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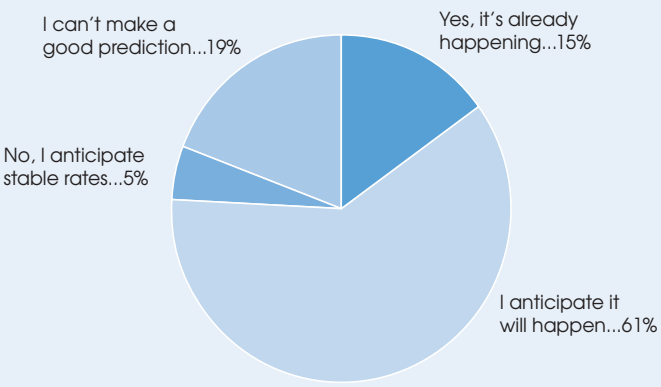
LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Labs Bracing For Private-Payer Rate Cuts

Fifteen percent of lab executives report that private insurance companies (e.g. Aetna, BCBS, Cigna, United, et al.) have already begun to lower their clinical lab test reimbursement as a result of reductions to Medicare's 2018 Clinical Laboratory Fee Schedule, according to a survey conducted by *Laboratory Economics* in early February. Another 61% anticipate it's just a matter of time before they do, while only 5% are expecting stable rates from private insurers. "They will do what they always have done—use Medicare as a benchmark and then lower their reimbursement," commented a lab executive from Georgia. *Continued on page 5.*

Will private insurance companies lower their clinical lab test reimbursement as a result of reductions to Medicare's 2018 CLFS?



Source: *Laboratory Economics'* survey February 2018 (n=153)

ACLA Files For Summary Judgment, But Judge's Decision Unlikely Until Spring

As scheduled, the American Clinical Laboratory Association (ACLA) filed a motion for summary judgment on February 14 in its lawsuit against the U.S. Department of Health and Human Services (HHS). The lawsuit argues that CMS wrongly excluded the vast majority of labs, including nearly all hospital labs, from reporting private-payer data used to calculate new Medicare clinical lab test rates.

A decision from Judge Emmet G. Sullivan is not likely at least until after HHS files its response (due by March 16), and probably won't come until after all counter-arguments have been filed in mid-April.

Historically, the courts have shown a high level of deference to interpretations of statutes made by those government agencies charged with enforcing them. "There's a high bar to challenging an agency, but it's not out of the question," according to Karen Lovitch, Practice Leader of the Health Law Practice at Mintz Levin (Washington, DC). *Continued on page 2.*

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ACLA Files For Summary Judgment *(cont'd from page 1)*
In its motion for summary judgment, ACLA argued that HHS's exemption of hospital laboratories from the PAMA reporting requirements is inconsistent with the statute's design, structure, and purpose. "Collecting data from a small, cherry-picked sample of laboratories does not come close to completing the task that Congress assigned. The Secretary's refusal to comply with Congress's mandate should not be tolerated. Instead, the Court should strike down the Secretary's final rule."

Although it may be a long shot, if Judge Sullivan rules in favor of ACLA, then the reimbursement rates for the 2018 Medicare CLFS would revert back to the 2017 levels, HHS would need to re-write the definition of "applicable laboratory" so as to include hospital labs, and the private-payer data collection process would start over from scratch.

***Laboratory Economics'* PAMA Teleconference Highlights**


Karen Lovitch

During *Laboratory Economics'* special teleconference on February 1, Lovitch noted that ACLA may be using the suit to gain the attention of Congress and to force HHS to the bargaining table. ACLA is likely to be seeking an amendment to PAMA that would require hospital outreach labs to report their private-payer lab test rates during the next data collection period (Jan. 1, 2019 to June 30, 2019). CMS will use this information to set CLFS rates for 2021-2023.


Tom Hirsch

In the meantime, the prudent thing to do is assume that this year's 10% rate cut for most routine lab test codes on the Medicare CLFS will be followed by additional 10% reductions in both 2019 and 2020 as scheduled, advised Tom Hirsch, President of Laboratory Billing Solutions (Portsmouth, NH). "These cuts will eliminate any margin for most labs, unless they take corrective action. The train has left the station and you better start dealing with it quick."

The million dollar question now is "Can labs stop private insurance companies from reducing their rates based on the new lower Medicare CLFS rates?" Labs have their greatest negotiating leverage for new assays, according to Lale White, President of XIFIN Inc. (San Diego). And she notes that hospitals that negotiate their contracts as a percentage of billed charges have leverage. "But for routine commodity tests, it's really difficult and a lot of payers have a 'take it or leave it' attitude when it comes to contracts."

Below we summarize answers by Lovitch, Hirsch and White to some of the key questions raised during *LE's* special teleconference, *Medicare's Market-Based Payment Start-Up: Strategic Options & Compliance Red Flags for Laboratories*.

Are there any penalties for applicable labs that did not report their private-payer data to CMS as required by PAMA?
Yes. The statute authorized CMS to impose civil monetary penalties of up to $10,000 per day for each failure to report or each misrepresentation or omission in reporting applicable information. "But as far as I know, CMS hasn't done anything to figure out if any labs that were supposed to report, did not," said Lovitch.

If hospital outreach labs are required to report their private-payer payment rates in the next reporting period (Jan. 1, 2019 to June 30, 2019), can they do it?
White noted that most hospital outreach labs bill through their hospital's main billing department where lab payments are posted in a bundled fashion for an entire claim instead of at the CPT code

level. As a result, the level of detail needed to report PAMA data has historically not been retained. "I'm hoping that hospitals have started to retain their ERA data and source data from which they could actually extract private-payer payments details."

Are there any winners under the new market-based CLFS?
Single source labs and specialty genetic labs fared the best with PAMA because they control their market pricing, according to White. Myriad's myRisk Hereditary Cancer Test, Veracyte's Affirma Gene Expression Classifier, Genomic Health's Oncotype Dx Breast Cancer Test, and CareDx's AlloMap all received rate increases of between 6% and 14%.

In addition, White noted that hospital outreach labs that do business under the hospital's NPI with contracts that are "a percentage of billed" have the ability to establish their own market pricing with private payers. "If these labs manage their contracts well and begin to run their labs as a revenue center with financial controls, they will not only have better margins than commercial labs, but they will have an opportunity to gain market share in regional areas where smaller labs will be disadvantaged."

Has CMS issued further guidance on Advanced Diagnostic Laboratory Tests (ADLTs)?
No. CMS has stated that it will require laboratories to submit documentation to support their application for ADLT status, including evidence of their empirically derived algorithms and how their test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. However, CMS has yet to release the application to be used for this purpose or any other guidance on the process, according to Lovitch.

What's the process for labs to follow in applying for a proprietary laboratory analyses (PLA) code and how is Medicare paying for these tests?


Lale White

The process, as well as the current list, are on the AMA website. CMS issued about 30 PLA codes last year, noted White.

CMS is obligated to accept claims for the new codes. However, Medicare coverage is not guaranteed. Commercial payers are also not obligated to provide coverage for these new codes. Most labs that applied for codes have policies in place with at least some payers and agreements that the PLA is the code to use.

The downside to getting a PLA are that they now become established on the CLFS and therefore become reportable under PAMA. If not covered, the tests are now easier to identify by payers and easier to edit for denial versus using a not otherwise classified (NOC) code that may result in attachments and/or subsequent appeals that require more thorough payer consideration for payment or denial.

White said that getting a PLA code is generally beneficial only after coverage and pricing from private payers has been established.

Why did CMS choose not to finalize the private-payer rates for the definitive drug testing "G" codes?
CMS made a revision to its final CLFS for 2018 which excluded the private-payer rates calculated for the definitive drug screen codes (CPT G0480-G0483) because their code descriptions and Medicare rates were changed in 2017, after the initial private-payer survey period had ended, explained White.

The new calculation for the 2018 Medicare rates for these codes was derived from the fee for CPT 82542, resulting in a less drastic 2.7% reduction (*see page 13*).

In the future, rates for the definitive drug screen codes will probably be based on a pure PAMA private-payer market analysis.

Is there a potential compliance problem for labs customizing chemistry test panels (n-1) to take advantage of Medicare's new Automated Test Panel (ATP) payment policy?
"This is a loophole that I think will be quickly addressed by CMS. And I wouldn't advise labs to try and resuscitate their business by, for example, offering a metabolic profile with three less tests so they can bill for the individual tests and get four times the money," said Hirsch.

Anytime a laboratory is offering a panel on its requisition that was created by the laboratory, it should implement compliance safeguards to encourage physicians to order only medically necessary testing, advised Lovitch. She said that custom panels and medical necessity are a focus of Medicare contractors and enforcement agencies.

According to Lovitch, compliance safeguards for custom panels should include, at a minimum:

- Offering only those custom panels for which the laboratory can document clinical utility for each test included.
- Clearly disclosing the contents of each test panel on the requisition.
- Educating physicians regarding Medicare's medical necessity requirements (e.g., in the annual notice to physicians, on the lab's website, in marketing materials, etc.).
- Including a medical necessity certification on the requisition and requiring a physician signature.

What are some strategies that labs should consider to cope with the rate reductions?
The PAMA reporting exercise showed that the financial systems that are in place at many labs, especially at hospital labs, are simply not adequate to capture the level of data required to recognize revenue and make collections. Stronger more automated financial systems will help labs not only report PAMA pricing information, but could also help them collect an estimated 5-10% of revenue that's written off from their accounts receivable because it's too expensive to collect using manual labor, according to White.

In addition, Hirsch said that labs will need to look at their costs for collecting samples. "You see other industries under price pressure that have eliminated some service elements and made their customers provide it. Lower reimbursement is going to be a reality in the laboratory space. So if you have a phlebotomist in a doctor's office or visiting a nursing home that draws only seven patients per day, you may need to tell that office to draw those patients yourself, I can't afford to have an FTE there," noted Hirsh.

And finally Hirsch emphasized the need for all labs to move away from payer contracts that adjust based on the current Medicare CLFS. "If you have a payer contract that's set as a percentage of Medicare's CLFS, you need to have it fixed to the 2017 CLFS or earlier. If someone is negotiating with payers based on the current CLFS or one that can be adjusted every year, you're setting yourself up for death."

Long Term Care Association Files Brief Supporting ACLA Lawsuit

The National Association for the Support of Long Term Care (Washington, DC), a trade group representing ancillary service providers to nursing homes, has filed a brief supporting ACLA's lawsuit versus HHS.

The brief states that Medicare rates govern the vast majority of the revenues received by independent labs serving nursing homes (either because Medicare pays directly for the tests or because the nursing home or a Medicare Advantage plan pays for the tests at a rate expressed as a percentage of Medicare rates).

"By 2019—when the cuts would reach a cumulative total of 20%—it would not be profitable for most of these laboratories to stay in business," according to the brief. Most, if not all, independent nursing homes labs could be driven out of business and nursing home patients will lose access to the unique lab testing services they need. NASLTC has asked the Court "to take this extraordinary harm into account in considering the legal issues being litigated by the parties."

Labs Bracing For Private-Payer Rate Cuts (*cont'd from page 1*)

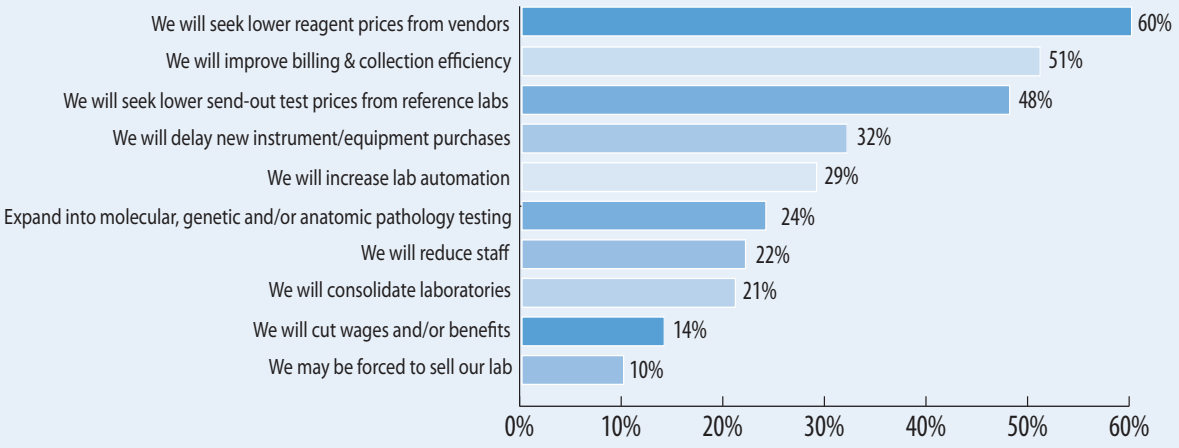
"It is our belief (based on conversations with payer representatives) that contractors with payment rates tied to current Medicare intend to implement changes as contracts allow. To date private insurers have been unwilling to renegotiate current contracts to a static fee schedule," according to a lab executive from the Midwest.

"I've seen new reduced fee schedules from several payers. In particular, Anthem in the managed Medicaid segment is moving the fastest," according to a lab executive from California.

Likewise an independent lab executive from Florida reported that Medicare Advantage plans are using cuts to the Medicare CLFS as an excuse to lower fee-for-service rates paid to contracted labs.

Meanwhile, *LE's* survey showed that 60% of labs will seek lower reagent prices from vendors as a result of lower reimbursement from payers. The next most commonly cited strategies included improving billing and collection efficiency (51%) and seeking lower send-out test prices from reference labs (48%). Ten percent of respondents said they may be forced to sell their laboratory.

What adjustments will your lab make as a result of lower Medicare rates?



Source: *Laboratory Economics'* survey February 2018 (n=153)

The 153 lab executives responding to the survey represented 73 independent labs, 46 hospital labs, 11 anatomic pathology labs or groups, six national lab companies, seven physician office labs and 10 lab consultants and vendors.

The CLFS Limbo Stick

Private insurance companies have based their lab test pricing on Medicare rates since the introduction of the Clinical Lab Fee Schedule in 1984. And now Medicare is basing its CLFS rates on private insurance companies, thereby creating a circular system in which CLFS rate reductions trigger rate reductions by private payers, which trigger more CLFS reductions and so on.

"The CLFS in now caught in a game of laboratory limbo," notes a lab executive in Texas.

Lower rates from private payers this year will affect the next PAMA data collection period (Jan. 1, 2019 to June 30, 2019). Several other factors will contribute to a scenario that is likely to result in another round of significant Medicare rate cuts for clinical lab tests when the next pricing reset is implemented in 2021.

Factors That Will Influence All Future PAMA Rate Calculations:

1) As our survey highlights, most lab executives report that private-payer lab test prices are being ratcheted down, or will be soon, as a result of lower Medicare rates.
2) Acquisitions made by LabCorp and Quest Diagnostics will put pressure on pricing. Insurance contracts at acquired labs are converted to the lower-priced contracts held by the national labs. This means that the low prices paid to LabCorp and Quest will represent an ever-increasing portion of the data submitted to CMS each time it recalculates rates.
3) Quest is likely to become an in-network provider, alongside LabCorp, to United Healthcare effective January 1, 2019. This coincides with the start of CMS's next data collection period. As a result, Quest will be reporting lower private-payer rates for a substantial book of business.
4) The potential inclusion of hospital outreach lab pricing data would have a big positive effect on the next recalculation by CMS. However, most hospital labs don't have the necessary financial systems in place needed to capture detailed pricing information for their outreach businesses. And therefore most may not be able to report their pricing data, even if required to do so.
5) Lower rates from Medicare and private insurance companies will lead labs to search for anywhere they can cut costs. An obvious target will be send-out test prices paid to the four main national reference lab companies: ARUP Laboratories, LabCorp, Mayo Medical Labs and Quest. Since prices paid for reference lab services are reported under PAMA, this will lead to still more downward pressure when CMS does its next rate recalculation.

Barring a legislative rewrite of the law, the above factors all but guarantee that future PAMA private-payer surveys will result in continued Medicare rate reductions for clinical lab tests. Medicare CLFS rate cuts are limited to 10% per year from 2018-2020, but the cap falls to -15% per test code starting in 2021.

"We have opened the door to further commoditization of our services. This historically has been driven by large commercial lab strategies to gain exclusive contracts. It is an inevitable and self-sustaining cycle that will require a creative and aggressive response from those who want to continue to be successful," according to a hospital lab outreach executive from the Northeast.

"The fact that labs have been charging commercial payers below Medicare and now have an issue that Medicare should not be charged those same amounts seems hypocritical. Labs have had plenty of time to change their contract pricing with their commercial payers. PAMA has been known for many years and it was very evident early on that there would be an impact on 'market price' if commercial contracts were priced less than Medicare. As a taxpayer, I am deeply concerned that we have been paying more for lab tests with our tax dollars than what the commercial insurance companies pay under contract," according to an executive at a proprietary molecular diagnostics lab.

LabCorp Reports Full-Year 2017 Financial Results

LabCorp (Burlington, NC) reported net income of $1.268 billion for the full-year 2017, up from $732 million in 2016. LabCorp's overall revenue increased by 8.3% to $10.441 billion in 2017.

LabCorp's traditional lab testing business increased its revenue by 8.7% to $7.171 billion in full-year 2017. The increase included organic requisition volume growth of 2.2% plus 2.8% from an increase in average revenue per requisition. In addition, lab acquisitions (including Pathology Associates Medical Laboratories (PAML) and Mount Sinai outreach lab) added 3.6% to revenue growth.

On February 6, LabCorp held a conference call with analysts and investors. Here are some comments on a few key topics from CEO David King.

Trump Tax Cut
LabCorp's adjusted tax rate (including federal, state and local taxes) will decline from 33.4% in 2017 to 25% in 2018. LabCorp will invest part of the tax savings into information technology and infrastructure improvements. The company also plans to pay a bonus to its employees, based on length of employment, in March. A big portion of the tax savings will also drop to LabCorp's bottom line, increasing earnings per share by approximately $1.30 per share, or roughly $135 million, in 2018.

Fastest-Growing Test Categories
LabCorp's fastest-growing sectors included prescription-drug monitoring, noninvasive prenatal testing, cancer genetic testing and genotyping testing provided to 23andMe.

Will Lower Medicare Rates Motivate Sale of Hospital Outreach Labs?
"I'm not sure that the impact of PAMA has been fully realized, particularly in—I was with a large health system CEO last week. And

LabCorp Financial Summary ($ millions)

	2017	2016	% Chg
Total revenue	$10,441.4	$9,641.8	8.3%
LabCorp Diagnostics	7,170.5	6,593.9	8.7%
Covance Drug Development	3,037.2	2,842.2	6.9%
Operating cash flow	1,459.4	1,175.9	24.1%
Capital expenditures	312.9	278.9	12.2%
Free cash flow	1,146.5	897.0	27.8%
Pretax income	1,134.9	1,105.5	2.7%
Net income	1,268.2	732.1	73.2%
Diluted EPS	12.21	7.02	73.9%
Total debt	6,762.1	5,849.5	15.6%
Cash & securities	316.7	433.6	-27.0%
Shareholders' equity	6,830.0	5,505.8	24.1%
Est'd number of requisitions	152.0	143.7	5.8%
Est'd revenue per requisition	47.22	45.93	2.8%
# Lab employees	37,000	36,500	1.4%
Avg. revenue per lab employee	$193,797	$180,655	7.3%

Source: LabCorp and *Laboratory Economics'* estimates for number of reqs and average revenue per req.

without getting into a lot of detail, I don't think the impact of PAMA on the laboratory operations at large health systems has necessarily been fully understood yet in the executive suites," noted King.

United HealthCare Contract
LabCorp's long-term national contract with United HealthCare expires at the end of 2018. "We've had an accelerated pace of discussions, very constructive discussions, and I'm hopeful that we'll reach some sort of a resolution in a relatively short time frame," said King.

Tight Labor Market
"Obviously, we're in a tight labor market….We think about wage rate inflation as sort of being in the 3% range, and that's how we sketch it out for the future."

Outlook for 2018
LabCorp expects revenue growth of 3% to 5% at its traditional lab testing business in 2018, which includes the negative impact of the Medicare rate cuts plus a boost of roughly 2% from acquisitions.

Quest Reports Full-Year 2017 Financial Results

Quest Diagnostics reported net income of $772 million for full-year 2017 versus $645 million in 2016. Quest's overall revenue increased by 2.6% to $7.7 billion.

Quest reported that its requisition volume increased by 2.3%, including 0.8% gained from acquisitions.

Quest's average revenue per requisition was up 1% to an estimated $45 per req. The company said it experienced some "headwinds" on test unit pricing from private payers, which was offset by a mix shift to higher-priced esoteric tests plus an increase in the average number of tests per requisition.

A summary of key topics discussed by CEO Steve Rusckowski and CFO Mark Guinan on a February 1 conference call follows.

Fastest-Growing Test Categories
The company's fastest growing sectors included prescription-drug monitoring with growth of more than 20%. Tests growing by double-digit rates included Quest's branded noninvasive prenatal screening test ("QNatal Advanced") as well as hepatitis C screening.

Meanwhile, Quest's anatomic pathology business declined by 1.9% to $612 million in 2017.

Fallout from PAMA Medicare Rate Cuts
Rusckowski anticipates a judge's decision on the ACLA lawsuit by midyear.

He said that the PAMA price cuts will reduce its Medicare clinical lab rates by 4% in 2018, and by 10% in both 2019 and 2020.

Guinan said that the PAMA private-payer rate survey has made it clear that the biggest national labs offer the lowest pricing. In discussions with private insurers, Quest's message is "We are part of the solution.

We give the best value and you know that when you drive more volume through one of the national labs, it's much better than it going somewhere else," according to Guinan.

Quest Diagnostics Financial Summary ($ millions)

Revenue by product	2017	2016	% Chg
Gene-based and esoteric	$2,449	$2,335	4.9%
Anatomic pathology	612	624	-1.9%
Routine	4,309	4,179	3.1%
Drugs of abuse	NA	NA	NA
Other*	339	377	-10.1%
Total revenue	7,709	7,515	2.6%
Operating cash flow	1,175	1,069	9.9%
Capital expenditures	252	293	-14.0%
Free cash flow	923	776	18.9%
Pretax income	1,030	1,086	-5.2%
Net income	772	645	19.7%
Diluted EPS	5.50	4.51	22.0%
Total debt	3,784	3,734	1.3%
Cash & securities	137	359	-61.8%
Shareholders' equity	4,955	4,660	6.3%
Bad debt %	4.1%	4.1%	0.0%
Days sales outstanding	46	47	-2.1%
Employees	45,000	43,000	4.7%
Est'd number of requisitions	163.8	160.1	2.3%
Est'd revenue per requisition	$44.98	$44.53	1.0%

*Other revenue includes clinical trials testing, info tech services and testing for life insurance companies.

Source: Quest Diagnostics and *Laboratory Economics'* estimates for number of reqs and average revenue per req.

Trump Tax Cut

Quest is a significant beneficiary of lower corporate tax rates and will realize approximately $180 million in tax savings in 2018. Of this amount, roughly $120 million will fall to Quest's bottom line, raising its earnings per share by approximately $0.85. Quest says it will invest most of the rest into advanced diagnostics, information technology enhancements, and improvements at patient service centers (PSCs). Quest also plans to pay a bonus of up to $500 to about 40,000 employees, or a total of about $20 million, this year.

Acquisitions

Quest spent a total of $581 million on seven acquisitions completed in 2017. Its largest deal was the acquisition of Shiel Medical Laboratory (Brooklyn, NY) in December for $170 million cash plus up to $15 million of contingent consideration to be paid based on the achievement of certain volume benchmarks.

Most recently, Quest acquired Mobile Medical Examination Service (MedXM-Santa Ana, CA) in early February. MedXM contracts with doctors, nurse practitioners and physician assistants who visit elderly people in their homes and evaluate their health on behalf of Medicare Advantage plans such as Anthem Blue Cross and Blue Shield and Health Net of California. These home health reviews include a medical history review, brief physical exams and documentation of any existing medical conditions. Medicare Advantage plans use this information to help document health risk scores for Medicare beneficiaries. Medicare pays higher rates for sicker patients.

Drug Store Partnerships Expanding

Rusckowski said Quest has now opened patient service centers in 184 Safeway, Tom Thumb, Randalls and Vonns stores in 12 states—primarily California, Colorado and Texas. In addition, Quest opened six locations in Wal-Mart stores in 2017, including five in Florida and one in Texas. These PSCs serve patients with doctor-ordered lab tests and are aimed at increasing access and convenience.

Potential for United HealthCare Contract?

"We'd love to get access through United as one of their national partners. We are working on that. We feel good about the progress we're making," said Rusckowski.

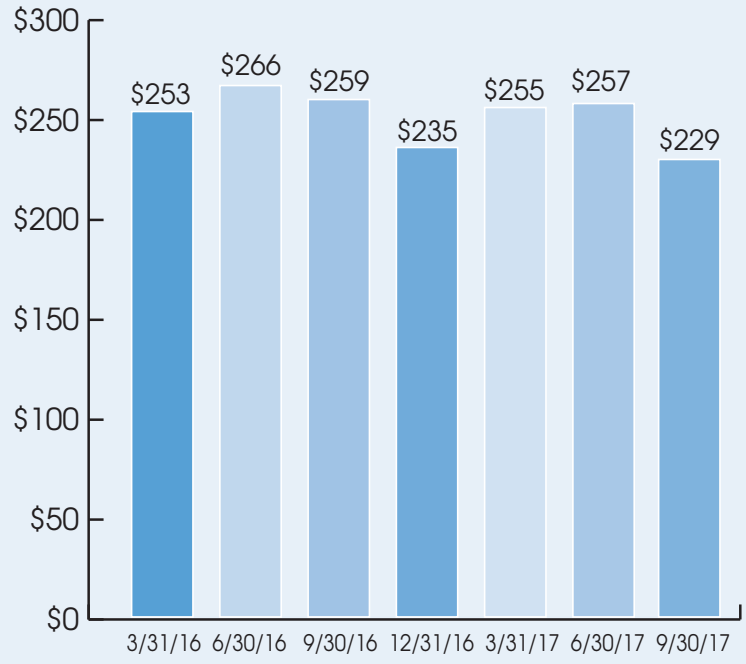
Bio-Reference Labs Searching For New President

OPKO Health (Miami, FL) says that Gregory Henderson, MD, PhD, has resigned from his position as President of Bio-Reference Laboratories (Elmwood Park, NJ), effective immediately. The company has begun a search for his replacement and, in the interim, a committee of senior management will assume operational responsibilities.

Henderson became President of Bio-Reference in March 2016, which followed OPKO's acquisition of the company for $950 million in August 2015. Previously, Henderson had been Vice Chairman of Pathology and Director of Laboratory Outreach at the Mount Sinai Health Network in New York.

At the time of the acquisition, OPKO had forecast 10+% annual revenue growth at Bio-Reference. But the company's latest report shows declining revenue. OPKO reported that Bio-Reference had an operating loss of $35.7 million for the nine months ended September 30, 2017, versus a gain of $11.1 million in the same period a year earlier; revenue fell by 5% to $741 million.

Quarterly Revenue at OPKO's Bio-Reference Labs ($ millions)



Source: OPKO Health

Separately, in April 2017, the Civil Division of the United States Attorney's Office for the Southern District of New York (SDNY) informed Bio-Reference that it believes that, from 2006 to the present, Bio-Reference had, in violation of the False Claims Act, improperly billed Medicare and Tricare for clinical laboratory services provided to hospital inpatient beneficiaries at certain hospitals. OPKO says that Bio-Reference is still reviewing and assessing the allegations made by the SDNY, and, at this point, has not determined whether there is any merit to the SDNY's claims, nor can it determine the extent of any potential liability.

Industry Groups Raise Concerns About CMS Proposed Requirements for High-Complexity Testing

A request by the Centers for Medicare and Medicaid Services (CMS) for input on who should be allowed to perform moderate- and high-complexity testing under CLIA is raising concern among many in the laboratory industry.

In a January 9 *Federal Register* notice, CMS announced that it is soliciting comments on whether a bachelor's degree in nursing should be considered equivalent to a bachelor's degree in biological sciences when determining educational requirements for performance of moderate-and high-complexity testing. CMS in 2016 issued guidance stating that it considers these degrees equivalent but is now considering whether to formalize this guidance in the CLIA regulations.

CMS believes that the change is needed to address a shortage of testing personnel at physician office laboratories in rural areas.


Blair Holladay, PhD

Blair Holladay, PhD, Chief Executive of the American Society for Clinical Pathology (ASCP), tells *Laboratory Economics* that ASCP does not support allowing those with nursing degrees to perform high-complexity testing given the sophistication of molecular and genetic testing, which many nurses are not adequately trained to perform and interpret.

"A person who performs high-complexity testing should have a four-year degree in medical laboratory science or degree in biology or chemistry," says Holladay. "We feel strongly that high-complexity testing personnel should be someone who graduated from an accredited school and who has taken a certification exam."

While many industry groups are still compiling their comments for CMS, the American Association for Clinical Chemistry (AACC) sent a letter to CMS after the guidance was announced in 2016. In their letter, the AACC went on record opposing allowing nurses to perform high-complexity testing.

"AACC agrees that nurses are invaluable members of the healthcare team," the association wrote. "However, their education and training necessarily covers a breadth of medical disciplines and therefore does not delve into the depths of scientific concepts underlying clinical laboratory testing. CMS's decision to accept nursing degrees as the equivalent to the currently accepted degrees would exempt nurses from having to complete valuable clinical laboratory training prior to performing patient testing."

Julie Khani, president of the American Clinical Laboratory Association (ACLA) says that ACLA member laboratories recognize the need to have qualified personnel in moderate- and high-complexity testing CLIA laboratories. "We will work with CMS to help the agency best understand how different educational degrees could fulfill the personnel requirements under CLIA," she tells *Laboratory Economics*. ACLA is also assessing for potential comment the other areas of CLIA regulation referenced by CMS in the request for information, Khani adds.

In addition to seeking input on personnel and histocompatibility requirements, CMS is also asking for comments on alternative sanctions for Certificate of Waiver labs who have participated in referrals of proficiency testing, appropriate sanctions for PT referral, and the updating and collection of fees under CLIA. Comments on the request for information are due by March 9.

Lab Stocks Down 5% Year To Date

Prices for 16 publicly-traded lab stocks were down 5% on an unweighted average basis through February 16. In comparison, the S&P 500 Index is up 5.7% year to date. The top-performing lab stock so far this year is Genomic Health, up 12%. At the two largest public labs, LabCorp is up 11% and Quest Diagnostics is up 6%.

Company (ticker)	Stock Price 2/16/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$1.80	$1.85	-3%	$44	NA	1.5	1.4
CareDx (CDNA)	5.71	7.34	-22%	163	NA	3.5	NA
Enzo Biochem (ENZ)	6.89	8.15	-15%	323	NA	3.0	3.6
Exact Sciences (EXAS)	48.86	52.54	-7%	5,850	NA	27.4	11.1
Foundation Medicine (FMI)	74.90	68.20	10%	2,740	NA	20.6	42.7
Genomic Health (GHDX)	32.91	29.39	12%	1,140	NA	3.4	6.6
Interpace Diagnostics (IDXG)	0.95	1.02	-7%	26	NA	1.7	0.6
Invitae (NVTA)	6.48	9.08	-29%	343	NA	5.0	2.6
LabCorp (LH)	177.79	159.51	11%	18,100	14.6	1.8	2.7
Myriad Genetics (MYGN)	32.81	34.35	-4%	2,290	17.6	2.9	2.5
NeoGenomics (NEO)	7.52	8.57	-12%	605	NA	2.4	3.6
Opko Health (OPK)	3.85	4.90	-21%	2,154	NA	1.9	1.0
Psychemedics (PMD)	21.29	20.56	4%	117	19.2	2.9	6.8
Quest Diagnostics (DGX)	104.53	98.49	6%	14,250	19.0	1.8	2.9
Sonic Healthcare (SHL.AX)	23.86	21.40	11%	10,090	23.4	2.0	2.6
Veracyte (VCYT)	5.70	6.53	-13%	194	NA	2.8	4.5
Unweighted Averages			-5%	$58,429	18.8	5.3	6.3

Source: Capital IQ

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Final Medicare Payment Rates for Key Clinical Lab Test Codes, 2018-2020

Code	Code Description	2017 Medicare NLA	Private-Payer Weighted Median	Absolute % Chg in Payment	2018 Payment with 10% Cap	2019 Payment with 10% Cap	2020 Payment with 10% Cap
80048	Metabolic panel total ca	$11.60	$8.06	-31%	$10.44	$9.40	$8.46
80053	Comprehen metabolic panel	14.49	9.08	-37%	13.04	11.74	10.56
80061	Lipid panel	18.37	11.23	-39%	16.53	14.88	13.39
80069	Renal function panel	11.91	7.94	-33%	10.72	9.65	8.68
80074	Acute hepatitis panel	65.34	38.79	-41%	58.81	52.93	47.63
80081	Obstetric panel	102.69	59.96	-42%	92.42	83.18	74.86
81206	Bcr/abl1 gene major bp	224.91	116.03	-48%	202.42	182.18	163.96
81211	Brca1&2 seq & com dup/del	2,195.48	2,395.84	9%	2,395.84	2,395.84	2,395.84
81235	Egfr gene com variants	331.82	324.58	-2%	324.58	324.58	324.58
81275	Kras gene variants exon 2	198.57	193.25	-3%	193.25	193.25	193.25
81519	Oncology breast mrna	3,443.36	3,873.00	12%	3,873.00	3,873.00	3,873.00
81528	Oncology colorectal scr	512.43	508.87	-1%	508.87	508.87	508.87
81595	Cardiology heart trnspl mrna	2,840.75	3,240.00	14%	3,240.00	3,240.00	3,240.00
82306	Vitamin d 25 hydroxy	40.61	26.37	-35%	36.55	32.89	29.60
82542	Column chromotography qual/quan	24.77	24.09	-3%	24.09	24.09	24.09
82607	Vitamin b-12	20.68	13.43	-35%	18.61	16.75	15.08
82728	Assay of ferritin	18.70	12.13	-35%	16.83	15.15	13.63
82746	Assay of folic acid serum	20.17	12.88	-36%	18.15	16.34	14.70
83036	Glycosylated hemoglobin test	13.32	8.50	-36%	11.99	10.79	9.71
83880	Assay of natriuretic peptide	46.56	39.26	-16%	41.90	39.26	39.26
83970	Assay of parathormone	56.62	36.76	-35%	50.96	45.86	41.28
84153	Assay of PSA total	25.23	16.38	-35%	22.71	20.44	18.39
84439	Assay of free thyroxine	12.37	8.03	-35%	11.13	10.02	9.02
84443	Assay thyroid stim hormone	23.05	14.87	-35%	20.75	18.67	16.80
85025	Complete cbc w/auto diff wbc	10.66	6.88	-35%	9.59	8.63	7.77
85610	Prothrombin time	5.39	4.29	-20%	4.85	4.37	4.29
87086	Urine culture/colony count	11.07	7.19	-35%	9.96	8.97	8.07
87624	Hpv high-risk types	48.14	31.26	-35%	43.33	38.99	35.09
88175	Cytopath c/v auto fluid redo	36.34	26.61	-27%	32.71	29.44	26.61
G0471	Ven blood coll snf/hha	5.00	5.00	0%	5.00	5.00	5.00
G0480	Drug test def 1-7 classes	117.65	NA	-3%	114.43	114.43	114.43
G0481	Drug test def 8-14 classes	160.99	NA	-3%	156.59	156.59	156.59
G0482	Drug test def 15-21 classes	204.34	NA	-3%	198.74	198.74	198.74
G0483	Drug test def 22+ classes	253.87	NA	-3%	246.92	246.92	246.92

Source: *Laboratory Economics* from Final 2018 CLFS