems caused by government and private payers in how coverage guidelines and prices are to be set for the 114 new molecular test CPT codes.

Chief among these problems are prices so low that they jeopardize patient access, said the new coalition. It is comprised of molecular testing companies, clinical laboratories, patients, providers, diagnostic test manufacturers, pharmaceutical companies, venture capital investors, and clinical lab associations. The coalition says it represents more than 120,000 medical and laboratory professionals and their institutions that perform the majority of clinical molecular pathology tests.

Over the past four weeks, members of the coalition have met with members of Congress to complain about the process the federal **Centers for Medicare & Medicaid Service** (CMS) and its Medicare Administrative Contractors (MACs) are using to set prices for these new molecular test codes. Few molecular testing companies have been paid for these tests since January 1, the coalition said.

In addition to the fact that prices set for these new molecular test CPT codes are unexpectedly low, the coalition says there is a second important problem. That problem centers around the fact that neither CMS nor the MACs have made the process behind how they set prices transparent.

Process Needs Transparency

"CMS and the MACs must develop a secure process to collect and analyze targeted data and a transparent process to disclose the basis for their proposals and decisions when completing the gap-fill process to determine 2014 payment rates," the coalition said in a statement it delivered to members of Congress. Gap-fill is the method CMS and its MACs use to set rates.

In a letter to recently confirmed CMS Administrator Marilyn Tavenner, the coalition delivered a similar message, saying low reimbursement rates for molecular diagnostic testing could stifle

innovation and set back advancements in cancer care and treatment of other diseases for thousands of patients.

"A troublesome factor adding to the urgency of the issue is that these rates, while not final, are in effect today [and] retroactive to January 1, 2013. This is causing laboratories to make tough choices about the type of testing they can afford to offer Medicare beneficiaries…," the letter to Tavenner said. For many laboratories the new rates are below the cost of performing the test, the letter added.

Low Rates Criticized

For example, the coalition's letter to Tavenner suggested that advances in molecular diagnostics now enabling personalized medicine are in jeopardy as a result of low reimbursement rates. The low rates also jeopardize the use of diagnostic tests to characterize a patient's disease and guide targeted therapy.

"Knowing how a patient might respond at a molecular level to a particular treatment allows a physician to determine the best course of care at given points in time, preventing trial and error treatments, saving healthcare dollars, and delivering better care faster," the letter said.

In a statement to members of Congress, the coalition said, "Analyses indicate that some of the new codes are priced far below the amounts paid by Medicare for these same tests in 2012, and in some cases below sustainable levels."

What compounds this problem is the fact that state Medicaid programs are adopting Medicare's low reimbursement rates for molecular diagnostics, according to the coalition's statement to members of Congress. "The low payment rates may result in a lack of access to molecular diagnostic testing not only for current Medicaid beneficiaries, but also for the expected new populations who will receive Medicaid coverage in the near future," the statement said.

State Medicaid programs are developing ways to use funds from the Affordable Care Act to insure those who have been uninsured previously.

The statement delivered to members of Congress said CMS must provide immediate relief from the low prices and disclose the basis for its decisions.

Mischaracterizing Tests

MACs are denying molecular test claims and reducing rates without justifying their decisions and they are denying payment by mischaracterizing tests as investigational, the coalition said.

JoAnne Glisson, Senior Vice President of the **American Clinical Laboratory Association**, said laboratory directors and pathologists should tell CMS, the MACs, and members of Congress about the problems their lab organizations face from low reimbursement rates. ACLA is a member of the new coalition.

"Any lab can weigh in with CMS, and we urge labs to send copies of their correspondence to CMS to their contractors," she said. "The contractors can change the prices they set."

Engage CMS And MACs

Genevieve Tang, a consultant with **Quorum Consulting** in San Francisco, California, agreed with Glisson that lab directors and pathologists should express their concern about reimbursement rates. "We are encouraging our client labs to continue to engage their MACs," she said. "Although CMS said providers should send any information they have on molecular test pricing to CMS and send copies to the MACs, we encourage our clients to directly engage the MACs because some MACs have already revised certain prices upward." TDR

—Joseph Burns

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TriCore Lab Adds Value With Consults, Better TAT

Pathologists and Ph.D.s get out of laboratory and do rounds with doctors at client hospitals

CEO SUMMARY: Motivated by the goal of delivering more value to clinicians and client hospitals, the lab team at TriCore Reference Laboratories in Albuquerque, New Mexico, is proactively introducing new services. One such initiative is to travel to hospitals to participate in rounds and consult with physicians regularly. Another initiative improved the accuracy of* C. diff. *diagnosis while dramatically reducing lab test turnaround time. These changes help client hospitals improve patient outcomes.

As healthcare moves swiftly toward outcomes-based reimbursement, innovative labs are responding with new ways to deliver more value to referring physicians.

In Albuquerque, New Mexico, one lab organization is pursuing a dual strategy designed to support physicians in achieving improved patient outcomes while contributing to a reduction in the cost-per-diagnosis and the overall cost-per-episode of care.

At **TriCore Reference Laboratories**, one half of this strategy is devoted to getting pathologists and Ph.D.s out of the laboratory so they can consult directly with physicians in patient care settings.

The second half of the strategy is to harness specific diagnostic technologies in tandem with enhanced lab informatics capabilities to deliver more accurate lab test results in a shorter period of time. The goal is to help doctors and nurses more consistently access lab test results as they are reported and then act in a timely fashion to deliver the most appropriate care to their patients.

It is widely recognized by the pathology profession that clinicians get much more value from lab testing services when pathologists, Ph.D.s, and lab scientists are physically present and available to provide consultations.

This is why TriCore's scientific team has begun making the rounds with clinicians in Albuquerque hospitals and they meet with treating physicians one day a week at the hospital and at TriCore's central laboratory. This effort is led by Michael J. Crossey, M.D., Ph.D., TriCore's Executive Medical Director and interim CEO, and Karissa Culbreath Ph.D., D(ABMM), a Scientific Director of Infectious Disease at TriCore.

More Effective Alerts

In support of this direct interaction, TriCore has built alerts into its laboratory information system (LIS). This allows its client services department to call significant lab test results to treating physicians and nurses on hospital floors at its client hospitals.

"Implementing these new added-value laboratory services requires adoption of a different culture within the lab," noted

Crossey. "As this happens, laboratorians can become actively engaged with treating physicians and floor nurses in order to make recommendations to improve patient care."

In fact, TriCore's lab team is learning that the combination of these lab test alerts and providing active consultation outside the laboratory produces impressive results, including better patient care at lower cost. These new lab services directly contributed to improvements in how physicians utilize lab tests. As well, there are improvements in how physicians receive lab test results and act upon them in ways that contribute to better patient outcomes.

Added Value Strategy

That is where the second part of TriCore's added value strategy comes into play. "Sometimes lab directors can take many steps to improve lab test sensitivity and even turnaround time (TAT)," observed Culbreath. "But if the treating physicians are unable to view or act on these results fairly quickly, these improvements will not advance patient care or cut costs for hospitalized patients."

To address this problem and convert it into an opportunity, TriCore revamped the way it communicated alerts to clinicians. One major success in this effort came from how the laboratory changed the way it handled testing for *Clostridium difficile* (*C. diff*) infections.

"In order to deliver more value to clinicians, we wanted to achieve three goals," stated Crossey. "First, we wanted to adopt a test methodology which would improve the sensitivity and specificity. That would provide clinicians with a more accurate test result.

"Our second goal was to reduce turnaround time," he continued. "This is particularly important to hospitals because of the emphasis on reducing hospital-acquired infections (HAIs).

"Third, as noted above, it is important that clinicians pay attention to critical results and act upon them in a timely way," commented Crossey. "That is why we established different protocols for alerts associated with *C. diff* testing."

The changes in how alerts for *C. diff* test results are communicated to clinicians at client hospitals have increased the value of new testing methodologies implemented at TriCore. "For positive *C. diff* test results, our lab's call center staff telephones the floor nurse, referring physicians, and hospital epidemiology soon after the results become available," said Culbreath.

Collaborative Relationship

"Alerting the floor nurse and referring physicians is unusual for many labs and that is particularly true for a reference lab," she noted. "But TriCore does this to further its collaborative relationship with its hospital clients."

To achieve the goals of improved accuracy, faster turnaround times, and reduced cost-per-diagnosis, TriCore changed the way it tested for *C. diff*. That took place in May 2011. How and why TriCore revised the way it tests for *C. diff* offers important lessons about how a laboratory's pathologists and Ph.D.s can become more involved in consulting with referring physicians.

"Two years ago, we used a batched ELISA-based assay that we ran for *C. diff* once or twice a day," explained Culbreath. "However, as most hospital lab professionals know, this left several opportunities for improvement unaddressed.

"First, because *C. diff* results were available only once or twice daily, this delayed the diagnosis," she commented. "Second, without a diagnosis, the hospital staff did not know whether to continue to quarantine the patient and implement additional downstream infection control requirements. For both reasons, a more accurate answer delivered more quickly was expected to be a big winner in the diagnosis and treatment of *C. diff*.

"We considered the different alternatives," added Culbreath. "This included using polymerase chain reaction (PCR) test-

ing for all patients suspected of having *C. diff*. Numerous PCR platforms can provide a rapid diagnosis, but PCR is more costly than the enzyme immunoassay (EIA) we were using at that time. So we developed a testing algorithm that uses PCR testing only when absolutely necessary for a diagnosis.

Batch Tests Eliminated

"This produced a dramatic reduction in turnaround time for *C. diff*," observed Culbreath. "Previously, our batch tests for *C. diff* generated results in 24 hours. Now we produce results for most patients in as little as one hour, and if PCR tests are needed, not more than two to three hours. Clinicians recognize the significant benefits from this improvement." *(See sidebar at right.)*

"Our diagnostic algorithm gives us better overall sensitivity because the original EIA was not very sensitive," stated Culbreath. "Our new test methodology has enhanced sensitivity.

"Because of that improved sensitivity, we can limit testing to one specimen per patient per episode of diarrhea," she added. "This significantly reduced the need for serial testing for *C. diff* that we did previously with the less sensitive ELISA test.

Rates of Diagnosis Climbed

"Our data shows that we cut serial testing for *C. diff* by 41.5%," she observed. "Better yet, with the improved sensitivity of our new methodology and protocols, our lab increased the number of patients identified with *C. diff*. This is a valuable benefit to our client hospitals, who all have programs to reduce hospital-acquired infections.

"This is an interesting point and strikes to the heart of the ongoing discussion in labs about cost-per-test versus cost-per-diagnosis," added Culbreath. "We cannot say all of that increase in the *C. diff* detection rate is due to the change in our testing methodology and algorithm. There could be an increase of *C. diff* in the community or because of other factors.

C. Difficile Test Changes Deliver Improvements

TWO YEARS AFTER implementing new methodologies and protocols for *Clostridium Difficile* (*C. diff*) testing, TriCore Reference Laboratories has delivered significant improvements that have contributed to improved patient care. TriCore provided these key metrics on its *C. diff* testing program:

- **TURNAROUND TIME (TAT):** 80% decrease, from average of 37 hours (EIA) to average of 7 hours (PCR).
- **LESS SERIAL TESTING:** Reduced from 68 tests-per-1,000 (EIA) to 7 tests-per-1,000 (two-step PCR).
- **IMPROVED DIAGNOSIS:** New two-step PCR test and algorithm increased *C. diff* positive rate by 121%.
- **REDUCED COST PER DIAGNOSIS:** Despite higher cost per test, new PCR test and algorithm reduced the lab's average cost-per-diagnosis for *C. diff* by 40%.

"The point is that when we switched to this new algorithm, our rates of positive diagnosis for *C. diff* went up and we reduced the cost-per-diagnosis, which is an important factor for us," she observed. "The algorithm we currently use calls for a slightly more expensive first step and a much more expensive second step. However, because we don't have to run serial tests because of the lower sensitivity of the ELISA assay, we reduced the average cost per *C. diff* diagnosis.

"This is an important benefit that might be overlooked if we didn't emphasize it," Culbreath stressed. "It's easy to compare the cost of one test to another and take steps to shift utilization to the lower-cost test.

"But the cost-per-diagnosis is more complex than that," she emphasized. "We want to help clinicians get to a more efficient and less expensive diagnosis overall

for their patients. Our two-step *C. diff* algorithm allows us to do that."

Crossey was quick to point out that TriCore's capability to reduce both the time to diagnosis and the average cost of diagnosis for *C. diff* created an opportunity for the laboratory's pathologists to engage client hospitals in a new way.

"One of our sponsors is **Presbyterian Hospital**, which the federal **Centers for Medicare & Medicaid Services** (CMS) has designated as a Pioneer ACO," said Crossey. "All ACO models are designed to improve efficiency and Presbyterian is no exception.

"Our lab team is in discussions with Presbyterian's medical staff to help them consider the value of the downstream effects that result from improved use of laboratory testing," he said. "For example, if better use of lab testing allows the hospitals to take a patient out of isolation sooner or de-escalate antibiotics sooner, or change to the correct antibiotic more quickly, then there are substantial cost savings associated with each of those improved outcomes.

Lab Scientists Do Rounds

"We are demonstrating these points in actual practice," continued Crossey. "Dr. Culbreath, Stephen Young, Ph.D., also a scientific director of infectious disease, and I go on infectious disease rounds every Monday with the infectious disease physicians and the infectious disease pharmacists, for example. When it comes to antibiotic stewardship, that trifecta is a very powerful team."

"We believe that having this kind of relationship with our referring physicians will propel us into the next era of lab medicine," added Culbreath. "In that era, it will be more about the clinically-actionable information labs can deliver as opposed to simply delivering lab test results." TDR

—Joseph Burns

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Two-Step *C. diff* Algorithm Incorporates PCR Testing

CHANGING THE EXISTING TEST METHODOLOGY was one way the team at TriCore Reference Laboratories believed it could improve testing for *Clostridium difficile* (*C. diff*) infections and deliver more value to referring physicians while contributing to improved patient outcomes.

"At that time, we used an enzyme immunoassay (EIA) when testing for *C. diff*," stated Karissa Culbreath, Ph.D., a Scientific Director of Infectious Disease at TriCore. "An alternative approach to our existing protocol involved using a two-step algorithm to detect the two markers for *C. diff:* glutamate dehydrogenase antigen (GDH) and the *C. diff* toxin. Under this algorithm, we could test every sample in a time frame that is close to STAT testing.

"We adopted the use of a card-based assay that—in terms of speed—is about as fast as point-of-care testing, but it is run in our central laboratory," commented Culbreath. "If the card-based assay showed both the GDH and *C. diff* toxin were positive, we would consider the patient as being positive for *C. diff.*

"That result takes about 30 minutes," she said. "If the test showed the patient to be negative for both markers, we consider the patient to be negative for *C. diff* infection.

"The problem was that only about 85% of results with this assay are either both positive or both negative for *C. diff*," Culbreath emphasized. "The remaining 15% of tests generate one positive and one negative for these two markers.

"It is for those samples that we then perform the more expensive PCR test," she commented. "Our lab produces that result in just 60 to 90 minutes. This improves the accuracy of the *C. diff* diagnosis and greatly shortens the time-to-answer for our referring physicians."

Medicare Update

OIG Tells CMS It Could Save $910 Million on Lab Test Costs

Report was made public last week and a sign that CMS officials want more power to set prices

IT IS ONE MORE POWERFUL SIGN of the changing times. Last week, the Office of the Inspector (OIG) publicly released a study it had done of the prices paid for lab testing and how the Medicare program could use this information to reduce the cost of Part B clinical laboratory testing.

It was *The Wall Street Journal* that first published a story on June 11 about this new OIG report. It noted that OIG estimated that the Medicare program could save $910 million per year in lab testing costs. This was based on the OIG's newly released study.

To put this in context for pathologists and clinical laboratory executives, the OIG says that Medicare paid $8.2 billion for Part B clinical laboratory tests in 2010. Thus, savings of $910 million would be a reduction of 11.1% in payments to the nation's clinical laboratories during that year.

Lab Test Fees Under Attack

The OIG's report is a sign of the times because, on all fronts, clinical laboratory test fees are being attacked and reduced. The fact that someone in the federal **Department of Health and Human Services** (DHHS) chartered the OIG to perform this study indicates that a strategy is in play.

It appears that the goal of that strategy is to give Medicare program officials the statutory and regulatory powers they desire to bring the fees for Part B clinical laboratory testing down to the levels paid by Medicaid programs and private health insurers.

This is a high-risk strategy for both the Medicare program and the clinical laboratory industry. That's because it is widely acknowledged that many state Medicaid programs currently pay fees that hardly allow a lab to recover the marginal cost of performing the tests.

OIG Studies Lab Prices

The OIG's report is titled "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings." Its release date is June 2013 and it is publication number OEI-07-11-00010.

In this report, the OIG studied just 20 types of lab tests that represent the highest volume of claims submitted to Medicare. It collected payment data from 50 state Medicaid programs and three of the Federal Employee Health Benefits (FEHB) plans. It looked at three factors, which are themselves a window into thinking at DHHS.

The three factors were: 1) how each entity formulated its lab test fee schedule or payment rates; 2) whether the patient was charged a co-payment; and, 3) if that program counted the lab test charges toward a member's deductible.

Among the four objectives laid out in the report, the OIG wanted to determine "the amount Medicare could have saved if it had paid a rate equal to the lowest insurer's payment rate for the 20 selected lab tests."

Using that as a standard, the OIG wrote that "Our approach provides a conservative estimate of potential savings to the Medicare program because using Medicaid claim payment amounts or an FEHB plan's lowest rate could produce greater differences in comparison to Medicare-allowed amounts."

Cutting to the chase, the OIG wrote that "Medicare could have saved $910 million in 2011 if it had paid the lowest insurer's payment rate for 20 lab tests."

Potential Deep Price Cuts

The examples provided in the report demonstrate the radical change in pricing that would result if the Medicare program were to drop Part B clinical lab test fees to the levels discussed in the OIG report. For the commonly performed thyroid panel (HCPCS Code 84443), Medicare reimbursed $348 million for 14.8 million tests during 2011. Had Medicare "paid providers for these tests at the lowest established rate among the insurers we surveyed, it could have saved approximately $140 million, or 40%," noted the report authors.

In a memo to Daniel R. Levinson, dated April 26, 2013 and signed by Marilyn Tavenner, Acting Adminstrator of the **Centers for Medicare & Medicare Services** (CMS), she noted that the OIG had written "The OIG recommends that CMS seek legislation that would allow CMS to establish lower payment rates for lab tests."

In response, Tavenner wrote, "The CMS appreciates OIG's recommendations and the valuable work reflected in this report. CMS is currently exploring whether it has the authority under the current statute to revise payments for clinical diagnostic laboratory services consistent with the OIG's recommendation."

This is a forewarning to the lab testing industry that CMS is accumulating data it can use with Congress to support legislation that would give it more direct control to set prices under the Medicare Part B Clinical Laboratory Test Fee Schedule.

2011's Top Four Part B Tests Account for $1 Billion in Cost

DATA FROM THE REPORT on Medicare Part B clinical lab testing spending in 2011 reveal that just four tests accounted for $1 billion of that spending.

In its report, the Office of the Inspector General concluded that the Medicare program could save as much as $910 million per year if it changed how it prices Part B clinical laboratory testing.

Top Four Tests in 2011

HCPCS	Description	Total Medicare Allowed Amount in 2011 in Millions	Percent Medicare Allowed Amount in 2011	Medicare National Limitations Per Test in 2011
80053	Comprehensive metabolic panel	$319.9	6.5%	$14.87
80061	Lipid panel	$310.6	6.3%	$18.85
82306	Vitamin 25(OH)D	$223.4	4.6%	$41.66
80048	Metabolic panel, total calcium	$94.0	1.9%	$11.91
TOTAL SPEND:		**$948.2**		

Source: Office of the Inspector General, June 2001, report OEI-07-11-00010.

Further, the OIG report notes that a number of Medicaid programs require patient co-pays for clinical laboratory testing. This may be a sign that CMS would like to argue to Congress that it should reinstate a 20% patient co-pay for clinical lab tests.

Two Big Concerns For Labs

Given the collective reimbursement cuts enacted in recent years, to subtract an additional $910 billion from the annual revenue of clinical labs throughout the nation would guarantee a tidal wave of lab bankruptcies, not to mention depriving millions of patients—both Medicare and non-Medicare—access to a first-rank medical laboratory in their community. That's because it will be the smaller, local laboratories that will be first to close their doors. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Big news last week was the unanimous decision by the Supreme Court that natural genes cannot be patented. The case was brought against **Myriad Genetics, Inc.**, by the **American Civil Liberties Union**, the **Association for Molecular Pathology**, and several other plaintiffs. The decision invalidated some of the patents held by Myriad for the BRCA 1 and BRCA 2 genes. However, the court ruled that synthetically created exon-only strands of nucleotides, known as complementary DNA (cDNA), is patentable. Investors are trying to determine how the ruling might affect Myriad. Meanwhile, within hours, several lab organizations issued public announcements that they would offer tests based on the BRACA 1 and BRCA 2 genes.

MORE ON: *Myriad*

For the laboratory medicine profession, the Supreme Court ruling was generally welcomed. Pathologists and laboratory professionals believe that multi-gene assays will become the norm. There will be tests that incorporate hundreds or thousands of genes. With the Supreme Court decision, it means that labs will not have to hunt down the patent holders for genes used in these multi-analyte assays nor pay royalties when using a natural gene in their tests.

DIGITAL PATHOLOGY MARKET GROWTH

Financial analysts are predicting strong and steady growth in the market for digital pathology systems. A new report issued by **Frost & Sullivan** estimates that, in the United States, sales of digital pathology systems will grow from $77.2 million in 2012 to $205.7 million in 2017. In Europe, Frost & Sullivan predicts sales will increase from $62.23 million in 2012 to as much as $143.6 million in 2019. This represents compound annual growth rates (CAGRs) of 17% for the United States and 12.7% for Europe. This is further confirmation that digital pathology technology is improving and pathologists are interesting in acquiring and using these systems.

TRANSITIONS

- Jerry Baker is the new President and CEO for **HIT Application Solutions** (HIT) of Exton, Pennsylvania. Baker has held executive positions at **Halfpenny Technologies** and **3M Health Information Systems**, as well as at other companies.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 8, 2013.