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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

Road Map to Most Pressing Trends In Healthcare

YOU SHOULD FIND THIS ISSUE OF **THE DARK REPORT** TO BE A USEFUL ROAD MAP to several of the major trends now confronting clinical labs and pathology groups across the United States. One trend involves payer efforts to control the cost of lab tests. A second trend centers upon accountable care organizations (ACO) and the national drive to create effective new models of integrated clinical care.

Of course, one surprise in a year that is just six weeks old is the list of molecular test prices posted by **Palmetto GBA** on January 28. As you will read on pages 3-6, several important new molecular CPT codes, such as for BRAF and EGFR, have a price that is below the cost of performing these tests. Blame this situation on many factors, including the complex web of bureaucratic requirements that must be followed by Medicare carriers.

Yet the consequence is financial distress—at least in the short term—to those labs which perform those tests while these problems are straightened out. At the same time, patient access to these tests may be negatively affected and that creates its own set of problems for a Medicare program that is attempting to improve patient outcomes and encourage early, accurate diagnosis.

Moving forward in this issue, on pages 7-13, you will read about the current state of the marketplace for ACOs. I expect you to be as surprised as I was to learn that about 10% of the American population is already affected by an ACO program of one sort or another. This is a much faster pace of adoption than I would have predicted just 12 months ago! It is why the topic of ACOs will be front and center at our upcoming 18th annual *Executive War College* in New Orleans on April 30-May 1, 2013.

Those ACO intelligence briefings are followed on pages 16-18 by a profile of the pan-health system effort at **Intermountain Health** in Salt Lake City, Utah, to cut costs across the system by $400 million over a five-year period. The clinical laboratory is to contribute to a $25 million cost reduction as its slice of the pie. What makes this notable is that Intermountain Health is a quality leader, so this huge cost-cutting program is a sign of how painful current and coming cuts in Medicare reimbursement will be to hospitals.

Once you absorb the significance of these intelligence briefings, I think you will agree that I am on safe ground to predict that much financial pain lies ahead for any clinical lab or pathology group that fails to respond to these trends. TDR

Low 2013 Molecular Rates May Bankrupt Some Labs

Prices for some high-volume molecular test fails to cover the lab's cost to perform these tests

CEO SUMMARY: Many of the recently issued reimbursement rates for molecular diagnostic tests are inadequate and in fact are lower than the cost of running the tests, lab experts say. Smaller laboratories that specialize in developing and selling molecular tests could be forced to close. As many as 20 or more molecular labs operate in California and are facing the prospect of appealing the low rates and awaiting a decision on these appeals.

FOLLOWING THE RELEASE of 2013 pricing for molecular test CPT codes that lab industry experts say are too low and, in some cases, less than a lab's cost of performing these tests, **Palmetto GBA**, the nation's largest Medicare carrier, once again finds itself in the lab testing industry spotlight.

On January 28, Palmetto issued its 2013 reimbursement rates for 79 of the 104 new molecular testing CPT codes. The rates are effective for Medicare Part B Medical Laboratory Tests in Jurisdiction 1, which is California, Hawaii, and Nevada. The dramatically low rates for some of the most commonly ordered molecular CPT codes brought immediate and strong criticism.

"Palmetto Genetic Test Rates Could Bankrupt California Genetic Labs, Force Thousands Out of Work, and Slow the Advances of Personalized Medicine" was the headline of the press release issued by the **California Clinical Laboratory Association** (CCLA) on February 6.

Experts in clinical laboratory reimbursement say many of the rates are inadequate and some are lower than the cost of running the tests. Also, they predict that a significant number of labs, particularly in California, will be forced to downsize or close if the unexpectedly low prices for these molecular CPT codes are not properly addressed.

"These rates will be particularly devastating here in California because there are so many molecular labs in this state," noted Lâle White, CEO of **XIFIN, Inc.**, a San-Diego based company that provides revenue cycle management services to medical laboratories. "I estimate that more than 20 labs in California are greatly affected by these low rates.

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

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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).

"Keep in mind that, since January 1, 2013, no labs have been paid for the 104 molecular tests that the **Centers for Medicare & Medicaid Services** (CMS) has identified," she explained. "Now add to this news the fact that some of these new Medicare Part B rates for the highest volume diagnostics don't even cover the costs of performing these tests and you can see the problem."

On its web page that lists the 2013 pricing for the new molecular CPT codes, Palmetto wrote, "As instructed by CMS, Palmetto GBA has determined a gap-fill allowance for the 2013 MoPath CPT codes. The fees were based on the detailed analysis of multiple lab applications and a standardization of the submitted stacks. All services to produce the assay result, including the work for microdissection, were evaluated and included in the listed fee... We will continue to update this fee schedule as the remaining MoPath services are evaluated."

Low Rates, But High Volume

"Prices for about half of the CPT codes that Palmetto issued are essentially in line with the recommendations of the **American Clinical Laboratory Association** (ACLA) and the large national labs," observed White. "But the reimbursement for the molecular test codes that make up the highest volume of testing are problematic, such as BRAF and EGFR.

"For example, the rates for BRAF and EGFR are below costs and these tests represent a large portion of the molecular testing volume," she continued. "This is a major financial problem for all labs, but is particularly true for smaller labs that have a limited and targeted menu. These very common, high volume tests are priced way too low.

"Take those molecular diagnostics labs that have a patented test and may run other tests to round out their menu," stated White. "With such a limited molecular test menu, these labs could be in financial trouble, particularly if they have not yet achieved profitability.

"Because these smaller molecular labs are still trying to develop their tests and their markets, they have a big expense base," White explained. "Their funds are spent on research and development and on educating oncologists and pathologists about the value of these tests.

Lab Investors Uneasy

"Another problem for small labs is that, because they are not profitable, they are backed by investors," she added. "In recent years, those investors have been uneasy because of the uncertainty over pricing, coding, and FDA regulations for molecular and genetic tests.

"All labs that offer molecular testing as part of their broader menu perform these high volume tests: BRAF, KRAS, and EGFR," stated White. "So technically, most labs are affected.

"However, I can think of least 20 labs in California that solely perform molecular testing. Will they be forced to close?" asked White. "That's hard to say because their investors will make that decision. Since these labs typically have negative cash flow, they may have to shut down or down size if their investors don't pony up."

Test Volume Growing

Donna Beasley, DLM(ASCP), recently the Laboratory Specialty Vice President at **McKesson Revenue Management Solutions**, agreed. She said that molecular testing represents the biggest volume growth in lab testing in recent years.

"Many smaller labs may not survive through the period of any appeals and process rate adjustments," observed Beasley. "While all labs will feel the effect, the larger labs may continue operations but turn away from developing new molecular diagnostic tests as investor angst increases with the reduced rates. Were this to happen, it would be a big loss

Website Analyzes Fee Reports and Calculates Losses From Palmetto's New Molecular Rates

TO CALCULATE THE FINANCIAL IMPACT of Palmetto GBA's 2013 prices for the high volume molecular CPT codes, a website called **Market Access Analysts** published an analysis. For such high volume molecular tests as KRAS, BRAF, and EGFR, the prior code stack reimbursement was compared to the prices announced on January 28 by Palmetto for the Medicare J1 region.

"While the impact of these [Palmetto] rates is still being determined, a simple analysis seems to suggest a significant reduction in reimbursement for certain diagnostic tests," the site said. "Using the CPT code stacks identified by **Quest Diagnostics Incorporated** for the KRAS, BRAF, and EGFR tests and the CMS 2012 Clinical Lab Fee Schedule (CLFS), we've calculated an estimated 2012 rate for comparison with the newly proposed 2013 MolDx prices."

Molecular Test	Calculated 2012 CLFS Rate	Palmetto 2013 Rate	Difference $	Difference %
KRAS	$211.20	$225.28	$14.08	+6.7%
BRAF	$257.34	$57.51	$(199.83)	-77.7%
EGFR	$299.88	$116.25	$(183.63)	-61.2%

Source: http://marketaccessanalyst.wordpress.com

for physicians and patients who might benefit from the molecular tests."

Michael Arnold, Executive Director of the **California Clinical Laboratory Association** (CCLA), held a meeting by conference call with his members last week (on February 5). He heard that one lab had already laid off 25% of its staff.

In its press release about this issue, issued on February 6, CCLA wrote, in part, that: "...Palmetto, the outgoing Medicare contract administrator for California and several other states, upended the clinical laboratory industry last week by announcing surprise reimbursement rates that in many instances are below the costs of doing the tests. The impact of this development could force clinical laboratories performing genetic testing to close their doors—reducing patient access to these important new clinical laboratory tests."

"These new reimbursement rates for molecular and genetic testing have no relationship to reality," commented Arnold in the CCLA press release. "They will result in laboratory closures, lost jobs and a reversal of recent advances in personalized medicine. Patient access to many life-saving genetic and molecular tests may no longer be available."

At the national level, representatives from ACLA hope to meet with CMS officials to discuss transparency and reimbursement under the gapfill process for molecular testing, said JoAnne Glisson, ACLA's Senior Vice President. "We will raise these issues. But first we want to see if more pricing information from the other Medicare contractors will be made public," she said.

Labs Can File Appeals

Laboratories in Medicare region J1 can file appeals to Palmetto. "Part of the iterative process of setting prices for molecular tests involves the filing of an appeal," stated White. "This can be done if the price for a test does not appear to reflect that the price was appropriately determined under the regulatory guidelines for establishing a rate.

"Through appeals, the reimbursement rates are likely to change," added White, "and in the process, the prices will become more equitable.

"Palmetto is trying to do the right thing. It just didn't have enough time to

do it properly," concluded White. "But Palmetto has been very good about talking to stakeholders. They listen to what labs say and try to be responsive."

Palmetto officials did not respond to requests for comment by press time.

California's Labs Feel Pain

California has a large concentration of independent laboratory companies. Thus, it is no surprise that labs in the Golden State are first to feel the financial squeeze represented by Palmetto's release of its 2013 pricing for these molecular CPT codes.

Further, because of the advanced biotech research that is centered in California, a significant number of these laboratories have just a few proprietary molecular and genetic tests that make up the majority of their specimen volume. That makes these specialty lab companies particularly vulnerable to financial loss—even bankruptcy—should reimbursement rates be set at rates that may be less than the cost of performing these tests.

For these reasons, the molecular specialty testing labs in California may be useful "canaries in the coal mine." They give the lab industry a way to gauge the short-term and long-term financial and clinical impact of the pricing decisions made by Medicare officials and the different regional Medicare contractors.

New Molecular CPT Codes

In the meantime, it can be expected that labs will file appeals and lab industry associations will engage in conversations with CMS, Palmetto, and the other Medicare contractors over the issue of rates for the new molecular CPT codes. TDR

—Joseph Burns

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Understanding Gap-Fill and Cross-Walking Processes

SEVERAL EXPERTS in laboratory coding, billing, and reimbursement have called attention to the fact that the process of establishing reimbursement for the new molecular CPT codes is in its earliest stages. Additional steps have yet to happen.

"As a starting point, Palmetto GBA has asked stakeholders to provide comments and cost information for reconsideration of the newly-published rates," stated Lâle White, CEO of XIFIN, Inc., in reference to the newly-published molecular test prices for Medicare region J1. "California labs will be providing data to the contractor," she noted.

Experts say such data collection is part of what is required to establish pricing through the gap-fill methodology mandated by CMS. However, Medicare pricing instructions indicate that—when a new test is comparable to an existing test—the price of the new test should be cross-walked rather than gap-filled.

What is a challenge to Palmetto and other Medicare contractors is that most of the tests that make up the new molecular CPT codes were previously coded with specific methodology codes that had a fee schedule reimbursement rate. That is why many lab industry comments submitted during the public comment period suggested that the new molecular CPT codes be crossed-walked to the prior methodology codes. Then, Medicare contractors could develop a median price to be used where different versions of the test were grouped into one code.

Billing and coding experts say that, for the most part, it appears that Palmetto tried to use that methodology. However, it was handicapped by the lack of cost data to complete a gap-fill analysis. For that reason, the appeals filed by laboratories and the submission of additional data will play a big role in helping Medicare contractors develop fair and appropriate reimbursement levels for each of the new molecular CPT codes.

ACO Numbers Increase, Now Cover 10% of Nation

Medicare added 106 new ACOs in January, new private ACOs are forming in many regions

CEO SUMMARY: A recent report by a consulting firm that tracks the ACO industry indicates that, as of the end of 2012, ACOs of all types involved—in some manner—between 25 and 31 million patients. Moreover, Medicare and private ACOs are located in regions where 45% of the population of the United States lives. These facts confirm that it would be timely for local clinical laboratories and pathology groups to develop appropriate strategies for serving the ACOs in their communities.

PREDICTING THE ROLE OF PATHOLOGISTS and clinical laboratory testing in the developing market for accountable care organizations (ACOs) is anyone's guess right now.

Of equal importance is how ACOs will pay for clinical lab tests and anatomic pathology services. That's because the number of ACOs continues to grow at a fast pace. For example, on January 11, officials at the federal **Centers for Medicare & Medicaid Services** (CMS) announced 106 new ACOs.

That brings the total number of Medicare ACOs to 259. With these new ACO organizations, Medicare officials estimate that ACOs now cover as many as 4 million Medicare beneficiaries.

Private Sector ACOs

In the private healthcare sector, ACO growth is equally swift. In its report titled "The ACO Surprise," consulting firm **Oliver Wyman** of New York City estimates that, as of the end of 2012, between 25 million to 31 million patients were already affected in some manner by an ACO. This report was issued in November 2012. It did not include the lives covered by the 106 new Medicare ACOs announced last month.

Oliver Wyman divided total national ACO enrollment into three groups as of November 2012:

- 8-14 million patients were part of non-Medicare ACOs.
- 15 million non-Medicare patients who get their healthcare services from a Medicare ACO.
- 2.4 million Medicare beneficiaries were covered by the 153 Medicare ACOs that existed in November 2012.

By Oliver Wyman's calculations, about 10% of the American population are now getting healthcare from an ACO. This is a fast ramp-up for this new model of integrated healthcare. Pathologists and laboratory executives should acknowledge this rapid market adoption, particularly since it moves patients out of the traditional fee-for-service setting and into care delivery systems that reimburse based on value.

In fact, there is a surprising twist in provider acceptance of ACOs. Oliver Wyman explained that organizations were

serving both non-Medicare patients and Medicare beneficiaries with their ACO.

This has come about because of the shift toward proactive and preventative care, accompanied by value-based reimbursement. The goal is for providers to achieve early diagnosis and active intervention with patients. To achieve this goal, it makes better sense to treat all patients—both commercial lives and Medicare beneficiaries—using the same clinical and operational workflows.

Side-By-Side Reimbursement

"We've seen a few organizations try to operate fee-for-service and value-based models side by side," stated Richard Weil, Ph.D., Partner at Oliver Wyman. "It [side-by-side reimbursement] doesn't work in the long term. The two [payment] models are simply incompatible.

"Besides, it takes an immense amount of work to set up an ACO," added Weil. "Once you've made that commitment, you want to reap the benefits—and there are immense benefits to being a value-based organization."

For laboratory executives and pathologists who remain skeptical about the growth and expansion of ACOs in the American healthcare system, Weil has some words of advice. "There's going to be a big growth spurt in 2013 [for ACOs]," predicted Weil. "The folks who were hoping that the ACO would go away are not going to get what they want."

Many Regions Have ACOs

Weil made another observation about the current state of ACO development. He notes that the locations of existing ACOs now coming into operation already give them access to about half the nation's population.

This fact has profound strategic consequences for most community hospital laboratory outreach programs, as well as local pathology groups. It means that they will need to deal with nearby ACOs sooner rather than later.

Weil was specific in his observation. He stated, "We would argue that this is remarkably quick growth for a new and complex form of payment and care delivery. But it is really only a fraction of the potential impact these provider organizations can have.

"The Medicare ACO programs were deliberately designed as a way to create a multi-payer care delivery model that could compete in the open marketplace with fee-for-service," he continued, "and it is reasonable to ask how many people live in markets where an ACO is one of their healthcare choices.

"The astonishing answer is nearly half of the US population," declared Weil. "When we examine the landscape on the level of primary care service areas (PCSA), 45% of the population live in PCSAs served by at least one ACO, with 17% in a PCSA served by two or more."

Watch ACO Success Stories

How will ACOs evolve? Weil says that the innovators and leaders will attract all the attention and will be the drivers of rapid change. "The averages [of ACO performance] won't drive change, but the success stories—the ACOs that manage to gain an edge on fee-for-service providers will," he predicted.

"Successful ACOs won't just siphon patients away from traditional providers and attract the attention of payers, employers, and partner organizations," predicted Weil. "They will change the rules of the game in the regions where they operate, leading purchasers to expect lower costs, higher quality, and greater patient satisfaction.

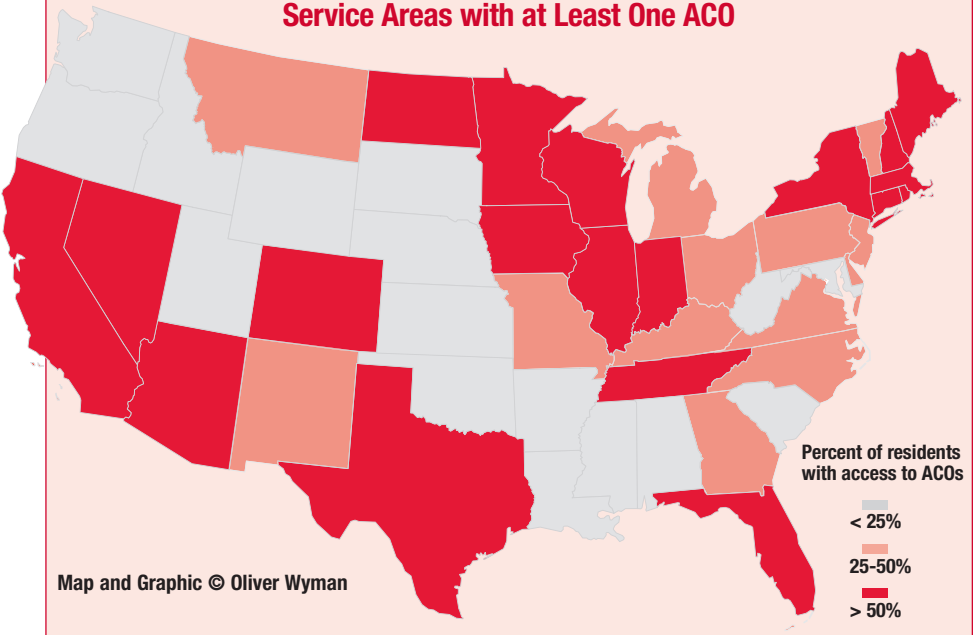
"As that happens, there will be a race to adopt the best models," he added. "Providers that fail to do so—or that commit halfheartedly to real change, will stand no chance."

With this analysis, THE DARK REPORT is the first in the laboratory testing industry to call the attention of pathologists and laboratory administrators to the rapid

Growth in the Number of ACOs Nationwide Demonstrates Momentum behind this Trend

IT HAS NOT BEEN EASY TO GET UP-TO-DATE DATA about the number of accountable care organizations (ACOs) that have been announced and are either in active organization or are already in the early stages of delivering clinical services to patients. Below is a map that was prepared by the New York city-based consulting firm Oliver Wyman. It shows the percentage of population in each state living in a community that is served by one or more ACOs. Further, Oliver Wyman estimates that between 25 million and 31 million patients are already affected by an ACO in their region.

40% of Americans Live in Primary Care Service Areas with at Least One ACO



Note: ACOs defined as providers participating in Pioneer ACO, Medicare Shared Savings, a Medicaid ACO, PGP Transition, or in a shared savings/risk arrangement with a commercial payer

Sources: News releases, company websites, Dartmouth Atlas PCSAs, Claritas, Oliver Wyman analysis

progress of ACO development in the United States today. In the story which follows on pages 10-13, THE DARK REPORT provides inside intelligence on the progress of ACO development by two well-known attorneys who are actively involved in ACO negotiations on behalf of their non-lab healthcare clients.

As you will read on those pages, ACO administrators are giving contract negotiations with hospitals, health systems, physicians, and health insurers priority. That gives pathologists and lab executives time to develop ways to sell the value of lab testing services to ACOs when it finally comes time to contract for lab testing services. TDR

Lawyers Share Insights About ACO Contracting

To date, nascent ACOs are negotiating to align participating hospitals and physicians

CEO SUMMARY: Most pathologists have yet to be involved in any substantial contractual negotiations that would allow them to assume a significant role in accountable care organizations (ACOs). Instead, hospitals and health systems are putting the building blocks in place by acquiring physician practices and installing the necessary infrastructure that their ACOs will need to deliver cost savings. That means pathologists have time to establish their value proposition with ACO administrators.

HUNDREDS OF ACCOUNTABLE CARE ORGANIZATIONS (ACO) now cover as much as 10% of the American population. That makes it essential for every laboratory and anatomic pathology group to have a strategy for providing lab testing services to these new models of integrated healthcare.

Fortunately, pathologists and lab executives have some breathing room. Lab testing is not yet on the radar screen of most ACOs because of bigger issues. That's the opinion of two healthcare attorneys who represent clients participating in the organization and development of ACOs.

"Physicians, hospitals, health systems, and health insurers are in active negotiations with each other as it relates to ACOs in their communities," stated Richard S. Cooper, Attorney at **McDonald Hopkins** of Cleveland, Ohio. "These nascent ACOs seem to be moving at a deliberate pace to develop the web of contracts necessary to align all the providers and define new roles to support the ACO's mission.

"Most ACO administrators are focused on priorities other than laboratory or pathology services at this moment," added Attorney Jane Pine Wood, a colleague of Cooper's at McDonald Hopkins. "To date, none of our client pathologists have been involved in any substantial contractual negotiations that would allow pathologists to assume a significant role in ACOs. Instead, health systems are still putting in place the building blocks."

Practical Insights

Cooper and Wood have practical insights to offer about the progress of the ACO trend. Their law firm's client list includes all categories of providers. Thus, each attorney is involved in different aspects of contract negotiations, strategy development, and the legal and compliance issues associated with organizing and operating an ACO.

"Each situation is unique, given that we are in the earliest days of the ACO trend," noted Cooper. "Providers of every type are struggling to identify their role in an ACO and understand the consequences that value-based reimbursement will have on their financial position."

"In some cases, we see organizations positioning themselves to become ACOs by buying up physician practices and installing

the infrastructure that their ACOs will need in the coming years," added Wood. "Other organizations—including academic medical centers and health systems that have risk-sharing contracts with physicians and other providers—are prepared to become ACOs in a relatively short time."

Cooper and Wood agreed that many of the fastest-moving ACOs are being developed from existing independent physician associations (IPA) or with physician-hospital organizations (PHO). IPAs and PHOs often have global contracting arrangements that can be easily adapted to the needs of the ACOs.

Using Existing Contracts

"This trend is quite visible in Massachusetts, New York, and other states," observed Wood. "It is happening where IPAs and PHOs have had at-risk contracts in place for a number of years with third party payers.

"Additionally, there are communities where some information technology infrastructure may already be in place," she continued. "Where that is true, it is easier and faster for the hospitals and physicians in that community to come together and add an ACO to that structure.

"The priority of many ACOs at this time is to ensure that the relationships with the direct referring physicians and their patients are on a solid basis," explained Wood. "We consistently see that as the first step in the development of ACOs."

Cooper and Wood emphasized that the Medicare program is only one mover in the ACO–risk trend. "At this time, Medicare ACOs are commencing operations, and increasing numbers of private payers are embarking upon similar risk-contracting models," noted Cooper.

No Bundled Payments Yet

"Keep in mind that there are no bundled payments or other discounted arrangements under Medicare ACOs," noted Wood. "The Medicare shared-risk ACO model continues to pay fee-for-service rates to providers, with shared savings determined on the back end, based upon overall financial performance.

Timing for Cost Reduction Linked to Base Line Year

"THERE IS ANOTHER ISSUE TO CONSIDER about Medicare ACOs and the important role that pathologists can play," noted Jane Pine Wood. "Pathologists should start to think about ways they can advise referring physicians about controlling costs for lab test ordering.

"But they should not do so right away," added Wood, an attorney with McDonald Hopkins, the law firm based in Cleveland, Ohio. "This might seem counterintuitive, but there's a good reason for it.

"As stated earlier, at this time Medicare pays fee for service in an ACO," she said. "The goal of the ACO is to cut costs compared with costs in a baseline year. If 2013 is to be the baseline year for costs in your ACO, you don't want to cut costs in the baseline year.

"Instead, costs should be cut in the first year after the baseline is set," stated Wood. "At the end of 2013, Medicare will look at what was spent on patient care. If costs decline in the next year, meaning 2014, then the ACO will get part of that recovery as a bonus payment.

"We know there is waste in clinical lab tests because unnecessary tests are routinely ordered for many hospital inpatients," she noted. "On the molecular side, some physicians are ordering high-end tests that may not be clinically appropriate.

"In certain areas of the country, there have been risk-sharing contracts between IPAs/PHOs and private payors that aim to keep lab costs down," explained Wood. "The private payers are trying to keep ancillary costs down or are doing so by negotiating for returns of withholds or bonus payments for keeping ancillary costs under control."

"For a Medicare ACO to make money (including its share in the cost savings), it must control the ordering decisions and the practice patterns of the doctors," she noted. "The first emphasis is on order patterns of primary care physicians. The second emphasis is on the ordering patterns of surgeons and specialists.

"This emphasis by Medicare ACOs on changing physician ordering patterns is relevant for labs and pathology groups," continued Wood. "Primarily, labs are the recipients of tests that are ordered by referring physicians and labs will be paid at Medicare allowable rates for whatever tests they run.

"The fact that Medicare will reimburse on a fee-for-service basis is why, at this moment in time, Medicare ACOs are not actively pursuing special deals for lab work," she said. "However, this is not true for risk sharing models under development by private payers. For some of these risk sharing models, the intent is to reimburse providers—including labs—via bundled payment contracts.

Bundled Payments Approved

"There is one important issue to watch regarding Medicare." advised Wood. "This involves bundled payments. Medicare officials are moving forward with this program.

"At the end of January, Medicare approved more than 500 organizations to start bundled payment programs," Wood noted. "This is the launch of the 'Bundled Payments for Care Improvement (BPCI)' initiative from the federal **Centers for Medicare & Medicaid Services** (CMS). We are waiting to see how many, if any, of these organizations develop a bundled payment scheme that includes laboratory testing services."

"In the meantime, CMS has either approved or is reviewing the applications for some 450 ACOs," added Cooper. "However, not all of these Medicare ACOs are in full operation yet.

"That has a practical consequence for labs and pathology groups," he stated. "It means many of the organizations planning to become ACOs or engage in risk-sharing contracts are not at the stage yet where they are ready to negotiate and enter into long term contracts with pathologists."

"Having said that, it's clear that health systems believe that ACOs and risk-sharing arrangements will be very important in the future from a strategic positioning standpoint," observed Cooper. "Therefore, if they have the market share and resources to develop an ACO-type model now, they believe they should take the necessary steps to do so now because that will put them in a strong position in the future.

"Until then, the short-term strategy for some health systems is to view ACOs as a way to capture market share," he noted. "This forces physicians and other community providers to align with the largest organizations in the market which are generally the ones driving ACO development.

"With these ACO building blocks in place, the health systems create a framework that aligns them with the integrated clinical care models that will be prevalent in the future," emphasized Cooper. "It is a strategy that I think is driven by the goal of becoming that community's dominant ACO.

"As they create this framework for ACOs, health systems are causing concern among the pathologists and those who run laboratories," he continued. "That is because, at the moment, hospitals and health systems are concentrating on acquiring physician practices.

Dilemma For Pathologists

"This creates an immediate dilemma for pathologists, particularly those who have outreach labs," he said. "It means they may lose access and market share as many of their referring physicians are acquired or absorbed into the local hospitals that are developing ACOs. As employees of the hospital, these former client physicians are often pressured to send their specimens to the lab of their parent hospital.

"By buying up referring physician practices as one step forward in the cre-

Timely Opportunity for Pathologists to Offer Ways to Deliver More Value to Physicians, ACOs

MOST PATHOLOGISTS HAVE A TENDENCY not to promote their good works. While this self effacing quality can be admirable in individuals, it may work to one's disadvantage in a pathology or laboratory setting, said Rick Cooper, a lawyer with McDonald Hopkins.

"Pathologists often fail to let people know the good things that they do daily that involve quality care, achieving cost savings, and keeping the medical staff happy," he said.

"In accountable care organizations (ACOs), pathologists will want be more proactively engaged with clinicians," continued Cooper. "As they do this, it is essential that they also become more adept at quantifying the benefits of their work. It will be necessary for pathologists to be comfortable 'tooting their own horn' so that ACO administrators appreciate their clinical and operational contributions."

In this respect, Cooper and Jane Pine Wood, his colleague at McDonald Hopkins, said that hospital contracts for Medicare Part A clinical pathology services are good models to use in ACO contracting. "Many pathology groups that we represent have successfully negotiated bonuses based on past cost savings in contracts for Medicare Part A services," said Wood.

"Some pathologists have the personality that's needed to effect change in a hospital," said Wood. "They recognize the benefits of spending more time advising physicians on how to more effectively use lab tests, along with the importance of explaining how their efforts saved money for the hospital. But other pathologists are more reluctant to collaborate with referring physicians.

"Some pathologists are concerned about the increased liability risk that comes with advising referring physicians more closely," she added. "Still others complain about the hassles and aggravation of working with other physicians.

"But for pathologists who want to have a potential income stream from cost savings in an ACO, it will be necessary that they work much more closely with referring physicians," explained Wood.

Cooper agreed, saying, "In an ACO where providers will share in cost savings, pathologists need to be bring something to the table that produces cost savings or improves the quality of care or both. If pathologists fail in this regard, they risk being viewed as little more than ancillary providers."

ation of their ACOs, health systems are realigning the physician marketplace," added Cooper. "It must be recognized that these events represent a fundamental shift in the marketplace for laboratory testing services. There will be fewer independent physicians who are free to choose their laboratory and anatomic pathology provider.

"That said, among our laboratory clients, those who are hospital labs are likely to have a place at the table when the time comes to negotiate with these dominant ACOs," he continued. "But if you're an independent lab, you have to ask yourself: how do you get a spot at that table?

"Consider this scenario: If the ACO is controlled by a hospital, that hospital is not likely to have an incentive to bring an independent lab to the table because it may want to mitigate competition in the area," stated Cooper.

"That's why we see our independent lab clients trying to forge mutually beneficial relationships with hospitals and health systems today," he said. "In an effort to position themselves for the ACO marketplace, they are actively seeking to develop joint ventures or form other types of partnerships that could tie them into ACOs." **TDR**

—Joseph Burns

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Manhattan Labs Gets Infusion of Equity Cash

➤Company will use $3.7 million investment to support growth, new services, and innovation

➤➤CEO SUMMARY: Manhattan Labs tapped a private equity company for growth capital last month. The company says its strategy is to deliver concierge-level quality lab services to the high-end physicians and patients within the tri-state area of New York, New Jersey, and Connecticut. These are savvy healthcare consumers who seek the best care from the best physicians and who recognize that quality lab testing is important if they are to identify future health risks.

IN WHAT MAY BE THE NATION'S MOST INTENSIVELY COMPETITIVE MARKET for clinical laboratory testing services, some professional investors are bullish on one fast-growing independent clinical laboratory company.

Just last month, **Manhattan Labs** of New York City announced it received $3.7 million in equity financing. The money came from **Trevi Health Capital LLC**, an investment firm also in New York City that specializes in investing in healthcare companies.

Manhattan Labs will use the new funding to beef up its marketing and sales department, develop signature tests, and open new patient service centers in the tri-state area of New York, New Jersey, and Connecticut.

➤Funding Will Support Growth

"We will use this funding to support our growth," said CEO Ken Cerney. "Our goals are to support better patient access in terms of patient service centers and to expand further into contiguous geographical areas."

As an independent lab company, Manhattan Labs focuses on what Cerney calls high-end physicians and patients. He noted that this strategy requires high quality service and good execution.

"Physicians and patients in the tri-state area demand a high level of lab testing services," he explained. "In these communities, consumers are quite savvy and they seek the best care from the best physicians.

➤Concierge-Level Lab Service

"Our strategy is to deliver personalized, and even concierge-level service," continued Cerney. "That is complemented by our ability to innovate and invest rapidly. We are prepared to add the new tests and equipment required of a nimble lab company in a competitive market."

Cerney explained that his lab team is in regular interaction with client physicians for the express purpose of understanding their changing clinical needs. This information then drives additions to the test menu offered by Manhattan Labs.

"We call on ob-gyns, *in vitro* fertilization specialists, cardiologists, rheumatol-

ogists, and internal medicine physicians," he explained. "These are our core client physicians.

"We meet with these physicians in roundtable discussions," he said. "They share with us the changes in their clinical practice and what lab tests would be most useful for them. Because of these sessions, we now run more than 45 stat tests in our midtown STAT lab on East 52nd Street. This list may be the most comprehensive list of stat tests in New York City.

Fast Test Tat Adds Value

"As an example, the women's health physicians wanted fertility tests because of the patients they see here in New York," noted Cerney. "These are affluent and professional women. They are often older and delaying pregnancy in favor of careers. They plan to have children later in life."

Cerney discussed another lab test that is tied to the rather unique needs of patients living in New York City. "For diabetes, our client physicians not only want a STAT blood sugar level but they want the Hemoglobin A1c as well," he explained. "This helps them better manage their patients and adjust dosages of patients who are on drug therapy.

"However, in New York, physicians tell us it is their patients who want to know the lab test results as soon as possible because that information is important to them," continued Cerney. "These patients understand that these tests are important to help them identify their downstream health risks.

"We believe that the most successful labs are those labs that listen to the patients' needs and partner with their client physicians," he added. "Given the recent anemic growth in the lab industry and the decline in patient visits to physicians, it is particularly important to have a strategy that differentiates your laboratory from the competition."

Manhattan Labs has two facilities, 170 employees, four pathologists, and runs 1.5 million billable tests per year. The company's core lab is in Pine Brook, New Jersey, about 25 miles west of the company's rapid response laboratory in midtown Manhattan.

Looking ahead, Cerney said that accurately predicting how the changing healthcare system will alter or disrupt the status quo in laboratory testing is a major challenge. "It's the beginning of a very interesting phase in healthcare," he noted. "Clearly payers are taking more aggressive steps to reduce costs. It's time that labs showed payers how significant dollars can be saved by recommending appropriate testing and helping payers avoid the downstream risk. That has to be the role of successful labs going forward." TDR

—Joseph Burns

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Company Building Up Its Executive Team

OVER THE PAST YEAR, Manhattan Labs has actively worked to beef up its executive team. The lab company has hired a number of new officers as part of its strategy to develop concierge-level laboratory testing services.

The newest member of the team is Tom Hitchcock, who joined Manhattan Labs earlier this month as Chief Information Officer. He had previously held positions with **Plus Diagnostics** and **Dianon Systems**.

On November 1, Ken Cerney started in his position as CEO. Prior to that, Cerney was President of **Strand Diagnostics, LLC**, in Indianapolis. He has also held positions with **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**.

It was on August 1, 2012, that Anthony Poggioli took up his responsibilities as Senior Vice President of Sales & Marketing. Poggioli's prior lab experience included positions at **Solstas Laboratory Partners** and **Carilion Laboratories**.

Intermountain Seeks Shared Accountability

The lab and all departments asked to improve quality of care while also boosting efficiency

CEO SUMMARY: Intermountain Healthcare is one of the nation's largest and most respected institutions. Its quality improvement efforts are well documented. Intermountain is pursuing an ambitious goal to limit cost increases to the rate of inflation. To reach this goal, every clinical department is being asked to contribute savings and increase efficiency. The clinical lab is already achieving significant results as Intermountain's Clinical Services seeks to cut $25 million in costs over five years.

HOSPITAL LABORATORIES ARE UNDER increased pressure to cut costs by substantial amounts. This is often done as part of a larger cost-cutting initiative at the parent hospitals or health systems of these laboratory organizations.

One good example of this trend is **Intermountain Healthcare**, based in Salt Lake City, Utah. It is now one year into a five-year program designed to achieve $400 million operating expense reductions by 2016. Every department will contribute, including the clinical laboratory.

"Intermountain's goal is to limit annual cost increases to near the Consumer Price Index (CPI) inflation rate," explained Stephen Mikkelsen, MS, MT(ASCP), the Laboratory Services Operations Director. Mikkelsen outlined Intermountain's cost-cutting efforts at THE DARK REPORT'S *Lab Quality Confab* in San Antonio, Texas, in November.

"Many people think this low rate increase is unobtainable," he noted. "For clinical departments, that means $400 million in cuts system-wide. In the clinical services, we have to cut $25 million."

The not-for-profit health system serves residents in Utah and southeastern Idaho. Intermountain has 33,000 employees, 22 hospitals and about 1,000 physicians in its **Intermountain Medical Group**. It also has an affiliated health insurer, **SelectHealth**.

"The cost controls are an essential element in Intermountain's effort to evolve into a shared accountability organization, one that accepts responsibility for the quality, cost, and overall care of a defined population," commented Mikkelsen. "Accountability is shared among hospitals, physicians, patients, payers, and suppliers.

Suppliers Viewed as Partners

"Not only must we limit what we charge, but our partners and suppliers also must limit what they charge," continued Mikkelsen. "If you want to partner with us, you need to help us achieve our goals. To work with us, a provider or partner cannot simply maximize profit at our expense."

"That is part of the definition of 'shared accountability'," he said. "Payers need to reduce their premiums and physicians must charge less too."

Transforming Core Lab into Service Center Helps Drive Down Average Cost Per Lab Test

AT INTERMOUNTAIN HEALTHCARE, the central laboratory serves as both a high-volume core lab and as a pseudo-reference lab. "As the health system's biggest lab, it has the highest volume, the most automation, and the lowest costs per tests," said Steven Mikkelsen, MS, MT(ASCP), Intermountain's Laboratory Services Operations Director.

"Essentially, our core lab is a service center for all the other labs," he explained. "We want to drive as much volume to it as possible. The average cost in the core lab in 2012—including molecular and high complexity, flow cytometry, and general chemistry tests—was $9.48 per test. In the other 21 hospitals, the average cost per test was in the $12 to $15 range because they do not have the same economies of scale.

"The labs in the other hospitals run only those tests needed to support the emergency departments, intensive care units, and some inpatient care," explained Mikkelsen. "They send all their esoteric tests or samples that are more stable to the core lab.

"It was 2009 when we made the core lab into a service center with the expectation that costs would come down," he noted. "In the first couple of years, the costs in the core lab were about $10 or $11 per test.

"That declined to $8.39 per test in 2011, which was great," he added. "Our average cost per test rose last year to $9.48 because of the increased spending we incurred to add a significant number of molecular and high complexity tests. This year [2013], our costs will come back down because of that investment.

"We are also better at sharing the core lab's efficiencies with the referring hospitals," noted Mikkelsen. "The core lab bills the outlying hospital labs at cost for any tests it runs for them.

"Because the core lab's costs are lower than the costs to run those tests in their own facilities, the hospitals see some savings," he stated. "At year end, if there is any net operating income above break even, we return that amount back to the labs in the outlying hospitals. This year we returned over $2.6 million back to those hospitals."

"Integral to the shared accountability strategy at Intermountain is a goal to improve the quality of care on the theory that high quality leads to lower costs," observed Mikkelsen. "We have one of the nation's most respected authorities on healthcare quality to lead this effort.

"That individual is Brent C. James, M.D., M.Stat., who is the Executive Director of Intermountain's **Institute for Health Care Delivery Research** and Vice President of Medical Research and Continuing Medical Education. "Dr. James is taking steps to inject quality into everything that we do, along with eliminating the unwarranted variation that is so common in healthcare today."

James was one of the authors of the recent report from the **Institute of Medicine**, *Best Care at Lower Cost, The Path to Continuously Learning Health Care in America.* The report cites examples from Intermountain's quality improvement efforts. *(See TDR, October 8, 2012.)*

Cutting Lab Costs

For its part, the clinical laboratory intends to cut operating expenses by $5 million over five years. "This will generate cost reductions supporting the clinical services goal of $25 million," noted Mikkelsen. "Our lab's annual operating budget is $135 million. To do so, our lab must improve quality and efficiency while eliminating unwarranted variation."

Intermountain's laboratory service performs more than 11 million billable tests annually. Its core lab in downtown Salt Lake City does 3.7 million of those tests.

Collectively, the labs in each of its 22 hospitals perform the remaining 7.3 million tests.

"Our vision is to standardize care among all of our 2,500 contracted and employed physicians," stated Mikkelsen. "The problem is that, when 2,500 doctors are asked how they treat their patients, you'll get 2,500 different answers.

"We are working to determine, for example, if lab test results we deliver to doctors will contribute to patient care," he continued. "Some tests obviously contribute to patient care, such as cardiac markers.

"But in other areas, the contribution to improved clinical outcomes from lab tests ordered by a physician may be less clear," stated Mikkelsen. "On this point, we are working with primary care physicians to evaluate the tests we currently run to see what outcomes they produce. In a year, we hope to publish the results of our efforts.

Improving Use of Lab Tests

"Here is another question: How do we know that the physicians who get our test results use them correctly?" he asked. "To answer this question, we work closely with cardiologists, ob-gyns, primary care, and other physicians. Also, we analyze data by reviewing lab and patients' records to see where we can improve how tests are used.

"A good example is prenatal testing. If the patient is healthy and not at high risk, the **American College of Obstetricians and Gynecologists** (ACOG) has a list of tests that physicians should order," he commented. "To determine if our physicians followed ACOG guidelines, we recently reviewed the tests doctors order across our entire enterprise, including all 22 hospitals.

"The variation won't surprise laboratory professionals," said Mikkelsen. "Tests that were ordered ranged from $275 to over $500. That was a head scratcher because—if we have guidelines from ACOG—why the variation in ordering practices? That led to more questions. Can we standardize what we order for patients? Can we eliminate some tests? If so, can we save the health system and patients some money?

"We next asked cardiologists about new cardiac marker tests," recalled Mikkelsen. "If new tests are more sensitive and specific, why do we use older tests that are not as sensitive or specific?

Physicians Recognize Value

"One consequence of these reviews is that clinicians now recognize that we are the experts on lab tests," he noted. "That has increased their willingness to ask for our advice about tests. In this way, we started to come to a consensus.

"Here is a case in point," he continued. "A worried patient came to my office with a lab order for 92 tests. Her doctor wanted to confirm his diagnosis that she might have lupus with the use of these 92 lab tests.

"What concerned the patient was that she had no medical insurance and had to pay for the tests herself," stated Mikkelsen. "She was in tears, since she had no idea how she would pay for these tests. She asked if all 92 tests were necessary.

"When I met with her doctor, the doctor admitted being unsure about which tests to order and so asked my advice," he added. "Together, we went through the published research and decided she needed only four tests, each of which was appropriate and affordable for this patient.

"But even more important were the lessons learned," emphasized Mikkelsen. "As a result of this case, that doctor has a closer relationship with the lab and said he would now call the lab more frequently.

"We think we are well positioned to achieve the clinical services' five-year cost reduction target of $25 million," concluded Mikkelsen. "We think we can gain $1.5 million per year in savings through improved utilization. The other $3.5 million per year must come from greater productivity and reduced waste in our clinical labs." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Would it surprise you to learn that just five organizations control 91% of California's health insurance market? At the top of the list is **Kaiser Permanente**, which holds a 40% share of the California market. Following, in order, were **Anthem Blue Cross** (23%), **Blue Shield of California** (14%), **Health Net** (9%), and **UnitedHealth Group** (5%). The numbers were compiled and published in a report issued by **CitiGroup** Financial Analyst Carl McDonald. He used nationwide data on 2011 premiums and enrollment for large and small employers, as well as for individuals buying their own policies.

MORE ON: *Health Insurance Market*

This concentration of the nation's largest market for health insurance shows the consequences of two decades of consolidation within the health insurance industry. It demonstrates why the top five managed care organizations in the Golden State have ample clout to negotiate low prices for clinical laboratory testing.

LIFELABS TO BUY BC BIOMEDICAL

In British Columbia last month, **LifeLabs** announced that it would acquire **B.C. Biomedical Laboratories**. Once the sale is closed, LifeLabs will hold a 90% market share of the lab testing done on non-hospital patients in British Columbia. Private laboratory providers in British Columbia have often been the target of criticism because of their status as for-profit companies. The sale likely allows the physician group that owns B.C. Biomedical Labs to exit the market before further lab test price cuts by the provincial health system erode the market value of their lab company.

ADD TO: *LifeLabs*

There is some irony to this development. Following the announcement of the merger agreement, provincial health officials expressed concerns about the consequences of the near-monopoly that would result after the merger. These concerns included whether lab test fees might increase, as well as reduced patient access if LifeLabs were to eliminate redundant lab testing facilities and patient service centers. "Right now patients in British Columbia have very good access—probably quite a bit better than some of the other provinces," stated Margaret MacDiarmid, B.C. Health Minister, after notifying Canada's federal Competition Bureau to "closely examine the potential impacts of the deal."

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 4, 2013.

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