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YEAR END TOP 10

TOP TEN STORIES FOR LAB INDUSTRY IN 2013

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

Good Information Drives Good Decisions

RECENT DEVELOPMENTS DEMONSTRATE that a long-standing business adage remains as true today as when many of us first learned it decades ago.

I am referring to the pithy piece of management wisdom often written as: "You need good information to make good decisions." It is a trait held in common by well-run corporations and effective executives. It makes the point that the time spent accumulating accurate data and metrics on an issue creates the foundation for smart and informed decision-making.

What brings this to mind today is the news, presented on pages 10 through 12, that the lab industry has finally funded a study of national and local pricing for clinical laboratory tests that compares the prices Medicare Part B pays for lab tests with the price that private insurers pay. Commissioned by the **American Clinical Laboratory Association** (ACLA), the research was done by **Avalere Health** of Washington, D.C. and used a claims database involving 56 million Americans that contained 2013 pricing for clinical laboratory testing.

Many of you probably ascribe to the popular wisdom that a significant number of private health insurers pay less—sometimes significantly less—than Medicare Part B. Researchers at Avalere determined that the popular wisdom is wrong. With the exception of certain regions and certain tests, Medicare Part B actually pays less than private payers for clinical laboratory tests. You can find a summary of the report on the ACLA website.

Of course, the devil is in the details. ACLA has released a summary of the finding. I, for one, would like to see more details about the study, its methodology, and how researchers factored in the variety of deeply-discounted pricing arrangements that are known to exist between the largest health insurance companies and the national lab companies.

Certainly it is time that the clinical laboratory industry paid to have credible and detailed studies performed about the actual prices that Medicare Part B pays for clinical lab tests and compares those to the prices paid by the private payers that operate in every region of the nation. The lack of good information has meant that our legislators in Congress and the administrators of the Medicare program have not had accurate and complete knowledge upon which to make their decisions when it comes to establishing prices for the Part B clinical laboratory testing fee schedule. TDR

2013's Top 10 Lab Stories Point to Tougher Times

Throughout the year, labs found themselves dealing with shrinking budgets and falling test prices

CEO SUMMARY: For 2013, the big story was money—or, more accurately, less money for providers. This was not limited to clinical labs and pathology groups, but was equally true of hospitals and physicians. In THE DARK REPORT's annual lookback at the year's 10 most important stories for the lab industry, the main theme is that government and private payers are reducing reimbursement at an unprecedented pace. In response, most clinical laboratories and anatomic pathology groups are actively reducing their operational costs and looking for ways to boost productivity.

EACH YEAR for more than a decade, THE DARK REPORT has presented its list of top lab industry stories. But never has such an annual list contained the seeds of bad news like 2013.

When gauging the impact of 2013 on clinical laboratories and pathology groups, it is easy to identify finances as the number one challenge confronting the lab testing industry at this time. Payers are proactively taking steps to reduce the prices they pay for laboratory tests.

This is clearly revealed by THE DARK REPORT's list of the "Top 10 Lab Industry Trends for 2013." Most of these stories involve payer actions or market events that reduced the money flowing to clinical laboratories and pathology groups.

In practical terms, this means that nearly every laboratory organization in the United States is expecting to be paid less money for the same volume of services. In some cases, there have drastic price reductions for specific CPT codes and lab tests. *(See trend 1 on page 5.)*

Similarly, at the national level, the number of hospital inpatient admissions is in the midst of a multi-year decline. As well, hospitals are being paid less for inpatient services. For hospitals experiencing a decline in revenue, one obvious response is to cut the budgets of all clinical services, including the laboratory. *(See trend 5 on page 7.)*

During 2103, there were other important changes to the outreach marketplace that had negative financial consequences for hospital laboratory outreach programs. One such story was that of health insurers excluding hospital outreach labs from their provider networks. Another

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story was that of office-based physicians selling their medical practices to hospitals, health systems, and even private insurers. *(See trend 6 on page 7.)*

Compounding the gloom that marked 2013 was the failure of the federal **Centers for Medicare & Medicaid Services** (CMS) and private payers to implement the 114 new molecular test CPT codes that took effect on January 1, 2013. Labs performing these tests went four or five months into the year without payment for these molecular test claims. There were bankruptcies and lab closures as a result of this situation. *(See trend 3 on page 6.)*

Lab Cost-Cutting Trend

It should be no surprise then—given the trends described above—that lab cost-cutting was a top 10 lab industry story for 2013. With hospitals cutting lab budgets and payers slashing lab test prices, smart laboratories responded by accelerating their cost-cutting programs. That is one reason why consultants offering Lean and process improvement services to labs had a boom year. *(See trend 2 on page 5.)*

For the anatomic pathology profession, 2013 may eventually be recognized as a watershed year, for two reasons. First, this is the year when a host of price cuts for a number of important pathology procedures were enacted.

Medicare's Final Rules

Second, this was when CMS published draft rules for 2014 that proposed draconian price cuts to important anatomic pathology procedures. Yes, the final rules published at the end of November did ease back some of the worst proposals. But not completely. *(See TDR, December 3, 2013.)*

Thus, moving into 2014, pathology group practices will see less reimbursement from Medicare—and it can be expected that private payers will impose similar price cuts. Additionally, Medicare intends to move ahead with its plan to bundle anatomic pathology procedures and clinical lab tests into its hospital Outpatient Prospective Payment System (OPPS).

All of this is not likely to turn out well for pathologists. Historically, Medicare has not treated pathology appropriately when establishing bundled pricing. The example of inpatient DRGs from the early 1980s is a prime example.

At the same time, pathology group practices will need to respond to the changes in the outreach marketplace, along with the growth of accountable care organizations (ACOs) and similar new models of integrated clinical care. Pathologists can expect that the traditional business model of the private group practice is unlikely to survive these developments. If true, then 2013 will be a watershed year for the entire anatomic pathology profession, since the largest proportion of pathologists work in private group practices. *(See trend 4 on page 6.)*

Good News During 2013

For those who prefer to focus on the positive aspects of the market, the good news is that whole human genome sequencing and rapid gene sequencing is poised for wider clinical acceptance. By the end of 2013, multiple vendors were offering advanced gene sequencing systems capable of generating faster, cheaper, and more accurate gene sequences. *(See trend 9 on page 9.)*

Similarly, there was good news from some of the nation's largest patient-centered medical home (PCMH) programs. In just a few years of operations, several PCMHs reported cost savings in the tens of millions of dollars annually, accompanied by measurable improvement in patient outcomes. *(See trend 7 on page 8.)*

Another story that was positive is that the Affordable Care Act (ACA) did not have much impact on clinical labs and pathology groups in 2013. *(See trend 10 on page 9.)* But, given recent media revelations about the design of insurance products offered through the health exchanges, that may not be true by the end of 2014! TDR

TDR 1

2013 | TOP TEN | ONE

Collectively Across All Payers: 2013 Was Year That Labs Were Paid Less

WITH HINDSIGHT, pathologists and clinical lab managers may look back and acknowledge that 2013 was the year that the worm turned on reimbursement for lab testing services.

Across the board, the collective weight of coverage and reimbursement decisions during 2013 by all classes of payers—Medicare, Medicaid and private health insurers—meant less money for lab testing services. Scanning back three decades, there is no comparable year where medical laboratories saw such an across-the-board reduction in what they are paid for lab tests. *(See TDRs, February 11 and July 8, 2013.)*

Again, to emphasize, the cumulative effect of various payer decisions on coverage and reimbursement through the course of 2013 meant an overall reduction in the revenue paid to nearly all lab organizations.

Evidence supports the conclusion that the payer pricing dynamics that surfaced during 2013 will be the "new normal" for coming years. This will be particularly true for lab testing that is routine, highly-automated, and provides minimal clinical utility for the physician and the patient.

Lab executives can expect to see payers take active steps to reduce their spending on lab testing. It is likely that capitated pricing and bundled reimbursement (think outpatient/outreach "DRGs") will become quite common.

TDR 2

2013 | TOP TEN | TWO

Cost-Cutting and Productivity Now Essential Themes for Medical Labs

GIVEN THAT REDUCED REIMBURSEMENT for lab tests is one big story in 2013, then it is perfectly logical that more intense cost-cutting by labs of all sizes is an equally significant story this year. *(See TDR, May 6, 2013.)*

The three primary sectors of the lab industry are all experiencing less money. Reduced lab test prices mean less revenue for independent clinical labs. Anatomic pathology groups saw significant cuts in several important CPT codes, not to mention the end of the TC Grandfather Clause in 2012 that compounded this year's price cuts.

Hospital laboratories are experiencing a financial double whammy. First, outreach programs are seeing reduced lab test fees. Second, hospitals are shrinking their lab budgets in response to reduced inpatient admissions and associated revenue.

Across the land, lab organizations are devoting more attention and resources to cost-cutting and productivity improvement. At last October's *Lab Quality Confab* conference, a record number of attendees showed up to learn effective ways to use the techniques of Lean, Six Sigma, and process improvement in their labs.

There is a direct consequence to this trend. Increasingly, the most successful lab managers will be those who bring both scientific expertise and cost-cutting savvy to their labs' operations and workflow. To survive in the coming decade, it will be essential for all laboratory organizations to master the skills of continuous improvement.

TDR 3

2013 | TOP TEN | ➤ THREE

CMS Was Unprepared to Administer New Molecular CPT Codes on Jan. 1

WHEN JANUARY 1, 2013, ARRIVED, the federal **Centers for Medicare & Medicaid Services** (CMS) was not ready to implement the 114 new Molecular Tier I and Tier II CPT codes.

This was equally true for the majority of private health insurance plans. The direct consequence of this situation was that clinical laboratories and pathology groups submitting claims for these CPT codes went unpaid for months. It was not until the late spring that most Medicare Administrative Contractors (MACs) and private payers began processing these claims. *(See TDRs, April 15 and May 28, 2013.)*

The disruption and chaos that resulted from this lack of preparedness still lingers. Many labs suffered financially because of the interruption to timely processing of their molecular test claims during the first part of 2013.

For the second half of the year, it was mixed news. In reviewing molecular test claims, some MACs declined to cover certain molecular assays. In other cases, the price established for reimbursement was less than what had been paid for the same test when billed under stacked codes during 2012.

The financial damage that was done to individual lab companies and to the lab test industry as a whole is significant. Some labs with proprietary molecular tests went out of business. Other labs are dealing with "no coverage" decisions or deep price cuts to their most important molecular tests.

TDR 4

2013 | TOP TEN | ➤ FOUR

Economics of Private Practice Pathology Unraveled on Multiple Fronts During 2013

EVENTS OF THE PAST 24 MONTHS have not been kind to the business model of the pathology private group practice.

This year, on January 1, the Medicare program implemented a 52% reduction on the technical component (TC) for CPT 88305. For many pathology labs, this represented a substantial decrease in revenue. The impact of the 88305 price cut was compounded by the termination of the TC Grandfather clause that took effect on July 1, 2012. As a result of both cuts, histology labs operated by many private pathology groups are losing money or barely breaking even. *(See TDR, November 11, 2013.)*

It is also true that smaller pathology groups lack the capital they need to beef up their information technology to connect to the EHRs of physicians and hospitals, as well as to support advanced diagnostics and digital pathology

At the same time, smaller pathology groups also don't have the money to invest in more complex diagnostic technology. Nor do these small groups have the ability to recruit the subspecialist pathologists they need to perform these procedures.

To this list of woes must be added the approaching end of payment by fee-for-service and the ongoing consolidation of hospitals and doctors into integrated care organizations. These trends are harbingers that the classic era of the pathology private group practice is soon to end.

TDR 5

2013 | TOP TEN | FIVE

Nationwide, Hospitals See Decline In Inpatient Admissions, Revenue

IN RECENT YEARS, THE HOSPITAL INDUSTRY has experienced a decline in inpatient admissions. At the same time, many hospitals are reporting a decline in average revenue per inpatient as payers reduce reimbursement for these services.

These facts have not gotten much attention within the lab testing industry. Yet each trend portends important changes for clinical labs and pathology groups.

First, the decline in inpatient admissions is partially a consequence of more office-based physicians practicing proactive care with the goal of keeping their patients out of hospitals. Collectively, their efforts are bearing early fruit.

Second, RAC audits and Medicare penalties for readmissions have caused hospitals to admit a larger number of patients for observation and bill for these services under the Hospital Outpatient Prospective Payment System (OPPS).

MedPac, in its report to Congress in March, 2012, wrote, "Inpatient admissions per FFS beneficiary declined 1% per year from 2004 to 2010 and 1.3% from 2009 to 2010. Inpatient use also has declined among non-Medicare patients, and as a result inpatient occupancy has declined as well."

Both developments are significant for a simple reason. Every hospital that sees a decline in its inpatient revenue will then seek to reduce the budgets of each clinical service, including the clinical laboratory. That is why hospital labs are devoting more attention to cost-cutting initiatives during 2013.

TDR 6

2013 | TOP TEN | SIX

Hospital Laboratory Outreach Model Runs into Tough Market Challenges

ONE WAY TO CHARACTERIZE THE EVENTS of 2013 as they relate to hospital laboratory outreach programs is to say that the year brought multiple headwinds to the established business model of laboratory outreach.

First, many national health insurers took deliberate and even aggressive steps to exclude local clinical labs—including hospital lab outreach programs—from their provider networks. This is because private payers see hospital laboratories as high-cost providers, at least compared to the national lab companies. *(See TDR, July 8, 2013.)* Second, in a growing number of cities, physician groups have been selling themselves to local hospitals or health systems. This reduces the size of the outreach market for competing hospital outreach programs.

Third, the parent hospitals are seeing flat or even declining inpatient admissions. Faced with less revenue, these institutions are cutting the budgets of their clinical services, including their laboratories. This is starving hospital lab outreach programs of the capital they need to upgrade services, like the information services and LIS-to-EHR interfaces, that are necessary to retain existing clients and win new business.

Several health systems sold their outreach labs to national labs during the year, including **Dignity Health** and **Muir Health**. These actions were seen as indicators of a tougher outreach market.

TDR 7

2013 | TOP TEN | ➤ SEVEN

Patient-Centered Medical Homes Are Producing Significant Savings

FOLLOWING YEARS OF INCUBATION as a model of proactive clinical care, patient-centered medical homes (PCMHs) are delivering impressive results in both improved patient outcomes and a reduced overall cost of care.

Examples from Maryland and Michigan are providing solid evidence of the potential for PCMHs to bend the healthcare curve in positive ways.

In June, **CareFirst BlueCross BlueShield** in Maryland announced that its PCMH program involving about 1 million members had saved $38 million in year one and $98 million in 2012, the second year of the program.

A similar story played out in Michigan. In July, **Blue Cross Blue Shield of Michigan** (BCBSM) published a clinical study indicating that its PCMH program saved an estimated $155 million during its first three years of operation. The practices participating in this PCMH program provide care to 1 million BCBSM members and another 2 million Michigan residents.

These are substantial cost savings and are a direct result of improved health outcomes for the patients served by PCMH practices. In fact, to date, PCMH programs like the Maryland and Michigan examples are reporting more significant gains than the earliest results disclosed by the Medicare Pioneer accountable care organizations, admittedly only in their second year.

Pathologists and clinical lab managers may want to be more proactive at developing added-value lab services that target PCMH physicians.

TDR 8

2013 | TOP TEN | ➤ EIGHT

Strong Growth in Number of ACOs, Enrollment Now in Tens of Millions

EVERYONE KNOWS THAT THE NEXT BIG THING IN HEALTHCARE is expected to be accountable care organizations (ACOs) and similar new models of integrated clinical care. 2013 was the year that hundreds of ACOs were announced or began operations.

The Medicare program was first to organize ACOs. However, in many regions across the country, it didn't take long for prominent hospitals and health systems to organize ACOs in conjunction with physicians and private health insurers.

The year opened with **Oliver Wyman**, the consulting firm based in New York City, estimating that 259 Medicare ACOS were in operation. Oliver Wyman estimated that between 25 million and 31 million Americans were enrolled in Medicare and private ACOs at the end of 2012. *(See TDR, February 11, 2013.)*

As of September 2013, the **Leavitt Partners Center for Accountable Care Intelligence** estimated that 493 ACOs were either in formation or already in operation. It was also noted that the formation of new ACOs had slowed over the course of 2013.

What remains unclear is how ACOs will reimburse clinical labs and anatomic pathology providers for their lab testing services. No definitive trend in ACO reimbursement for lab testing has been identified.

TDR 9

2013 | TOP TEN | NINE

Whole Human Genome Sequencing Poised to Play Big Role in Clinical Care

DURING THE COURSE OF 2013, two things happened that made it more feasible to use whole human genome sequencing for clinical purposes.

First, and most importantly, the latest-generation rapid gene sequencing systems offer more accuracy, shorter sequencing times, and increased automation. Each of these attributes makes it simpler and easier to use gene sequencing for clinical purposes.

Second, the cost of sequencing continues to fall. One manufacturer has gene sequencing equipment that makes it possible to sequence an entire human exome in just a few hours for $875. The price of this gene sequencing system is about $125,000.

Not surprisingly, academic center laboratories are acquiring the advanced equipment necessary to do next-generation gene sequencing in support of clinical diagnostics and announcing collaborations in this field.

That is why **Baylor College of Medicine** (BCM) in Houston, Texas, is partnering with **DNAnexus** (a platform-as-a-service company) and **Amazon Web Services** (the cloud computing provider). BCM has already sequenced 3,751 whole genomes and 10,771 whole exomes, representing about 14,000 individuals.

Most importantly, ongoing technology improvements will only improve the gene-sequencing process. These improvements will be mirrored by advances in big data analysis of genetic data. This will make it feasible for more labs to offer gene testing.

TDR 10

2013 | TOP TEN | TEN

Affordable Care Act: Big in 2013, Little Change for Lab Industry–Yet!

IN 2013, ONE OF HEALTHCARE'S BIGGEST STORIES has been the steady implementation of specific elements of the Affordable Care Act (ACA). To date, most elements of the ACA have had little impact on how providers use laboratory tests. *(See TDR, May 6, 2013.)*

Rather, it was the launch of health insurance exchanges—accompanied by the cancellation notices sent to millions of Americans who had individual health insurance policies—that generated regular national headlines this fall. But there will come a time when labs see some form of change or disruption associated with the ACA.

For example, the health insurance exchanges are now offering enrollment in Bronze, Silver, Gold, and Platinum plans for coverage in 2014. Private payers that offer these products are establishing narrow provider networks as a way to minimize their costs.

Narrow networks can often exclude hospital lab outreach programs and independent labs, due to their higher prices compared to the national labs. The extent of this trend and how it may alter competition in different regions is not yet apparent.

Also, the Bronze, Silver, Gold, and Platinum plans require patients to pay a deductible for lab tests for each date of service, up to $45. This will become obvious in 2014 and may increase patient bad debt levels for many labs. TDR

Study Reveals Medicare Already Pays Low Rates

Most of the time, Medicare is paying less than private health plans, with some exceptions

CEO SUMMARY: Researchers studied a database containing laboratory test prices paid in 2012 on behalf of 56 million Americans covered by private health plans and determined that, for most tests, and in most regions, Medicare already pays less than private health insurers for clinical laboratory tests. There are exceptions, but the findings provide a credible critique of the conclusions in the clinical laboratory test price report issued by the Office of Inspector General earlier this year.

MEDICARE ALMOST ALWAYS GETS the lowest rates for clinical laboratory tests nationwide, except for some tests in certain regional markets. These are the findings of a new study recently performed by **Avalere Health**, a healthcare advisory company in Washington, D.C.

For the clinical lab testing industry, this research may be the most comprehensive investigation ever done of laboratory test prices paid by public and private payers in all 50 states. Its findings are expected to inform the debate over what price levels are appropriate for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS).

Avalere analyzed claims data from the MarketScan databases developed by **Truven Health Analytics**, a healthcare data aggregator in Ann Arbor, Michigan. Truven Health said its MarketScan databases are built on information collected since 1995 from more than 180 million patients.

"The data for this study included 2012 prices paid on behalf of 56 million Americans by non-government health plans (predominantly those contracting with self-insured employers) in more than 398 metropolitan statistical areas (MSAs)," stated Eric Hammelman, Vice President at Avalere. "The data represented the entire clinical lab testing market. It included data from both hospital-based labs and non-hospital-based labs (independent commercial labs)."

The **American Clinical Laboratory Association** (ACLA) commissioned Avalere Health to do this study. Hammelman and other Avalere researchers gathered and analyzed the data.

More Complete Picture

"This analysis was done so that policymakers would have a fuller picture of laboratory test pricing," stated Alan Mertz, President of ACLA. "In particular, it provides a more detailed analysis than that of the federal **Office of Inspector General** (OIG), which issued a report in June of this year."

When reporting on the OIG report, *Bloomberg News* said that for 20 of the highest-volume lab tests, if Medicare paid the lowest price of what any of the 50 state Medicaid programs and three health plans

Researcher Suggests More Questions To Ask On Pricing of Medicare Part B Clinical Lab Fees

TWO SIGNIFICANT FINDINGS EMERGED from a study of clinical laboratory test prices, said researcher Eric Hammelman, Vice President of Avalere Health.

"First, commercial insurers tend to pay hospitals a bit more than they pay non-hospital or free-standing commercial labs," Hammelman explained. "Second, big markets tend to have lower prices than smaller markets. But both of those statements are not always true.

"The question we should ask is this: If Medicare wants to get the best price, how does it define 'best price' and where does it look to find the lowest price in its search to define best price?" he asked. "At this time, Medicare does not differentiate among lab test providers. It pays the same price no matter where the test is done.

Diverse Test Prices

"However, when you look geographically, you find a diverse range of prices with private payers," he continued. "There are hospital-versus-nonhospital settings and urban-versus-rural differences."

Here is where Hammelman frames a question that has dogged Medicare policymakers since inception of the program back in 1966. Medicare treats all lab providers equally—but the private health insurance market does not, because it recognizes how volume can drive the prices for lab tests higher or lower.

"Medicare argues that it's the biggest payer and therefore it should get the best price," observed Hammelman. "But what the data reveals is that private health insurers and labs view pricing from a dynamic and a competitive viewpoint.

"Let me explain," he said. "The data on lab test pricing show that, where a private health insurer can guarantee volume to a lab, that lab will offer a better price. That's because there is a lower marginal cost-per-test when the lab is receiving larger volumes of specimens.

Medicare Test Volume

"But Medicare obviously is not guaranteeing any lab high volume," said Hammelman. "Therefore, can it be argued that Medicare should get the lowest price? Or should policymakers acknowledge that a lab provider has marginal costs that Medicare is not covering because it does not send sufficient volume so the laboratory can realize economies of scale?

"Further, Medicare has more compliance rules that make the cost of testing that much higher," he added.

The long-term care (LTC) segment of the lab testing marketplace supports this point. Medicare pays the same for a test done on a patient in a LTC facility as it does for a well patient in a doctor's office—despite the higher costs the lab incurs to provide lab testing services to LTC facilities.

This is why publicly-traded lab companies abandoned the long-term care market more than 20 years ago. Medicare beneficiaries in LTC facilities are served by small, independent lab companies that operate on profit margins of 4% or less.

If those smaller lab companies cannot cover their costs from Medicare's continually-declining Part B lab test fees, they will go out of business. That will leave Medicare beneficiaries in LTC facilities without access to lab testing.

paid, the federal **Centers for Medicare & Medicaid Services** (CMS) could have saved $910 million in 2011. *(See TDR, June 17, 2013.)*

The Avalere study raises doubts about the OIG report. While confirming that some commercial health plans pay less than CMS pays, the Avalere study also shows

that CMS almost always pays below average rates in markets nationwide.

The data included the numbers from **Quest Diagnostics Incorporated** and **Laboratory Corporation of America,** said Hammelman. These numbers are aggregated along with data from all commercial labs and so are not broken out separately.

Hammelman pulled data from the MarketScan databases for 27 lab test CPT codes representing 15 routine low-dollar tests and 12 more high-dollar tests, including the top four Medicare codes when ranked by cost. Collectively, these 27 codes represent about 49% of Medicare spending on the CLFS in 2012, Hammelman said.

A Representative Sample

"The prices were taken from the claims of about 50 million patients," he said. "Almost 150 million people have employer-sponsored health insurance, which means the MarketScan data represents one third of that total. The data set is large enough that we were looking at almost everything."

On every routine code reviewed, Medicare paid lower rates than the weighted commercial mean price paid, stated ACLA in its press release. "For example, commercial payers paid an average of $20.26 for a complete blood count (CBC)... Medicare's price is almost half at $11.02," wrote ACLA. "For column chromatography for drug screening, commercial payers paid $69.48 and Medicare paid $25.57.

"Commercial rates grew even more expensive than Medicare when services were provided in rural areas," noted ACLA. "For example, the study found that rates could more than double in low volume areas such as Boise, Idaho, compared to high volume areas such as New York City."

ACLA said the OIG failed to consider more than half of the private market. The OIG also incorrectly claimed that private payers receive a better deal on clinical lab tests than Medicare does, stated ACLA.

Commenting on the OIG study, Mertz said, "All too often, judgments are made from anecdotal reports or incomplete, thumbnail sketches that cherry pick some commercial rates. Avalere's analysis shows unequivocally that Medicare pays lower than average commercial rates. The argument that labs may be overpaid by Medicare is simply unfounded."

Hammelman explained that the OIG report involved a smaller number of lab test codes than Avalere studied. Also, OIG collected data on what Medicaid and health plans paid when contracting with the Federal Employees Health Benefits Program (FEHBP) whereas Avalere focused on the broader commercial market, he said.

"OIG went to the lowest or second lowest price—then published a paper that said Medicare is paying more than commercial payers and that if Medicare lowered what it pays to either what FEHBP pays or what Medicaid pays, then Medicare could save millions," Hammelman said. "The OIG report reinforced the idea that has been prevalent about the lab test market for years. That idea is that Medicare pays more than commercial payers and this idea has been widespread since **UnitedHealthcare** signed an exclusive contract with **LabCorp** in 2006." *(See TDR, October 16, 2006.)*

Demonstrate Lab Test Value

When ACLA announced the results of the Avalere research, Mertz explained that all labs understand the pressure on Medicare to cut costs. "ACLA recognizes that Medicare faces significant, long-term fiscal challenges," he said, "but we cannot let anecdotes and incomplete data guide long-term cuts that will ultimately harm Medicare beneficiary access to life-saving clinical laboratory diagnostics. ACLA is committed to working with Congress and the administration to demonstrate the value of labs and ensure adequate access for current and future Medicare beneficiaries." TDR

—Joseph Burns

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Tennessee BCBS Cuts Lab Fees to 52% of Medicare

Steep lab test fee cut is effective on Jan. 1, but providers are unsure which labs are affected

CEO SUMMARY: Blue Cross Blue Shield of Tennessee has notified physicians that, starting January 1, it will reduce what it pays for lab testing to 52% of Medicare fees. Officials with the state medical association have been unable to get definitive answers to questions about what tests would be affected. Medicare officials have said consistently that no other payer should get a lower rate than the Medicare program for any service, including lab tests, and this situation raises questions about compliance.

In the Volunteer State, **Blue Cross Blue Shield of Tennessee** (BCBST) has sent letters to all physicians announcing that, effective January 1, 2014, it will pay only 52% of the 2013 Medicare price for laboratory tests.

Since that letter was sent in the first week of November, physicians, pathologists, lab directors, and officials with the **Tennessee Medical Association** have been unable to get definitive answers to questions about which tests would be affected. This situation also raises compliance questions for lab test providers because Medicare officials have said consistently that no other payer should get a lower rate than the Medicare program for any service, including lab testing services.

At the same time, because BCBST is the state's largest private health insurer, in-office physician labs, clinical laboratories, and anatomic pathologists in Tennessee are wondering if they will be able to survive financially if BCBST cuts all laboratory test prices to just 52% of Medicare rates.

Given the language of the BCBST letter, it was unclear if paying 52% of Medicare would be applied to all clinical laboratory testing or just to a segment.

"Officials from our hospital have met with officials from BCBST over this issue and we have yet to get a straight answer from this insurer," explained a lab manager who asked not to be named for fear of retribution. "We don't know if the price cuts are coming on the clinical laboratory fee schedule (CLFS), the physician fee schedule (PFS), or if they will affect all lab tests for inpatient, outpatient, and outreach testing. BCBST is not talking about this situation."

No Response from BCBST

BCBST is the largest commercial payer in Tennessee. It serves 35% of patients in many rural areas. BCBST officials did not respond to requests for comment from The Dark Report.

Yarnell Beatty, Vice President, Advocacy, for the medical association, said the society's 8,000 members were concerned about the effect of the price cuts on patient care. After meeting with BCBST on November 11, society officials remained unsure about where the cuts will fall.

"We met with them in November and since then they have changed their stance," stated Beatty. "Originally the cuts would have covered hospital-based labs but now they have backtracked on that and said the cuts would not affect hospital-based labs.

Uncertainty Over New Policy

"One BCBST official said the cuts would not affect independent labs, but our members have told us they understood the cuts would affect independent labs," he added. "At the moment, it appears that physician-based labs would be affected but hospital-based labs won't be cut."

The *Times Free Press* of Chattanooga reported that the BCBST announcement does not affect hospitals or independent labs but that it will affect physicians' in-office laboratories.

In its letter to physicians, Blue Cross Blue Shield of Tennessee said, "Our rates for physician labs are higher than national and local market levels." To control these costs, BCBST would implement a new rate for currently contracted physician labs effective January 1, 2014, the letter said.

Beatty has three specific concerns about the cuts. "First, our physician members are receiving mixed signals about which labs will be affected and, as a result, they don't understand the scope of the cuts," he said. "Second, if the cuts go into effect, the labs will receive much less than what they are getting paid by other payers. However, the association doesn't know what others are paying and we can't collect rates from our members because that would be an antitrust violation.

Members Comment On Rates

"Our members who do know market rates, tell us that, if BCBST makes these cuts, it will be paying much lower than what others are paying," he said. "Yet, BCBST claims these cuts will bring it in line with market rates. Our members should know.

"The third issue about these low lab test srates is that patient care could be affected," stated Beatty. "It is possible that many patients would be inconvenienced if it turned out that physicians stopped performing lab services because they could not recover their costs. That would be a key impact." TDR

—By Joseph Burns

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BCBS of Tennessee May Be Copying Its Medicaid Strategy

LAST YEAR, BLUE CROSS BLUE SHIELD OF TENNESSEE adopted an exclusive contract with **Quest Diagnostics Incorporated** to serve Medicaid patients.

"In that program, BCBST paid 52% of Medicare rates to labs serving state Medicaid patients," said a hospital official who asked to remain anonymous. "When BCBST cut what it paid for testing for Medicaid patients, few providers stopped seeing Medicaid patients. Since most providers continued to see Medicaid patients, BCBST may be wanting to try the same strategy on a wide scale beginning January 1."

Also, there is the example of **Blue Cross Blue Shield of Mississippi**. In recent years, it cut the amount it pays for clinical laboratory and anatomic pathology tests to 75% of what Medicare pays.

"Another factor that played a role in the reimbursement cuts for testing for Medicaid patients was that BCBST made an exclusive contract with Quest Diagnostics Incorporated," continued this individual. "This meant no other labs could participate in serving Medicaid patients in Tennessee, even if they were willing to match the price BCBST paid to Quest Diagnostics."

In September 2012, BCBST sent a letter to physicians in the state saying it was consolidating lab testing with Quest Diagnostics and that all testing for patients in its TennCare program should go to Quest. BCBST made exceptions only for "emergency-room-based lab services and outpatient observation lab services."

Lab Briefs

LABCORP, BRLI ISSUE REVISED GUIDANCE OF LOWER EARNINGS

IN RECENT WEEKS, at least two public lab companies have issued downward earnings guidance for 2014. These changes are based, in part, on expected reimbursement reductions from the Medicare program.

It was December 10 when **Laboratory Corporation of America** told investors that its full year 2013 earnings per share (EPS) guidance was expected to be $0.05 less. More notably, LabCorp's EPS guidance for 2014 was $6.50. That was 14.2% less than the street consensus of $7.57. LabCorp does expect its revenue to grow 2% during 2014.

"We continue to operate in a very difficult environment," stated David P. King, Chairman and CEO, in the company's press release on this matter. LabCorp characterized the market as "challenging" and went on to say that "the operating environment will continue to negatively impact financial performance through 2014." LabCorp listed four factors as contributing to this situation:

- Ongoing muted utilization environment;
- Continued increases in [the number of] Americans with high deductible and high co-insurance plans;
- Ongoing government payment and reimbursement issues; and
- Uncertainty related to the implementation of the Affordable Care Act.

Just 16 days earlier, on November 27, **Bio-Reference Laboratories, Inc.** (BRLI) issued its guidance for its fiscal fourth quarter and preliminary fiscal 2014 guidance. The fourth quarter guidance was for a lower EPS of $0.40 compared to the street consensus of $0.55.

During fiscal 2014, BRLI expects revenue to increase by 10% and to be entirely driven by increased specimen volume. Its net income guidance was growth of 15%. The street consensus for both numbers was 13% and 15%, respectively.

BRLI's press release noted that: "...the Company believes there is an ongoing recalibration of reimbursement for the industry, which has resulted in substantial downward pressure from many payers regarding reimbursement." BRLI went on to say that it "had to negotiate contract modifications to reimbursement rates and conditions of payment and/or eligibility with dozens of health plans representing a substantial number of lives nationwide."

In reaction to these developments, the stock price for LabCorp dropped by about 11% following its announcement. Similarly, after posting revised guidance on November 27, Bio-Reference Lab's shares declined by almost 21%.

EPIC, THE EHR FIRM, TO OPEN SOURCE CODE TO OHSU IN PORTLAND

ONE OF THE NATION'S MOST SECRETIVE HEALTH INFORMATION COMPANIES will open its source code for education and research purposes with **Oregon Health Sciences University** (OHSU) in Portland, Oregon.

Based in Verona, Wisconsin, **Epic Systems Corporation** has one of the better-selling electronic health record (EHR) systems in the country. *Healthcare IT News* reported that Epic's arrangement with OHSU will be its first partnership with an academic informatics program.

For its part, Epic will provide two EHR systems. OHSU will use one for research purposes. The other will be used in medical education.

OHSU already runs the Epic EHR in its hospitals and clinics. It has been using the VistA EHR in its teaching activities. This is the Veterans Health Information System and Technology Architecture (VistA) that is an open-source EHR.

In its press release announcing the partnership with Epic, OHSU wrote: "The EpicCare research environment—including access to Epic source code—will allow OHSU faculty and students to investigate usability, data analytics, simulation, interoperability, patient safety and other research topics. It also will enable the prototyping of solutions to real-world health care problems that can be addressed by informatics technology."

For education purposes, OHSU wrote that the Epic EHR: "will provide students in OHSU's graduate program in biomedical informatics access to EpicCare for learning purposes. Students in both OHSU's on-campus and distance learning programs will pursue coursework based on Epic's electronic health record system. Educational activities will include learning to configure screens, implementing clinical decision support, and generating reports as well as performing other front-end and back-end activities."

Epic sees this partnership as a door opener to establish similar arrangements with other academic centers. In the OHSU press release, Bret Shillingstad, M.D., Epic clinical informatics physician, was quoted as saying: "We see this partnership with OHSU as a great way to accelerate the optimization of electronic health records. Once the environments are established, Epic and OHSU will assist other Epic academic customers in establishing similar laboratory environments for their programs."

OHSU says it will offer classes and research projects using the live Epic EHR system by March 2014. That is the start of the spring term.

5 ILLINOIS HOSPITALS BAND TOGETHER TO TRAIN MEDICAL TECHNOLOGISTS

DISTANCE LEARNING UNDERPINS a collaboration by five hospitals in Northwest Illinois to increase the number of medical technologists (MTs) that graduate in their communities.

The project is called the **Northwest Illinois Healthcare Collaborative**. Participating are **Rockford Memorial Hospital**, **OSF Saint Anthony Medical Center** (all in Rockford), **FHN Memorial Hospital** (Freeport), **Katherine Shaw Bethea Hospital** (Dixon), and **CGH Medical Center** (Sterling).

The academic partner for this collaboration is **Weber State University** (WSU) of Ogden, Utah. Julie Mann is President of the collaborative and the Chief Administrative Officer of KSB. She stated that the goal is to provide "our client laboratories with an opportunity to educate laboratory personnel without taking them away from their work sites."

The use of long distance training for medical technologists and clinical laboratory scientists has grown steadily over the past decade. Further, hospital administrators are waking up to the fact that support for MT training is necessary if there are to be enough properly-trained personnel in their communities to staff the clinical laboratories in their hospitals. *(See TDRs, August 8, 2008; October 24, 2005; July 7, 2003.)*

ALBERTA HEALTH ISSUES RFP FOR $3 BILLION 10-YEAR CLINICAL LAB DEAL

ITS OFFICIAL! On December 11, the **Alberta Health Authority** (AHS) in Edmonton issued a request for proposal (RFP) for what may be the world's single biggest clinical laboratory testing contract.

Officials at AHS want to find a single private laboratory company that will build a new, state-of-the-art clinical laboratory facility in Edmonton and operate it for 15 years, through the year 2030.

The goal of the contract is to consolidate and rationalize all hospital-based lab services, outreach/community testing, and lab specimen processing. Officials at the Alberta Health System will establish key service standards and performance metrics for the contract, which takes effect on January 1, 2015 TDR

Meaningful Use Stage 2 to Challenge Labs in 2014

Delay in MU stage 2 provides some relief, but deadline for ICD-10 stays at October 1, 2014

CEO SUMMARY: On December 6, the Centers for Medicare & Medicaid Services proposed to delay implementation of Meaningful Use (MU) Stage 2 until 2016. One reason is that only about 80 vendors have certified their products to MU Stage 2. That is a small proportion of the almost 900 vendors who hold MU Stage 1 certification for their electronic health record (EHR) products. If physicians must acquire a new EHR to comply with MU Stage 2, their laboratory providers will then need to build new LIS-to-EHR interfaces.

NATIONWIDE, A PERFECT STORM is brewing for information technology (IT) departments in hospitals, laboratories, and medical clinics.

This perfect storm will be caused by the need to meet meaningful use (MU) requirements at nearly the same time that physicians, hospitals, and clinical laboratories must switch from ICD-9 codes to the more-complex ICD-10 coding system that starts on October 1, 2014.

The good news for clinical labs and pathology groups is that on December 6, the federal **Centers for Medicare & Medicaid Services** (CMS) proposed extending the period providers need to demonstrate compliance with MU2 by one year. This would push the new deadline for MU2 compliance into 2016. Officially, federal officials said, MU Stage 2 compliance will be extended through 2016 and Stage 3 will begin in 2017 for providers who have completed at least two years in Stage 2.

"With these extensions, IT departments will have to juggle their priorities," stated Ken Willett, Vice President, Health IT Strategy for **Liaison Healthcare Informatics**. "Also, because of the uncertainty about what providers will need to do to meet the requirements of MU Stage 2, this proposed delay will take some pressure off of IT departments."

Liaison, based in Atlanta, helps hospital labs and clinical labs connect their laboratory information systems (LIS) to the electronic health record (EHR) systems of physicians and hospitals.

Few EHRs Meet Stage 2

Willett explained another problem that was causing grief for CMS. "To comply with MU Stage 1, providers could choose from more than 900 vendors with products certified to meet MU Stage 1," he noted. "Currently, only about 80 developers have products certified to meet MU Stage 2."

This is a double-edged dilemma. CMS officials recognized that many hospitals and physicians now use EHR products that were certified to MU Stage 1. These providers would be reluctant to buy another EHR product that is MU Stage 2

compliant. However, only about 10% of the 900 certified MU Stage 1 systems are certified as compliant with MU Stage 2.

"The fall-off in the number of certified Stage 2 products was predicted because it is more expensive and time-consuming for vendors to get their EHR products to meet Stage 2 than for Stage 1," explained Willett. "Now reality hits. Expectations are that many of the smaller EHR vendors—with a limited number of customers—will not be able to meet MU2 requirements and are thus likely to go out of business.

"If these smaller EHR vendors cannot continue to operate, physicians will have trouble accessing their longitudinal patient data," he added. "This fear helps to explain why about 17% of physicians today are considering switching to another EHR system."

This may be mixed news for clinical labs and pathology groups that have spent considerable money and time to interface their LISs to the EHRs of their client physicians. It means they would have to do a second interface if physicians bought a new EHR in order to meet MU Stage 2 requirements.

Established EHR Vendors

"For those physician groups considering a switch, the vendors getting the most consideration are the long-established EHR companies," said Willett. "Included are companies such as **AllScripts**, **Cerner**, **eClinicalworks**, **athenahealth**, **Practice Fusion**, and **GE**."

"Lab managers should know that many of the companies Ken named above are well established and had robust functionality established years before meaningful use was even a term used to describe an EHR system's functionality," declared Pat Wolfram, Liaison's Director of EMR and Lab Integration. "What we see now in the EHR market is that a number of smaller companies that shipped new EHRs over the past six years have only achieved MU Stage 1 compliance. Now, in order to meet MU2, they have a great deal of work to still do.

CORHIO Supports Full Menu of Functions and Services

In the Meaningful Use (MU) Stage 2 requirements, physicians using electronic health record (EHR) systems will need to incorporate certain functions that include lab test orders and access to lab test data.

- Computerized physician order entry (CPOE): must include lab test orders.
- Incorporate lab results, which will become a core measure.
- Electronic laboratory reporting (ELR) can be done either by sending directly from the LIS or by using the EHR.
- For hospitals, Stage 2 necessitates transmitting electronic lab test results to outpatient providers.

"Expectations are that some of these smaller companies will struggle and, when they do, their client physicians will replace those EHR systems," he continued. "In such instances, labs will need to develop new interfaces for physician clients who are moving on to their second EHR system.

"For hospital labs, the challenge is two-fold," he added. "First, hospital labs will need to support the efforts of physicians to bring their ambulatory EMRs to MU 'Eligible Providers' compliance. Second, they will need to update their LIS and informatics systems in ways that allow their parent hospitals to demonstrate compliance with 'Eligible Hospital' MU requirements. This second effort will allow the hospitals to collect the financial incentives CMS is paying for meeting the MU2 requirements."

"Independent labs may have it easier," added Willett. "They do not have to meet MU2 requirements internally. Rather, they need to work closely with their client physicians to ensure that their physicians have the lab data needed for such compliance." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Saudi Arabia is the second country to embark on the goal of sequencing 100,000 human genomes. Earlier this month, the **Saudi Human Genome Program** was announced. Funding for the program, expected to take five years, will be provided by the Saudi Arabian national science agency. The first country to declare this goal was the United Kingdom. In December 2012, Prime Minister David Cameron announced that the **National Health Service** of the United Kingdom had budgeted US$160 million to sequence 100,000 human genomes during the next three to five years.

MORE ON: *Genomes*

There is an interesting aspect to this genome sequencing program in Saudi Arabia. In 2008, Editor Robert Michel participated in an international symposium on laboratory medicine hosted by the Department of Pathology at the **Riyadh Military Hospital**, in Riyadh, Saudi Arabia. One presentation was delivered by Dr. Aida I. Al Aqueel. At the hospital, she is Consultant of Pediatrics Genetics, Metabolic and Endocrinology. Dr. Al Aqueel pointed out there is a tribal culture that is heavily consanguineous in the Middle East. Marriage between first cousins has been a cultural norm across the region for millennia. This has led to the "founder effect," generating a significant number of autosomal recessive diseases that are not seen in Western countries. This is one reason why the Saudi's human genome project may lead to unique and valuable insights about a variety of recessive genetic diseases.

STRAND IN PACT WITH EL CAMINO

Another development on the international market is the announcement of a collaboration between **Strand Life Sciences** of Bangalore, India, and 443-bed **El Camino Hospital** in Mountain View, California. The partners will establish a Strand Center for Genomics and Personalized Medicine at the hospital. Utilizing exome sequencing, the collaboration will support physicians with services in cardiology, oncology, pharmacogenomics, and personalized medicine. Although based in India, Strand has another U.S. connection. It received venture funding from **Burrill & Company** of San Francisco early in 2013.

Transitions

- **TriCore Reference Laboratories** of Albuquerque, New Mexico, named Khosrow R. Shotorbani, MBA, MT(ASCP) as its new CEO, effective February 2, 2014. Shotorbani has held executive positions at **ARUP Laboratories**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

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...how microbiologists and others at **Weill Cornell Medical College** are collecting specimens to identify the microbiome found in New York City subways and other public places. The findings will support public health initiatives.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, January 13, 2014.