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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CMS Is Considering Including Hospital Outreach Labs In Next PAMA Data Collection

CMS is seeking public comments on the potential to broaden its definition of "applicable labs" required to report their private-payer rates in the next PAMA data reporting period. Pricing information from Quest Diagnostics, LabCorp and a handful of other national labs dominated the last reporting period, which resulted in phased-in cuts of more than 30% for most high-volume routine tests on Medicare's Clinical Laboratory Fee Schedule (CLFS). A broader definition of applicable reporting labs that includes hospital outreach labs has the potential to stabilize rates beginning with the CLFS for 2021.

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Technical Rates for Most Pathology Services To Get Boost Under Medicare Proposed Fees For 2019

The Proposed Medicare Physician Fee Schedule for 2019 includes an 8% hike to the technical component for CPT 88305, which, if finalized, would raise it to $32.80. Meanwhile, the rate for the professional interpretation is being lowered by a proposed 2% to $39.29. Overall, the global rate for CPT 88305 will increase by a proposed 3% to $72.09.

In general, technical component fees for most key pathology services, including CPT codes 88341, 88342, 88304, 88307, 88309, et al., are proposed to increase, while most professional interpretation rates are set for small reductions.

Meanwhile, two areas where pathologists and labs will see significant rate reductions are flow cytometry and prostate biopsies.

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Quest's AmeriPath Sues Two Dermpaths For Alleged Violations Of Non-Compete Agreements

Quest Diagnostics' AmeriPath New York (Port Chester, NY) has filed a lawsuit against two dermatopathologists, Paul Chu, MD and Mark Jacobson, MD, alleging that they violated their non-compete agreements with the company.

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Quest's AmeriPath Sues Two Dermpaths (*cont'd from page 1*)

Both Chu and Jacobson first became employees of AmeriPath when they (and two other pathologist owners) sold their dermatopathology lab, Pathology Associates, to AmeriPath back in December 2004 for $44 million. Quest Diagnostics then acquired AmeriPath for $2 billion in 2007 and maintained employment of Chu and Jacobson for the next 10 years.

Most recently, Dr. Chu served as Executive Managing Director for AmeriPath's Port Chester laboratory (located just north of New York City) earning a base salary of $76,924 bi-weekly, for a total annual salary of $2 million. Dr. Chu's total compensation for 2017, including bonus, was more than $3.2 million, according to the lawsuit.

Dr. Jacobson had most recently been employed as Managing Director of AmeriPath's Port Chester laboratory with a base salary of $67,308 bi-weekly, for a total annual salary of $1.75 million. Dr. Jacobson's total compensation for 2017, including bonus, was more than $2.8 million, according to the lawsuit.

At the end of 2017, AmeriPath claims that Dr. Jacobson and the company mutually agreed to terminate the latter's employment without cause and without severance. AmeriPath says that the terms of Dr. Jacobson's employment agreement forbid him for one year (i.e., until December 28, 2018) from soliciting any existing AmeriPath employee to join him at another lab company.

However, AmeriPath alleges that Dr. Jacobson immediately breached his employment contract by planning with Dr. Chu, who was then still employed by AmeriPath, to form a competing dermatopathology lab company in nearby Hawthorne, New York (located approximately 15 miles north of Port Chester).

On March 30, 2018, AmeriPath fired Dr. Chu. AmeriPath says that because the termination was justified, Dr. Chu is prohibited under his employment contract from working at a competing dermatopathology lab within 25 miles of AmeriPath's Port Chester location for a period of one year.

AmeriPath's lawsuit seeks to stop Dr. Jacobson and Dr. Chu from working together at a new competing dermatopathology lab that they are allegedly forming. AmeriPath is also seeking compensatory damages and reimbursement for its attorneys' fees.

Dermpaths Say Non-Competes Invalid Due To Terminations

In his response to the lawsuit, Dr. Jacobson said that his breakup with AmeriPath was a termination without cause stemming from a salary dispute. As a result, Jacobson contends that AmeriPath waived his non-compete restrictions when it denied him $1.7 million severance.

Similarly, Dr. Chu says that he was terminated without cause and he is therefore entitled to either severance equal to one year's salary or alternatively a release from his non-compete agreement.

Both doctors deny conspiring together to form a new competing dermatopathology lab and have asked the court to dismiss AmeriPath's lawsuit in its entirety, with prejudice.

Managing Dermpaths Has Been A Challenge

Laboratory Economics observes that since Quest acquired AmeriPath, a number of high-profile dermatopathologists have left the company to form competing independent labs. These have included: Bradley Bakotic, DPM, DO, and Joseph Hackel, MD, who formed Bakotic Pathology Associates (Alpharetta, GA) in 2008; R. Wesley Wetherington, MD, who formed SkinPath Solutions (Smyrna, GA) in 2010; and Clay Cockerell, MD, who formed Cockerell Dermatopathology Laboratory (Dallas, TX) in late 2012.

Technical Rates for Most Pathology Services To Get Boost (*cont'd from p. 1*)

Overall, CMS estimates that the proposed changes for 2019 will decrease pathologists' Medicare fees by 1%, while independent technical lab rates will increase by 4%. Final rates are expected to be announced in October and become effective January 1, 2019.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) is proposed to increase by 1% to $112.46; professional interpretation down 2% to $36.77; technical component up 2% to $75.70. The global rate for CPT 88341 (IHC, additional slide) is proposed to increase by 4% to $98.77; professional interpretation down 1% to $29.56; technical component up 7% to $69.21.

Prostate Biopsies

Global reimbursement for G0416 is proposed to decline by 12% to $384.25, including a 19% cut to the technical component. If finalized, global reimbursement for the typical 12-core prostate biopsy will have been slashed by a whopping 70% over the past seven years.

Flow Cytometry

Following significant cuts made in 2017 and 2018, another round of cuts for key flow cytometry codes is proposed for 2019. CPT 88185 (flow cytometry, TC, add on) is proposed to drop by 19% to $24.87. And CPT 88189 (flow cytometry, interpretation, 16 or more markers) is proposed to decrease by 2% to $87.23.

Proposed Medicare Rate Changes for Key Pathology Codes for 2019

CPT/HCPCS	Short Description	Proposed 2019[1]	Actual 2018[2]	% Change
88184-TC only	Flow cytometry/1st marker	$66.33	$68.04	-3%
88185-TC only	Flow cytometry/each add'l marker	24.87	30.60	-19%
88187-26 only	Flow cytometry, read 2-8	39.29	48.24	-19%
88189-26 only	Flow cytometry, read 16+	87.23	88.92	-2%
88305-Global	Tissue exam by pathologist	72.09	70.20	3%
88305-26	Tissue exam by pathologist	39.29	39.96	-2%
88305-TC	Tissue exam by pathologist	32.80	30.24	8%
88307-Global	Level V, tissue exam by pathologist	293.06	270.00	9%
88307-26	Level V, tissue exam by pathologist	85.79	87.84	-2%
88307-TC	Level V, tissue exam by pathologist	207.27	182.16	14%
88309-Global	Level VI, tissue exam by pathologist	445.17	410.04	9%
88309-26	Level VI, tissue exam by pathologist	151.75	155.88	-3%
88309-TC	Level VI, tissue exam by pathologist	293.42	254.16	15%
88312-Global	Special stains, group 1	102.01	99.36	3%
88312-26	Special stains, group 1	27.76	28.08	-1%
88312-TC	Special stains, group 1	74.26	71.28	4%
88313-Global	Special stains; group 2	73.89	72.00	3%
88313-26	Special stains; group 2	12.62	12.60	0%
88313-TC	Special stains; group 2	61.28	59.40	3%
88341-Global	Immunohistochemistry (Add'l stain)	98.77	94.68	4%
88341-26	Immunohistochemistry (Add'l stain)	29.56	29.88	-1%
88341-TC	Immunohistochemistry (Add'l stain)	69.21	64.80	7%

88342-Global	Immunohistochemistry (1st stain)	112.46	111.60	1%
88342-26	Immunohistochemistry (1st stain)	36.77	37.44	-2%
88342-TC	Immunohistochemistry (1st stain)	75.70	74.16	2%
G0416-Global	Prostate biopsy, any method	384.25	434.52	-12%
G0416-26	Prostate biopsy, any method	183.48	186.84	-2%
G0416-TC	Prostate biopsy, any method	200.78	247.68	-19%

[1]Payments based on the 2019 conversion factor of 36.05; [2]Payments based on the 2018 conversion factor of 35.99
Source: *Laboratory Economics* from CMS

House Report Prods CMS To Close (N-1) Test Panel Pricing Loophole

The U.S. House of Representatives Committee on Appropriations has issued a report that "encourages" CMS to develop a new test panel pricing policy "to prevent wasteful government spending." The highly influential House Committee on Appropriations, along with its Senate counterpart, is responsible for legislation allocating federal spending.

CMS's new private-payer-based pricing system for lab tests paid through Medicare's Clinical Laboratory Fee Schedule (CLFS) included a change in the way that Medicare pays for test panels containing certain automated chemistry tests that has the potential to dramatically increase reimbursement.

CMS was forced to discard its longstanding way of paying for automated test panels (ATPs) because it was unable to collect private-payer pricing data for these unique panels. The ATP system was designed to remove the incentive for labs to maximize reimbursement by devising custom chemistry panels and billing for the component tests individually.

Under the new system that went into effect January 1, 2018, chemistry panels that are currently paid by Medicare in the range of $8 to $14 per panel can be manipulated by labs to increase reimbursement to as much as $77. For example, a Comprehensive Metabolic Panel (CPT 80053) includes 14 individual tests with a total Medicare reimbursement of $13 per panel. However, a laboratory may remove a single test from this panel (dubbed the "N-1 loophole") and then bill Medicare for the other 13 tests individually for a total of $77 (see *LE*, December 2017).

The House Committee on Appropriations' report (see https://docs.house.gov/meetings/AP/AP00/20180626/108473/HRPT-115-HR.pdf, page 89) states:

> *The Committee encourages the Administrator of CMS to develop and issue a panel pricing policy that ensures the agency is not paying more for a single clinical diagnostic laboratory test, or a group of individual clinical diagnostic laboratory tests, than it would for a clinical diagnostic laboratory testing panel that tests for the same analyte(s). The Committee encourages the Administrator to apply the policy to all types of test panels.*

Meanwhile, the American Clinical Laboratory Association (ACLA) is opposed to this report language and says that House Committee on Appropriations should instead work with ACLA on a broader reform to fix flaws in the way that CMS collects private-payer data to set CLFS rates. In a July 9 letter to Committee Chairman Rodney Frelinghuysen (R-NJ), ACLA stated that CMS wrongly excluded private-payer data from hospital outreach labs when it calculated new market-based rates for the CLFS.

CMS Urged to Consider Coverage for Blood Tests for Colorectal Cancer

Separately, the House Committee on Appropriations' report also urged CMS to consider coverage of blood tests for colorectal cancer as a means to increase the number of patients that get screened.

CMS to Add Record Number of Codes to 2019 CLFS

An unprecedented 100 new CPT codes will be added to the Clinical Laboratory Fee Schedule (CLFS) next year, with many of them representing a relatively new category of codes – Propriety Lab Analyses (PLAs).

PLAs are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test. PLAs include, but are not limited to, Advanced Diagnostic Laboratory Tests (ADLTs) and Clinical Diagnostic Laboratory Tests (CDLTs) as defined under PAMA.

"PLAs are more specific than CPT codes," explains Charles Root, PhD, CEO of CodeMap (Chicago). "In most cases, PLA codes are for brand-new lab-developed tests that don't easily crosswalk to other codes." Getting a PLA, which is issued by the American Medical Association (AMA), is much easier than the process for getting a regular CPT code, notes Root, adding that Genomic Health and Foundation Medicine were among the first to request these codes.

More than three dozen PLAs will be added to the 2019 fee schedule, along with almost 50 new molecular pathology codes and codes for new multianalyte assays with algorithmic analyses (MAAAs). Some of these are promotions from Tier 2 to Tier 1.

The Centers for Medicare and Medicaid (CMS) on June 25 received input from stakeholders on the new codes. Several organizations presented crosswalk or gapfill recommendations. For CPT 81X78 (BRCA1, BRCA2 full sequence analysis), the Association for Molecular Pathology (AMP) recommends crosswalking to CPT 81408 (DMD, full gene sequence, molecular pathology procedure, level 9, $2,000).

CMS is expected to issue preliminary recommendation on pricing for these codes in early September, which will be followed by a 30-day comment period. Final pricing will be announced in November.

Laboratory Economics notes that initial Medicare rates for PLAs are determined by crosswalking or gapfilling, and are then subject to PAMA private-payer surveys every three years. However, since PLA tests are only performed by a single laboratory, the sole performing lab can potentially have significant control over pricing.

A list of the new codes is available online at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.

Rosetta Genomics Files For Chapter 7 Bankruptcy

Rosetta Genomics (Philadelphia, PA) filed for Chapter 7 bankruptcy on May 31, after Genoptix Inc. abruptly abandoned its plans to acquire the company. Under a Chapter 7 bankruptcy, a company's assets are liquidated, rather than attempt a turnaround.

Rosetta was formed in 2000 and went public through an IPO in 2007 that raised $26 million at an overall company value of $79 million.

Rosetta operated a CLIA-certified laboratory in Philadelphia. Its lead product was a molecular microRNA-based assay, RosettaGX Reveal, which can diagnose thyroid nodules as benign or suspicious using a single-stained FNA smear, thereby preventing unnecessary thyroid surgeries.

But Rosetta experienced significant operating losses throughout its history as a result of payer coverage and reimbursement challenges. Accumulated losses totaled $161 million as of June 30, 2017 (the latest available reported results for Rosetta). Annual revenue was less than $3 million.

Spotlight Interview with Florida Hospital Laboratories' Tony Bull

Florida Hospital Laboratories, an outreach laboratory in central Florida, is part of the larger Adventist Health System, which includes 24 hospitals across three regions in Florida. With 2,500 beds, Florida Hospital, Orlando, the system's flagship hospital and one of the busiest in the country, serves as the main laboratory for the outreach program. The outreach lab employs 134 people and serves three counties in the Orlando region: Orange, Seminole and Osceola. *Laboratory Economics* recently spoke with Tony Bull, Director of Florida Hospital Laboratories.

Tony Bull

Who are your biggest competitors?
Quest, LabCorp and Orlando Regional Medical Center.

Has the outreach lab been growing?
Yes, the last three years our average growth rate was 14% per year by volume. Revenues are also rising, but not as quickly as the volume at 11% annually. We estimate that around 300 physician practices use us as their primary lab. We have refocused our efforts on growing draw site volumes, improving communication about our services with physician offices and concentrating on the nuts and bolts of the business – that means our couriers show up on time, and our turnaround times are excellent. Our pricing is competitive and is also posted on our website. That's one of our goals—pricing transparency—we started that last year. We wanted to help patients understand what they would be charged.

What is driving growth?
It's growing across the board, but we're seeing strong growth in microbiology and molecular testing. We are always working to bring more tests in-house. We currently offer about 3,100 tests. ARUP Labs is our primary reference laboratory.

Is the health system supportive of the outreach program?
The system is supportive of the outreach program and recognizes that it is profitable. We are part of an ambulatory services group, which is receiving a lot of support from the system right now.

Do you do your own billing?
We have our own billing division that is distinct from the hospital billing. We have a very clear picture of our revenue, our expenses and our profitability.

How are you driving future growth?
There are a number of things we're doing. We have an aggressive expansion plan for draw locations. We reduced our pricing to be competitive with the commercial labs. We are ramping up our interface capability with our clients. We're also focusing on our sales capability and marketing.

How are the PAMA Medicare cuts affecting your laboratory outreach program?
We're not seeing an effect yet, partly because our total growth is strong. We're actually seeing an increase in our overall Medicare revenue. I suspect we will start feeling it later this year. We do provide testing services to nursing homes, and we're watching very carefully how that business is doing and what the appropriate services levels are. We have no intention of stopping that service but we're looking at what we need to do to keep it viable. We're communicating with clients to talk with them about ideas to keep costs contained. For example, we may want to cut back on services that are not as important to them. We've talked about having two different tiers of service, maybe a bare-bones level and one with additional services at little higher cost. Right now, we provide stat services around the clock. We might cut back on that some, send phlebotomists in less often.

How is your laboratory coping with LabCorp's BeaconLBS preauthorization process for United Healthcare members?
Florida was the pilot site for Beacon, so the program is a little different in this state and encompasses less expensive, more routine testing. We support pre-authorization for expensive testing, such as genetics. It protects us against denied claims, but more importantly, protects patients from extremely high bills they didn't expect. We are still wrestling with the process for lower priced tests. We're not getting paid for a lot of them and haven't found a satisfactory solution yet.

What do you see as your biggest challenges?
One of the biggest is insurance contracting. Some payers are in exclusive agreements with the commercial labs, which leaves some gaps in our contracts. Connectivity is still a challenge. We're connected to about 75% of our clients, but we're still working on the other 25%. One of our other challenges is differentiating ourselves from the national laboratories. We've really focused on the patient experience. Right now, the average wait time is 10 minutes or less – we get the top rating from patients 97% of the time.

What about opportunities?
We're working to differentiate ourselves by providing a clearly better service level, by being extremely reliable and by making our services as convenient and affordable as possible. So far that's paying off. We are also focused on growth within Florida Hospital's Clinically Integrated Network and our system's focus on ambulatory services. We're well aware of the headwinds in the industry, but I think this is an exciting time and there are still great opportunities for growth.

CMS Is Considering Including Hospital Outreach Labs (*cont'd from p. 1*)
During the last PAMA reporting period, applicable labs were required to receive >50% of their Medicare revenue from the CLFS as recorded under their national provider identifier (NPI) number. The vast majority of hospital outreach labs do not have their own NPI number and use their parent hospital's NPI. As a result, nearly all hospital outreach labs were excluded from the 2017 data collection period. Only 21 hospital labs reported pricing information representing less than 1% of the data used in CMS's last rate-setting calculations.

In its Proposed Medicare Physician Fee Schedule for 2019, CMS asked for comments on whether it should allow labs to use Form CMS-1450 bill type 14x or CLIA certificate numbers to determine if they are an applicable lab. Doing so would allow most hospital outreach labs to report their private-payer data. The next data collection period will cover private-payer data from January 1, 2019 through June 30, 2019, and the next data reporting period will be January 1, 2020 through March 31, 2020, with the next update to CLFS occurring on January 1, 2021.

However, there is no guarantee that CMS will in fact broaden its definition of applicable lab. "We are confident that our current policy supports our collecting sufficient applicable information in the next data reporting period, and that we received sufficient and reliable applicable information with which we set CY 2018 CLFS rates, and that those rates are accurate," stated CMS in its Proposed MPFS for 2019.

ACLA Still Waiting for Judge to Schedule Oral Arguments in PAMA Lawsuit
Separately, *Laboratory Economics* notes that ACLA's lawsuit versus CMS has made little progress since being switched to U.S. District Judge Amy Berman Jackson in May. Both sides are still waiting for Judge Jackson to schedule oral arguments. The lawsuit was originally filed by ACLA on December 11, 2017. At the very minimum, ACLA is hoping that CMS will be compelled to collect private-payer data from a more representative sample of laboratories, including hospital outreach labs, during its next data collection.

Lab Mergers & Acquisitions Summary

Roche Paying Fancy Price For Foundation Medicine

Roche Holding recently agreed to pay $2.4 billion to buy the remainder of Foundation Medicine (Cambridge, MA) that it doesn't already own. The Swiss drug giant already owns roughly 57% of Foundation. The deal to buy the remaining 43% puts an overall value on Foundation of $5.3 billion, an amount equal to nearly 35 times Foundation's revenue of $153 million in 2017 and 24 times its estimated revenue of $225 million for 2018. Foundation performs genomic tests to guide cancer treatments at its CLIA-certified labs in Massachusetts and North Carolina. The transaction with Roche is scheduled to be completed in the second half of 2018.

Pharma Companies Have Failed Miserably With Laboratory Acquisitions

Roche is making a major commitment to laboratory services with its planned acquisition of Foundation Medicine, despite the fact that most pharma companies have not fared well when making similar bets.

- Miraca Holdings acquired Caris Diagnostics for $725 million in 2011, then sold it to Avista Capital Partners for $55 million in late 2017.
- Novartis bought Genoptix for $330 million in 2011, then sold it to Ampersand Capital for an undisclosed amount in early 2017.
- GE Healthcare purchased Clarient Inc. for $600 million in 2010, then sold it to NeoGenomics for $300 million in 2015.

LabCorp And Quest Are Seeking Acquisitions That Lower PAMA Pricing Risk

In 2015, LabCorp diversified by expanding into the drug development market with its $6.1 billion acquisition of Covance, a contract research organization (CRO) that provides preclinical and clinical services to pharmaceutical and biotech customers. In late 2017, LabCorp added to its CRO business by acquiring Chiltern (London, UK and Wilmington, NC) for $1.2 billion. Most recently, LabCorp acquired Sciformix Corp. (Westborough, MA), which provides safety and risk management services to pharma companies for post-market drugs, including medical review of adverse events, regulatory reporting and risk management.

Meanwhile, Quest acquired Mobile Medical Examination Service (MedXM-Santa Ana, CA) for $142 million 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.

LabCorp Wraps Up Loose Ends In PAML Acquisition

LabCorp's annual report shows it paid $689 million for its acquisition of Pathology Associates Medical Laboratories (PAML) in May 2017. The purchase price worked out to be roughly two times PAML's estimated annual revenue of $300 million.

As part of the deal, LabCorp acquired PAML's ownership interests in six joint venture outreach lab networks. Over the past 12 months, LabCorp has completed transactions giving it 100% ownership at five of these joint ventures. Most recently, LabCorp completed the conversion of clients previously serviced by PACLAB Network Laboratories (Renton, WA). PACLAB had been the largest PAML joint venture by far, managing the lab outreach operations for 13 hospitals in western Washington.

Meanwhile, at the one PAML joint venture where LabCorp did not obtain 100% ownership, MountainStar Clinical Laboratories (Salt Lake City, UT), the JV is being dissolved. However, LabCorp has entered into a separate agreement to provide outreach and outpatient testing services to the hospitals that had participated in the JV, including St. Marks Hospital, Ogden Regional Medical Center, and Lakeview Hospital.

Finally, as expected, LabCorp is in the process of shifting a lot of the testing that had been performed at PAML's main laboratory in Spokane to other LabCorp facilities in the Northwest. Earlier this year, LabCorp announced it was laying off approximately 200 PAML employees. After the layoffs, the company will employ about 500 people in Spokane. LabCorp plans to increase the Spokane facility's focus on drugs-of-abuse testing.

U.S. Dermatology Partners Buys Bethesda Dermatopathology Lab

U.S. Dermatology Partners (USDP-Dallas, TX) acquired Bethesda Dermatopathology Laboratory (BDL-Silver Spring, MD) effective May 1. BDL employs nine dermatopathologists and operates one of the largest dermatopathology labs in the nation.

USDP provides practice management services to 160 dermatologists and 58 midlevel providers at more than 80 locations in Texas, Kansas, Missouri, Arizona, Colorado, Louisiana, Maryland and Virginia. USDP is majority-owned by the private equity firm ABRY Partners (Boston, MA).

Laboratory Acquisition Summary, December 2017-July 2018 ($ millions)

Date	Buyer	Target	Purchase Price	Acquired Revenue	Price/ Revenue
Pending	Roche Holding	Foundation Medicine	$5,300	$153	34.6
Pending	Myriad Genetics	Counsyl Inc.	375	138	2.7
Jun-18	LabCorp	Sciformix Corporation	NA	NA	NA
May-18	U.S. Dermatology Partners	Bethesda Dermatopathology Lab	NA	NA	NA
Apr-18	MAWD Pathology	Cytocheck Laboratory	NA	NA	NA
Apr-18	Aurora Diagnostics	Cascade Pathology	NA	NA	NA
Mar-18	Quest Diagnostics	Cape Cod Healthcare Outreach lab	NA	NA	NA
Mar-18	LabCorp	PAML/Kentucky Laboratory Services	NA	NA	NA
Feb-18	Quest Diagnostics	MedXM	142	NA	NA
Jan-18	LabCorp	PAML/PACLAB Network Labs	NA	NA	NA
Dec-17	Aurora Diagnostics	CBM Pathology	NA	NA	NA
Dec-17	ACM Global Laboratories	ToxCo (DrugScan and DSI Medical Services)	NA	NA	NA
Dec-17	Quest Diagnostics	Cleveland HeartLab	94	NA	NA
Dec-17	Quest Diagnostics	Shiel Medical Laboratory	170	150E	1.1

Source: Laboratory Economics

Spotlight Interview with Cooper University Hospital's Director of Laboratories

Charlene Bierl, MD, PhD

Cooper University Hospital (Camden, NJ) is an academic tertiary care medical center (579 beds) affiliated with Cooper Medical School of Rowan University. The hospital's laboratory department has an annual budget of approximately $24 million and 152 FTEs (not including pathologists). *Laboratory Economics* recently spoke with Charlene Bierl, MD, PhD, Director of the Clinical Laboratory at Cooper University Hospital.

Approximately how many lab tests per year does Cooper University Hospital perform?
We perform approximately 1.7 million tests. Inpatient is approximately 65%, outpatient is 20%, the remainder is emergency room, observation, same-day surgery, et al. We have very little non-patient outreach (1.6%). However, we are aiming to collect more office-based draws from outpatients that are registered patients in the system.

What's the benefit of doing more office-based draws for hospital outpatients?
This is primarily driven by insurance-based quality metrics as well as patient satisfaction. A number of insurance companies are placing financial pressure on health systems to document better patient care, such as better diabetic care.

One way this is measured is through lab tests such as A1c and urine micro albumin. Once the patients leave the office, many will never go to get their labs drawn for a variety of reasons, thus resulting in suboptimal medical care and raising our failure rate (a "no test" is assumed to be a "failure" in these metrics).

In addition to the insurance and medical pressures, patients want "one stop shopping." They do not want to have to make a second trip to get lab work performed. Patient satisfaction is a very high priority.

Given the multiple needs, we evaluated whether this was better provided by us or by having one of the commercial laboratories come in to provide the service. Even with the PAMA cuts and patient capitation constraints from bundled payments, the numbers still appear to significantly favor us providing the service and keeping the volume that we can.

The Cooper Health System has more than 100 outpatient offices throughout Southern Jersey and Pennsylvania and handles approximately 1.4 million outpatient visits annually.

Can you elaborate on why Cooper has chosen not to expand in the non-patient outreach testing area?
We need to see how the margin on our current outpatient efforts looks. There are additional benefits that make collecting outpatients with small profits or break even still advantageous that do not exist for non-patients (e.g., EMR interfacing, population health, et al.).

Can you describe some of the cost-cutting measures that Cooper put in place over the past few years?
Our most aggressive efforts date back several years with many of them focused on utilization. For example, beginning in 2012, we began providing Cooper's internal medicine residents with weekly feedback on their individual test ordering patterns relative to their peers. A study published in *The American Journal of Managed Care* in November 2015 showed that the program reduced Cooper's test utilization by internal medicine residents by an average 21% per week.

We started sending the same type of reports to our hospitalist physicians in 2014, although it's much harder to analyze the change in utilization given the parallel growth of the department's responsibilities as well as institutional growth as a whole.

What else is Cooper doing to help reduce unnecessary utilization?
We have also looked at ASCP's Choosing Wisely recommendations (among other published efforts) to optimize our menu. This was a mixture of removing antiquated tests, replacing panels with a tiered reflex approach, and optimizing the hospital's EMR to encourage best practices. One specific example was with cardiac marker testing. We had removed CKMB from the cardiac panel in 2011, leaving troponin as the marker of choice but had not realized at the time that CK had remained a part of the panel in the EMR. So, we recently pulled CK out of the quick pick cardiac panel in the EMR, reducing the volume of this test.

Who is Cooper's primary reference lab? What are a few of the tests that Cooper will be bringing in-house over the next year or so?
Our primary is Quest Diagnostics, our secondary is ARUP Labs. We are in the process of validating NGS testing for oncology patients and hope to be live in less than a year. In general, we are very careful to balance the cost of in-house testing versus reference lab and will not bring in testing which a reference lab can perform at a lower cost unless it makes sense medically for a faster TAT. We have even decided to stop performing some low-volume tests and instead send them out, thus eliminating the cost of maintaining the analyte.

In addition to price, are there any other key factors you use when selecting a reference lab?
Definitely. We look at the breadth of the menu, how the menu was developed, as well as turnaround time and methodology for certain tests. We are looking to utilize tests that have a proven clinical benefit and looking for support on appropriate utilization of testing.

Is Cooper having any difficulty finding and hiring MTs, MLTs or phlebotomists?
Yes for MTs and MLTs, but we have less trouble finding phlebotomists.

LabCorp To Use Philips' Digital Pathology System

LabCorp has announced plans to implement the Philips IntelliSite Pathology Solution (PIPS) at four of its laboratories. Among the labs where the system is expected to be installed are LabCorp's pathology lab in Research Triangle Park, North Carolina, and at its Dianon pathology lab in Connecticut.

"LabCorp sees the potential of the Philips digital pathology solution to innovate their business models, with the opportunity for their customers such as a local hospital to have rapid, efficient access to a national network of LabCorp and other pathologists through the U.S., including specialists and sub-specialists," according to Marlon Thompson, General Manager of Philips Digital Pathology Solutions. "This will support faster turnaround time of pathology results in critical cases."

PIPS, which received FDA clearance for primary diagnostic use in April 2017, is an automated digital pathology image creation, viewing and management system.

Lab Stocks Up 31% Year To Date

Prices for 17 publicly-traded lab stocks are up 31% on an unweighted average basis through July 13. In comparison, the S&P 500 Index is up 2.7% year to date. The top-performing lab stocks so far this year are Natera, up 140%, and Foundation Medicine, up 100%. At the two largest public labs, LabCorp is up 17% and Quest Diagnostics is also up 17%.

Company (ticker)	Stock Price 5/15/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$0.88	$1.85	-53%	$24	NA	0.8	1.2
CareDx (CDNA)	12.39	7.34	69%	437	NA	8.6	13.1
Enzo Biochem (ENZ)	5.11	8.15	-37%	241	NA	2.2	2.8
Exact Sciences (EXAS)	63.76	52.54	21%	7,800	NA	25.3	11.3
Foundation Medicine (FMI)	136.70	68.20	100%	5,080	NA	28.3	267.0
Genomic Health (GHDX)	52.96	29.39	80%	1,870	NA	5.4	9.4
Interpace Diagnostics (IDXG)	0.95	1.02	-7%	26	NA	1.5	0.7
Invitae (NVTA)	8.29	9.08	-9%	557	NA	6.5	4.4
LabCorp (LH)	187.21	159.51	17%	19,150	15.2	1.8	2.7
Myriad Genetics (MYGN)	42.69	34.35	24%	2,980	22.1	3.8	3.2
Natera (NTRA)	21.59	8.99	140%	1,180	NA	5.3	NA
NeoGenomics (NEO)	13.89	8.57	62%	1,120	NA	4.2	6.5
Opko Health (OPK)	5.86	4.90	20%	3,280	NA	3.1	1.8
Psychemedics (PMD)	20.10	20.56	-2%	110	18.3	2.7	5.9
Quest Diagnostics (DGX)	114.95	98.49	17%	15,610	20.5	2.0	3.1
Sonic Healthcare (SHL.AX)	26.23	21.40	23%	11,140	24.0	2.1	2.8
Veracyte (VCYT)	10.31	6.53	58%	354	NA	4.7	9.5
Unweighted Averages			31%	$70,959	20.0	6.4	21.6

Source: Capital IQ

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