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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PUBLIC-LAB CEOs PAID AVERAGE $3.1 MILLION

The chief executives at 15 publicly-traded lab companies were paid an average of $3.1 million each last year, according to an analysis of shareholder proxy statements by *Laboratory Economics*. Altogether, the 15 CEOs earned a total of $47 million, including $10 million from salary, $6.9 million from bonuses, $29 million from stock and option awards, and $879,740 from other compensation.

Continued on page 5.

COMMON PATHOLOGY PRACTICE BILLING ERRORS (AND HOW TO AVOID THEM)

While most pathology practices, or their billing companies, track performance benchmarks for collections (net collection %), bad-debt writeoffs (bad debt %) and accounts receivables (days in A/R), most do not track a performance benchmark for contract adjustments, according to Al Sirmon, President and co-founder of Pathology Practice Advisors, LLC (Columbia, SC). "It's the 'black hole' of billing that often leads to underpayment from contracted insurance plans," says Sirmon.

Continued on page 9.

OPKO'S BIO-REFERENCE ACCUSED OF FALSE CLAIMS

OPKO Health Inc. (Miami) has disclosed that its clinical laboratory unit Bio-Reference Laboratories (Elmwood Park, NJ) is under investigation for allegedly violating the False Claims Act.

Details on page 10.

BILLING STRATEGIES FOR OUT-OF-NETWORK LABS

More states are taking up legislation to address balance billing, also known as "surprise billing," which occurs when patients receive an unexpected bill from a medical provider. Typically, this occurs when patients are treated by out-of-network providers who do not have contracts with a particular payer. Florida, New York and California have imposed limits on balance billing. Other states that have considered restrictions on balance billing in recent months include Arizona, Georgia, Minnesota, Oregon, Rhode Island, Texas, Washington and Utah. *Laboratory Economics* recently spoke with Richard Cooper and Elizabeth Sullivan, attorneys with the law firm of McDonald Hopkins (Cleveland), about billing strategies for out-of-network labs.

Continued on page 2.

Contents

BILLING STRATEGIES FOR OUT-OF-NETWORK LABS (*cont'd from p. 1*)

When is it permissible for a laboratory to balance bill a patient?


Richard Cooper

Cooper: If you're out of network, there's no contractual prohibition on balance billing (unless there is a state law barring it). Other possible restrictions would be a provision in your hospital contract that requires you to act as if you were in-network and thus caps the amount you can bill at the payer allowable amount. There's emerging activity in some states where they are trying to limit "surprise" bills.

Do you believe there has been an increase in balance billing as a result of more narrow networks?

Cooper: To some extent, it's been the opposite. A lot of labs have attempted to mimic what they would have billed if they had been in-network, so the patients are not out of pocket any more money than if they had used a participating laboratory. The reason they're doing that is to preserve their referral base. Some labs have gone beyond that and waived patient co-pays and deductibles, which carries with it some compliance risk. But from a practical standpoint, it's difficult for labs to know what the in-network amount is unless they receive an explanation of benefits from the payer. But some payers refuse to pay providers directly and will only pay the patient. Hopefully states will take that into account when they're passing these surprise law bills.

What are some issues related to out-of-network labs billing patients?


Elizabeth Sullivan

Sullivan: A significant issue is the lab trying to address patient and clinician satisfaction with respect to pricing, which can create compliance issues. Labs want to reduce patient payment responsibility when they are out-of-network. I don't think there are many labs that are wholly waiving co-payments and deductibles because it raises federal and state fraud and abuse concerns. The concern is that by waiving deductibles or co-payments, it could induce referrals.

In addition, we're seeing a lot of payers on the commercial side getting very aggressive on waivers or reduction in pricing. They are looking at billing practices and going after providers for submitting false claims based on a theory that the lab has misrepresented its actual charge. As an example, if the charge is $1,000 and the payer amount is $800, and the patient amount is $200 and the patient amount is waived, a payer may take the position that the real charge is $800 and that the lab has misrepresented the true charge resulting in the payer paying more than it should. Payers have had some success with these tactics. We are seeing behaviors changing where providers are no longer providing deep discounts to patients.

What can labs do if they are out-of-network but want to remain competitive on pricing?

Cooper: They can be very transparent, and tell the payers that they will act as if they are in-network and will accept the in-network rate. They can ask the payers to share the in-network rates with them. It's always going to be a bit of a risk, but if you're charging people what they would have paid if you were in-network, and you disclose that to the payer, that helps mitigate risk. It gets a little dicier when you can't determine what the in-network rate is or when there is a higher deductible or co-payment for out-of-network providers because then the payer forces you to charge the patient more. Labs should also make every attempt to get in-network and document rejections, so if it ever goes to court, they can argue that even though they made every effort to participate in the network, they were rejected and that this particular payer reduced the network size for economic reasons.

When should a lab turn over a bill to a collection agency?

Cooper: There is no obligation to turn a bill over to a collection agency. There is an obligation to make a good faith effort to collect. We usually recommend that labs send out at least two or three bills. The lab has to make a judgment call about the dollar amount involved and whether it's economically worthwhile to go through the collection process.

POPLAR FINALIZES PURCHASE OF BANKRUPT BOSTWICK LABS

Poplar Healthcare (Memphis, TN) has completed its acquisition of the assets of Bostwick Laboratories (Uniondale, NY), which had filed for Chapter 11 bankruptcy reorganization earlier this year (see *LE*, March 2017, p. 1). Poplar paid $6.5 million, including $1.1 million to satisfy the amount outstanding under Bostwick's 2014 False Claims Act settlement with the government.

Bostwick Labs operates a laboratory in Long Island, New York with about 128 employees, including 10 pathologists, that currently collects revenue of approximately $35 million per year.

Poplar employs about 32 pathologists and has branded its pathology services in five major business divisions: D-Path Dermatopathology, GI Pathology, OncoMetrix Definitive Cancer Diagnostics, UroPath Diagnostics and Women's Health Laboratories. *Laboratory Economics* estimates that Poplar's revenue was roughly $75+ million in 2016.

Poplar is likely to close Bostwick's Long Island lab and shift its customers, inventory and equipment to its Memphis facility. Bostwick Labs has filed notice with the New York State Department of Labor for a possible closing and layoffs at the Long Island lab.

Bostwick Labs was founded by uropathology expert David Bostwick, MD, in 1999. The company tried to raise as much as $100 million from an IPO offering in 2008, but the IPO never took place. In 2011, Metalmark Capital LLC, a New York private equity firm, acquired a majority stake in Bostwick Labs and Dr. Bostwick retained a significant minority stake. But all shareholders were wiped out by Bostwick Labs' bankruptcy filing.

Poplar to Pay $900K to Settle False Claims Act Allegations

In separate news, Poplar has agreed to pay $897,640 to settle allegations that it improperly billed the Medicare and Tricare programs for medically unnecessary IHC stains (CPT 88342).

Specifically, the U.S. Attorney's Office alleged that from 2006-2015, Poplar ran a promotional campaign known as "ID-ME" that made unsupported claims about its ability to use Tryptase Stains to diagnose a condition known as mastocytic or mast cell enterocolitis. The government alleged that Poplar's promotion of the test was not consistent with FDA approval requirements, and not supported by adequate scientific evidence.

The investigation that led to the settlement began after Gordon Wang, MD, a pathologist formerly employed by Poplar, filed a complaint against the company on behalf of the United States. As whistleblower, Wang will receive $205,841 from the proceeds of the settlement.

PIEDMONT PATHOLOGY TO PAY $601K TO SETTLE FALSE CLAIMS SUIT

Piedmont Pathology (Hickory, NC) has agreed to pay $601,000 to settle a case brought by the U.S. Attorney's Office alleging that the group billed Medicare and Medicaid for medically unnecessary special stains.

The allegations arose from a lawsuit filed by a whistleblower, Kim Geisinger, MD, a pathologist who worked for Piedmont Pathology from March 2012 to February 2014. The U.S. Attorney's Office intervened in the case in November 2016 and pursued allegations that Piedmont billed the government for special stains used on certain gastric biopsies before a pathologist had reviewed the routine H&E stained specimen.

Geisinger will receive approximately $120,200 from the settlement.

LABCORP COMPLETES ACQUISITION OF PAML

LabCorp has finalized its previously-announced acquisition of Pathology Associates Medical Laboratories (PAML-Spokane, WA) from former owners Providence Health & Services (75% stake) and Catholic Health Initiatives (25% stake). *Laboratory Economics* had speculated that the transaction might prompt a request for additional information by the Federal Trade Commission concerning possible antitrust concerns (see *LE*, March 2017), but the FTC took no action.

PAML brings LabCorp a major reference laboratory in Spokane (14+ million tests per year), as well as PAML's ownership stake in several hospital lab outreach joint ventures. The largest PAML JV by far is PACLAB Network Laboratories, which manages the lab outreach operations for 13 hospitals in the greater Seattle region. The hospital partners in PACLAB have agreed to sell their stakes to LabCorp, and once complete, PACLAB will be wholly owned by LabCorp.

Two other smaller PAML joint ventures, Colorado Laboratory Services (CLS) and Kentucky Laboratory Services (KLS), have also agreed to sell their interests to LabCorp.

LabCorp expects to take full ownership of PACLAB, CLS and KLS by early 2018. Until these transactions are complete, LabCorp says there will be no significant changes to PAML's main lab, PSCs or operations. Ultimately, the majority of test volumes at PAML's main lab in Spokane are expected to be redirected to LabCorp's regional laboratory in downtown Seattle near Swedish Medical Center.

LabCorp Finalizes Mount Sinai Deal

Separately, LabCorp says it has also completed its previously-announced acquisition of the assets of the Mount Sinai Health System Clinical Outreach Laboratories. LabCorp now operates over 140 patient service centers in metropolitan New York City, including several formerly operated by Mount Sinai.

Mount Sinai will continue to provide lab testing for patients registered at its hospitals, as well as to outpatients at its ambulatory facilities. Mount Sinai will also continue to provide lab testing services for physicians in their professional practices in the areas of anatomic pathology, molecular pathology and genetics.

CELLNETIX COMPLETES ACQUISITION OF PSIP

Effective April 1, CellNetix Pathology and Laboratories (Seattle, WA) has finalized its acquisition of Puget Sound Institute of Pathology (PSIP-Seattle). CellNetix announced an agreement to acquire PSIP in the fall of 2016 (see *LE*, November 2016).

PSIP has 90 employees, including 17 pathologists, at its freestanding technical lab in Seattle, which serves 11 hospitals and health systems throughout Washington.

CellNetix now has a combined total of 70 pathologists and performs more than 200,000 surgical cases and approximately 200,000 Pap tests per year.

CellNetix's David Corwin, MD, remains Chairman of the combined company and Kathleen Fondren remains CEO. Stewart Adelman, former CEO at PSIP, is now Chief Operating Officer of the combined company.

Separately, CellNetix says that it has repurchased its shares owned by PAML effective February 28. PAML had held a 22% stake in CellNetix since 2013, but CellNetix bought back the minority share to regain complete ownership.

PUBLIC-LAB CEOs PAID AVERAGE $3.1 MILLION IN 2016 (*cont'd from page 1*)
LabCorp's David King, age 60, was the highest paid lab CEO in 2016. He received five different categories of compensation last year that totaled $10.9 million. These included: 1) salary of $1.1 million; 2) stock awards of $7.7 million; 3) incentive plan cash bonus of $1.8 million; 4) increased pension value of $101,810; and 5) other compensation of $149,826, which included financial planning services, 401K matching contributions, long-term disability insurance, personal liability insurance, use of company car and home security services.

Quest Diagnostics' Stephen Rusckowski, 59, received total compensation of $10.3 million last year, including a salary of $1.1 million, cash incentives of $1.3 million, and stock and option awards of $7.5 million. He also received $311,249 in perks, which included $93,478 for personal use of a company car and driver plus $83,839 for personal use of company aircraft.

Myriad Genetics' Mark Capone, 54, received total compensation of $4.9 million. Capone received five different categories of compensation, including 1) salary of $800,000; 2) bonus of $512; 3) cash incentives totaling $727,200; 3) stock awards of $3.4 million; 5) "other" compensation totaling $11,048, which included company-paid life insurance premiums and matching 401K contributions.

Genomic Health's Kim Popovits, 58, received total compensation of almost $3.9 million, including salary of $686,400, bonus of $642,470, and stock and options worth $2.5 million.

Exact Sciences' Kevin Conroy, 51, earned a total of $3.2 million, including salary of $575,000, bonus of $625,313, stock and options totaling $2 million and other compensation of $15,900.

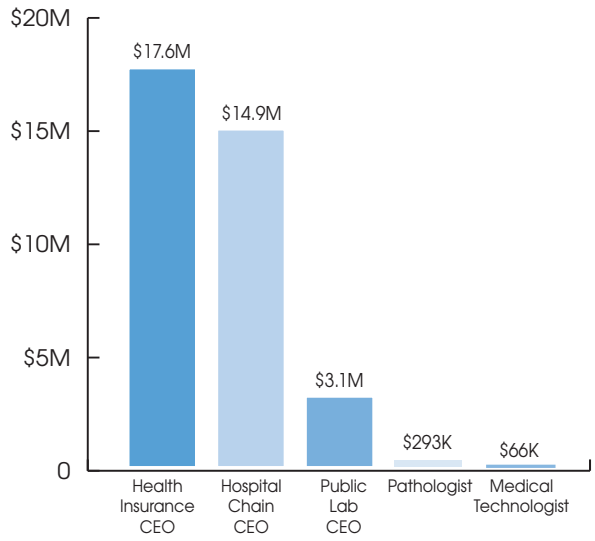
Separately, at the nation's largest health insurance companies, **Humana CEO Bruce Broussard** had the highest total compensation last year at $19.7 million. **Aetna CEO Mark Bertolini** earned $18.7 million, **UnitedHealth's Stephen Hemsley** received $17.8 million, **Anthem's Joseph Swedish** received $16.5 million and **Cigna's David Cordani** received $15.3 million.

Among the largest hospital chains, **HCA Holdings CEO R. Milton Johnson** earned total compensation of $21.3 million last year. **Universal Health CEO Alan Miller** received $19.9 million, **Tenet Healthcare CEO Trevor Fetter** received $12.4 million and **Community Health Systems CEO Wayne Smith** received $5.8 million.

Meanwhile, pathologists earn an average of $293,000 (including salary, bonus and profit sharing) per year, according to the Medscape Pathologist Compensation Report 2017. Self-employed pathologists earn an average of $384,000, while employed pathologists earned an average of $259,000.

And finally, the median annual medical technologist salary is $65,793, as of April 27, 2017, with a range usually between $60,284 and $73,388, according to Salary.com.

Compensation Comparison



Source: *Laboratory Economics* from SEC filings, Medscape and Salary.com

2016 Laboratory CEO Compensation

Company/Executive	Salary	Bonus and Incentives	Value of Stock & Option Awards	Other Comp*	2016 Total Comp	2016 Revenue Growth	2016 Stock Price Total Return
Aurora Diagnostics Daniel Crowley, 69, Chairman & CEO	$1,200,000	$0	$0	$0	$1,200,000	8%	NA
Cancer Genetics Inc. Panna Sharma, 46, President and CEO	532,245	50,000	0	4,248	$586,493	50%	-59%
CombiMatrix Mark McDonough, 47, President & CEO	362,600	166,250	206,383	0	$735,233	28%	-76%
Enzo BioChem Elazar Rabbani, PhD, 73, Chairman & CEO	555,478	575,000	87,600	189,427	1,407,505	5%	54%
Exact Sciences Kevin Conroy, 51, Chairman & CEO	575,000	625,313	1,980,320	15,900	3,196,533	152%	45%
Foundation Medicine Michael Pellini, MD, 51, President & CEO	511,808	263,055	1,642,500	48,955	2,466,318	25%	-16%
Genomic Health Kim Popovits, 58, Chairman & CEO	686,400	642,470	2,522,768	0	3,851,638	14%	-17%
Invitae Randal Scott, PhD, 59, Chairman & CEO	250,000	0	0	0	250,000	199%	-3%
LabCorp David King, 60, Chairman & CEO	1,133,333	1,785,419	7,683,109	251,636	10,853,497	11%	4%
Myriad Genetics Mark Capone, 54, President & CEO	800,000	727,712	3,361,875	11,048	4,900,635	4%	-61%
NeoGenomics Douglas VanOort, 60, Chairman & CEO	600,000	310,950	1,181,979	26,077	2,119,006	145%	9%
Opko Health Inc. Phillip Frost, MD, 80, Chairman & CEO	960,000	0	2,090,000	10,600	3,060,600	148%	-7%
Psychemedics Raymond Kubacki, Jr., 72, Chairman & CEO	462,500	118,750	98,280	10,600	690,130	45%	147%
Quest Diagnostics Stephen Rusckowski, 59, Chairman & CEO	1,100,000	1,341,340	7,500,006	311,249	10,252,595	0%	30%
Veracyte Inc. Bonnie Anderson, 59, Chairman & CEO	500,000	292,500	677,813	0	1,470,313	32%	8%
Totals, 15 companies	10,229,364	6,898,759	29,032,633	879,740	47,040,496		
Averages, 15 companies	$681,958	$459,917	$1,935,509	$58,649	$3,136,033	58%	4%

*Other compensation includes reimbursement for financial planning services, car allowance, personal liability insurance premiums, executive physical exams, home security systems, country club memberships, personal use of company jets and other perks.
Source: *Laboratory Economics* from company proxy statements

SPOTLIGHT INTERVIEW WITH LABS INC.'S GREGORY CLARK

LABS Inc. (Centennial, CO), which is owned by the nonprofit tissue processing organization AlloSource, specializes in testing for organ transplantation and biomedical applications. The company has 161 employees and performed 835,000 tests in 2016. LABS Inc. is headed by Gregory Clark, PhD, DABCC, President and CEO. Prior to joining LABS Inc. in early 2016, Dr. Clark was a Vice President at Pathology Associates Medical Laboratories (PAML). *Laboratory Economics* recently spoke to Dr. Clark about LABS Inc. and its future plans.

How many laboratories does LABS Inc. operate?
We currently have two laboratories. Our hub is in Centennial, Colorado, and we have another lab in Philadelphia. We're also building a laboratory at an organ procurement organization (OPO) facility in San Ramon, California, that's scheduled to open in October. We are hoping to add a couple more in the future.

Describe the testing services performed by LABS Inc.
We have extensive relationships with OPOs throughout the country, including Gift of Life in Philadelphia, Donor Alliance in Denver and Donor Network West in California. They require rapid turnaround time on testing of potential organ donors.

We not only do donor eligibility testing, which is stat nucleic acid testing for infectious diseases, but we do Human Leukocyte Antigen (HLA) matching of donor and recipients. We also do microbiology testing, especially on the tissue and biomedical side – including sterility testing and final product release testing. We are also in several adjacent medical spaces such as infectious disease testing for the in vitro fertilization (IVF) market. We have about 190 tests in our directory. We do 155 of them and send out 35.

Can you describe LABS Inc.'s payers and revenues?
We bill the OPOs and tissue processing companies that use our services. We don't work with third-party payers. We have a little bit of Medicare reimbursement from our renal transplant program. From 2015 into 16 we had more than 6.5% revenue growth. From 2016 into 2017, we're looking at 11%.

Which areas of testing are growing the fastest?
Right now, we're seeing lots of growth in our sterility and final lot release departments. We just built two new sterility suites. We'll see growth from the San Ramon facility. We're looking at growth in bone marrow transplant testing. We're validating an assay to help clinicians determine the completion of engraftment. We look at DNA profiles of the donor and recipient and sequence them, and over time monitor the development of the donor's DNA in the recipient (it's also known as Chimerism analysis). That should be coming online in the next month or so.

You recently announced that you are performing testing for the Zika virus. Tell us more.
Up until the beginning of this month we also serviced three blood centers, and the FDA mandated that they test all blood donors for the Zika virus (ZIKV). In response, since January, we've offered both Nucleic Acid Testing (NAT) for ZIKV and Enzyme Immunoassays (EIAs) specific for ZIKV IgM and IgG antibodies. We recently were awarded participation in an IND [investigational new drug] study of ZIKV for living donors of organs, tissues etc.

What do you see as the biggest challenges facing your organization?
Meeting labor needs is a large concern for us. Denver has a very low unemployment rate. We try to provide our employees with a full range of benefits. As medical costs continue to rise, that's going to be one of our largest expenditures. Also, medical technologist programs aren't as abundant as they used to be, so we'll see a decline in the availability of certified clinical laboratory scientists.

COMPARING PRODUCTIVITY AT QUEST, LABCORP, NEOGENOMICS AND AURORA

On a weighted basis, four publicly-traded lab companies collected average revenue of $47.75 per requisition in 2016. Average collected revenue per test was an estimated $15.98.

The four companies—Quest Diagnostics, LabCorp, NeoGenomics and Aurora Diagnostics (whose debt is publicly traded)—generated a weighted average of $179,432 in revenue per employee in 2016. The average number of requisitions processed was 3,758 per employee, while employees processed an average of 11,225 tests. These figures are based on the total number of employees at the four companies, including all administrative, couriers, sales and marketing, and lab technical staff.

In terms of billing and collection, the average bad-debt expense for the big three commercial labs is 4.2% with an average days in accounts receivables of 49 days. The combined revenue mix at the four publicly-traded labs is approximately 45.9% from fee-for-service healthcare insurance, 3.6% managed care capitation, 30.6% client bill, 16.5% Medicare & Medicaid, and 3.4% from direct patient billing.

Productivity Stats at Quest, LabCorp and NeoGenomics and Aurora Diagnostics for 2016

2016 Financials	*Quest Diagnostics*	*LabCorp Diagnostics**	*NeoGenomics*	*Aurora Diagnostics*	*Total*
Annual Revenue 2016	$7,515,000,000	$6,593,900,000	$244,083,000	$284,039,000	$14,637,022,000
Operating Income 2016	$1,277,000,000	$1,187,600,000	$2,574,000	$12,392,000	$2,479,566,000
Number of Employees	43,000	36,500	938	1,136	81,574
Employee Efficiency					
Avg. Annual Revenue per Employee	$174,767	$180,655	$260,216	$250,034	$179,432
Avg. Annual Operating Inc. per Employee	$29,698	$32,537	$2,744	$10,908	$30,397
Requisition Stats					
Annual Requisitions 2016	160,300,000	143,650,000	417,385	2,150,000	306,517,385
Avg. Revenue per Requisition	$44.53	$45.90	$531.92	130.00	$47.75
Avg. Operating Income per Requisition	$7.97	$8.27	$6.17	$5.76	$8.09
Avg. Reqs processed per Employee	3,728	3,936	445	1,893	3,758
Test Stats					
Annual Test Volume 2016**	480,900,000	430,950,000	626,078	3,225,000	915,701,078
Avg. Revenue per Test	$14.84	$15.30	$354.61	$86.67	$15.98
Avg. Operating Income per Test	$2.66	$2.76	$4.11	$3.84	$2.71
Avg. Tests processed per Employee	11,184	11,807	667	2,839	11,225
Billing Stats					
Bad-Debt %	4.1%	4.3%	4.9%	5.6%	4.2%
Days in AR	47	49	83	46	49
Revenue by Payer					
Private Patients	2.0%	5.0%	3.0%	3.0%	3.4%
Medicare	14.0%	13.1%	14.0%	22.0%	13.8%
Medicaid	3.0%	2.4%	2.0%	2.0%	2.7%
Client Payers (physicians, hospitals, et al.)	29.0%	32.0%	56.0%	15.0%	30.6%
Healthcare Insurers	48.0%	44.0%	25.0%	58.0%	45.9%
Managed Care Capitation	4.0%	3.4%	0.0%	0.0%	3.6%

*Data is for LabCorp's lab testing business only; **Test volume stats assume an average of 3 tests per requisition at Quest and LabCorp, and average 1.5 tests per requisition at NeoGenomics and Aurora Diagnostics
Source: Company reports and *Laboratory Economics'* estimates

COMMON PATHOLOGY PRACTICE BILLING ERRORS (*cont'd from page 1*)


Al Sirmon

Calculating the contract allowable as a percent of the charge price for each CPT code for each payer gives you a standard allowable percentage. This standard allowable percentage can then be compared with the actual claims paid percentage for each CPT code per payer, according to Sirmon.

There may be a slight difference between the actual and standard percentages since the standard assumes 100% collection (no bad debt). However, if the actual and standard have a variance of greater than 10%, then further investigation is needed to determine the reason, says Sirmon.


Chappy Manning

Meanwhile, Chappy Manning, RN, CPC, the other co-founder of Pathology Practice Advisors, explained in more detail five common pathology billing errors that can lead to inaccurate payments and/or potential compliance problems:

1. Lack of documentation specifying methodology and stain procedure for IHC and ISH. Most pathology practices have learned to use the new more specific IHC and ISH codes introduced by AMA in 2015. However, some pathologists have lagged in terms of incorporating the language and key words found in the new code descriptions, notes Manning. For example, if a multiplex antibody stain (88344) or multiplex probe stain procedure (88366, 88374, 88377) is performed and billed, then the pathologist's report should contain the word "multiplex" to differentiate it from a single antibody stain procedure (88342 & 88341) or single probe stain procedure (88365 & 88364, 88367 & 88373, 88368 & 88369). "Simply adding one key word can significantly reduce a practice's error rate. Auditors can't know if your coding is correct, if your reporting is not accurate and specific," emphasizes Manning.

2. Increased Scrutiny of Standing Orders. Led by Palmetto GBA, Medicare contractors are tightening up their medical necessity requirements for IHC and special stains, especially with respect to standing orders (i.e., automatic orders based on tissue of origin). In simplest terms, a ccording to Manning, Palmetto GBA and several other regional MACs (Noridian, First Coast and CGS) have determined: 1) Standing orders for special stains and/or IHC prior to review of the H&E stain are not reasonable and necessary; 2) The use of special stains and/or IHC when the diagnosis is already known based on morphologic evaluation is not reasonable and necessary; and 3) The utilization of standing orders solely to lower turnaround time or improve workflow does not prove medical necessity. "If you are billing for the same special stain(s) or IHC on every single liver or gastric biopsy referred to your practice, then chances are, you're in the wrong, or at least very much at risk for increased scrutiny" summarizes Manning.

3. Not capturing appropriate units of service. This happens most frequently from test orders received through a hospital interface. There can be a sense that these codes don't need to be reviewed closely because the lab's process is to enter every service into the system as it's ordered. And they are mostly reliable about getting the service/CPT entered into the system correctly – but where we see problems is with units of service, particularly with special and immunohistochemical stains, perhaps because the system defaults to "1" unit, and it's easy to skip the step of overriding to enter the correct number of units.

4. Correctly identifying the performing lab/provider in TC/PC arrangements. For example, if your pathology group performs interpretations on flow cytometry samples prepared by an outside technical lab, you should state clearly in your report the name of the organization that performed the professional interpretation and name of the organization that did the technical work.

Without clarification, your billing company might submit bills for work not being performed by your pathology group. "It's an issue that's popping up on billing audits we do, particularly when the billing situation can vary, such as if the lab performing the TC of your flow most of the time is occasionally asked to also perform the interpretation/26 portion," notes Manning,

5. Billing for the PC of clinical lab tests. Medicare generally does not reimburse pathologists for professional services related to clinical lab tests. However, there are approximately 20 clinical lab test codes (e.g., crystal ID 89060 and protein electrophoresis 84165-84166) that Medicare considers appropriate to reimburse for pathologist professional services, if certain criteria are met, including that the referring clinician specifically requested a pathologist's interpretation. This request can either be in the form of 1) a standing order for a pathologist's interpretation on specific clinical lab tests with written policy approval by a hospital's medical executive committee; or 2) a physician's written request for a pathologist's interpretation on a lab test order. This can include a requisition that gives clinicians check boxes for ordering certain clinical lab tests with and without a pathologist's interpretation. "Over the past few years, we've seen some pathology groups get in trouble with Medicare because they did not have a current hospital standing order in place before charging across the board," notes Manning.

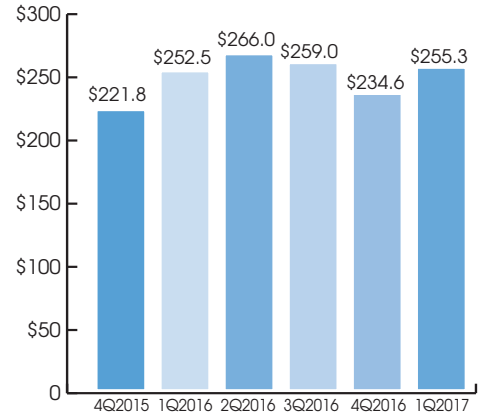
Finally, Sirmon notes that with more and more payment responsibility shifting to patients, billing and collection is becoming increasingly difficult. Ten years ago, the typical pathology practice might have gotten 80% of its payments from third-party payers and 20% from patients, but that's moving to a 60%/40% split. "The old benchmarks of less than 45 days in A/R with less than 10% bad debt and net collection % > 90% are getting harder and harder to achieve," observes Sirmon.

OPKO'S BIO-REFERENCE ACCUSED OF FALSE CLAIMS (*cont'd from page 1*)

The Civil Division of the United States Attorney's Office for the Southern District of New York (SDNY) has notified Bio-Reference Labs 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.

Bio-Reference says it is reviewing the allegations made by the SDNY, and, at this point, Bio-Reference has not determined whether there is any merit to the SDNY's claims, nor can it determine the extent of any potential liability.

Quarterly Revenue at Bio-Reference Labs ($ millions)



Source: OPKO Health

OPKO purchased Bio-Reference for $950 million in an all-stock transaction completed in August 2015. At the time of the acquisition, OPKO had forecast 10%+ annual revenue growth at Bio-Reference. But growth at Bio-Reference has slowed. In the three months ended March 31, 2017, OPKO reported that Bio-Reference grew its revenue by only 1% to $255.3 million.

Over the past 12 months, OPKO has restructured management at Bio-Reference by hiring a new President and CEO, Greg Henderson, MD, PhD. In October 2016, Bio-Reference also named Jane Pine Wood, Esq. as Chief Legal and Compliance Officer.

CHINESE COMPANY RELAUNCHES ATHEROTECH'S VAP TEST

Ningbo Medical System Biotechnology Company, a Chinese manufacturer of IVD reagents and lab instruments, has formed a new lab company, VAP Diagnostics Laboratory (Birmingham, AL), that has relaunched marketing for the VAP+ Lipid Panel. Ningbo acquired the rights to the technology for the test when it purchased Atherotech Inc. (Birmingham, AL) out of bankruptcy for $19.6 million last year (see *LE*, July 2016). At its peak in 2014, Atherotech recorded over $100 million of revenue from VAP testing.

The VAP (Vertical Auto Profile)+ Lipid Panel is an expanded lipid test that directly measures LDL-C ('bad" cholesterol). The testing technology was developed by Jere Segrest, MD, PhD, at the University of Alabama (UAB) in the early 1990s. Atherotech was spun out of UAB in 1999 to commercialize the test. In late 2010, New York Investment firm Behrman Capital acquired Atherotech. And in early 2016, Atherotech filed for Chapter 7 bankruptcy.

VAP Diagnostics Lab is headed by Chairman Zou Bingde and President Wang Haiping. Kenneth French is Director of Clinical Operations—he had previously held the same position at Atherotech.

VAP Diagnostics Lab faces the challenge of regaining trust from ordering physicians. Its relaunch of the VAP test is potentially hampered by a demand letter sent in February to some 2,100 former physician clients of Atherotech. The demand letter came from a lawyer for the Atherotech Bankruptcy Trustee and threatened these physicians with a lawsuit unless they paid the Bankruptcy Trustee 90% of the process and handling (P&H) fees they allegedly received from Atherotech before it filed for bankruptcy. The demand letter suggested to the physicians that they may be liable for an Anti-Kickback statute violation or a Stark Law violation.

Lawyers for Ningbo say that the Bankruptcy Trustee had no right to bring these claims, nor the ability to release the physicians from the alleged claims.

Kenneth French says VAP Diagnostics Lab opened in early March with 35 employees. French says that former Atherotech clients are coming back to the new lab company despite the demand letter controversy and the fact that the new company does not offer P&H fees. "They believe in the technology behind the VAP test. We're not gonna get them all back, but there's been a surprising amount of interest and volume so far. And we're hiring again," says French.

AURORA BUYS TWO MORE PATHOLOGY GROUPS

On April 17, 2017, Aurora Diagnostics acquired 100% of the equity of Pathology Associates (Princeton, NJ). Pathology Associates is a hospital-based practice with five full-time and two part-time pathologists based within the University Medical Center of Princeton. Aurora paid cash of $4.5 million at closing and issued contingent notes payable annually over three years up to a total of $0.5 million.

In addition, Aurora acquired Cleveland Skin Pathology Laboratory (Cleveland, OH) in early May. Terms of the transaction have not been disclosed. Founded in 1972, Cleveland Skin Pathology Laboratory is a physician-owned pathology practice providing dermatopathology services to dermatologists in the Midwest. The practice has six board-certified dermatopathologists.

Separately, Aurora reported a net loss of $16.2 million for the first quarter ended March 31, 2017 compared with a net loss of $7.6 million for the same period a year earlier; revenue declined to $67.8 million versus $68.8 million. Revenue at the practices Aurora operated for the full periods in both first-quarter 2017 and first-quarter 2016, fell by approximately 4%, including a 3% decrease in accession volume and a 1% decrease in average revenue per accession.

LAB STOCKS UP 37% YTD

Sixteen lab stocks have risen by an unweighted average of 37% year to date through May 15. In comparison, the S&P 500 Index is up 7%. The top-performing lab stocks so far this year are Cancer Genetics, up 196%; Exact Sciences, up 143%; and CombiMatrix, up 130%. At the two largest public labs, LabCorp is up 9% and Quest Diagnostics is up 17%.

Company (ticker)	Stock Price 5/15/17	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$4.00	$1.35	196%	$79	NA	2.9	3.0
CombiMatrix (CBMX)	6.10	2.65	130%	18	NA	1.3	2.5
Enzo Biochem (ENZ)	9.18	6.94	32%	425	13.5	4.0	4.8
Exact Sciences (EXAS)	32.43	13.36	143%	3,610	NA	27.1	11.7
Foundation Medicine (FMI)	35.55	17.70	101%	1,270	NA	11.2	10.0
Genomic Health (GHDX)	30.81	29.39	5%	1,060	NA	3.2	6.5
Invitae (NVTA)	9.83	7.94	24%	416	NA	13.2	5.1
LabCorp (LH)	140.53	128.38	9%	14,560	19.3	1.5	2.6
Myriad Genetics (MYGN)	22.26	16.67	34%	1,520	47.6	2.0	2.0
NeoGenomics (NEO)	7.63	8.57	-11%	605	NA	2.5	3.6
Opko Health (OPK)	6.80	9.30	-27%	3,800	NA	3.1	1.7
Psychemedics (PMD)	20.96	24.99	-16%	116	14.2	2.7	7.0
Quest Diagnostics (DGX)	107.59	91.90	17%	14,720	21.7	2.0	3.2
Rosetta Genomics (ROSG)	1.75	5.04	-65%	4	NA	0.5	0.7
Sonic Healthcare (SHL.AX)	23.21	21.40	8%	9,730	21.0	1.9	2.6
Veracyte (VCYT)	8.16	7.74	5%	276	NA	4.1	5.2
Unweighted Averages			37%		22.9	5.2	4.5

Source: Capital IQ

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