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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

COULD LAB COPAY ISSUE RE-EMERGE IN 2017?

Plans by the Trump administration and Republicans to repeal and replace the Affordable Care Act (ACA) raises many questions about just what the replacement would be and how to pay for it. As lawmakers look for potential savings from Medicare to offset likely budget deficits, the possibility of a lab copay could rear its ugly head once more, believes Dennis Weissman, President of Weissman & Associates. *More on page 10.*

Special New Year's Report:

LAB EXECS SHARE OUTLOOK FOR 2017

For an inside look at what may be in store for the clinical lab and pathology business this year, Laboratory Economics interviewed the top executives at a diverse group of 10 lab companies. Our interviews revealed a consensus foreboding that Medicare's repricing of the CLFS based on private-payer rates will lead to a substantial restructuring of the clinical lab industry. CEOs anticipate an average reduction of 5-10% to the CLFS in 2018 followed by massive consolidation of smaller hospital and independent labs. Other trends include growing consumerism in healthcare (e.g. shopping for low-cost labs) due to higher patient deductibles and copays. Meanwhile, despite rate reductions and increased payer scrutiny of claims, lab CEOs say molecular diagnostics continue to be a high-growth market. *Continued on pages 4-9.*

TEXAS PATHOLOGISTS SEEK TO DELAY BeaconLBS

The Texas Society of Pathologists (TSP) is requesting that UnitedHealthcare delay implementation of BeaconLBS in Texas, currently scheduled for March 1. "It's increasingly obvious to TSP that this system is not going to be beneficial for the health of Texans," says Kevin Homer, MD, President of TSP. Homer says the BeaconLBS system has a number of flaws that need to be fixed. "We are actively engaged with UHC, BeaconLBS and LabCorp. Implementation needs to be delayed until the system is reworked." *Continued on page 3.*

LABCORP TO BUY MOUNT SINAI'S OUTREACH LABS

LabCorp has entered into a definitive agreement to acquire assets of Mount Sinai's Clinical Outreach Laboratories, including seven patient service centers currently operated by Mount Sinai in New York City. The PSCs will be added to LabCorp's existing network of 120 patient service centers in the New York City area. The deal is expected to close by March 31. Other terms of the transaction were not disclosed. *Continued on page 2.*

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LABCORP TO BUY MOUNT SINAI'S OUTREACH LABS (*cont'd from p. 1*)
"We are confident this transaction will provide great benefits for our patients and physicians and allow Mount Sinai to continue to invest in our core strategic programs," said Donald Scanlon, Chief Financial Officer for Mount Sinai Health System.

LabCorp is buying only Mount Sinai's clinical lab outreach testing business, including cytology and cytology-related molecular testing. Mount Sinai will continue to provide laboratory testing for patients registered at its hospitals and ambulatory facilities as inpatients or outpatients, as well as laboratory testing services for physicians in their professional practices in the areas of anatomic pathology, molecular pathology and genetics.

Mount Sinai Health System includes seven hospitals, the largest are Mount Sinai Hospital (1,144 beds) and Mount Sinai Beth Israel (825 beds), as well as more than 300 ambulatory care practices throughout the New York City area.

In a statement, Mount Sinai said, "This particular business, while successful, is no longer a core business of Mount Sinai….This transaction will allow Mount Sinai to continue to invest in our core strategic programs, such as in cancer and cardiac services, and to advance our mission across the system."

The Mount Sinai deal follows LabCorp's acquisition of six regional lab service centers from Henry Mayo Newhall Hospital (Santa Clarita, CA) in April 2016. The labs had been co-managed by the hospital and United West Labs. "Our primary mission is to serve inpatients. Selling our outreach laboratory business will help ensure we can carry out our primary mission," said Bob Hudson, Senior Vice President and Chief Financial Officer for Henry Mayo, in a statement.

Over the past 10 years, LabCorp has acquired a total of eight lab businesses from hospital systems (including the pending Mount Sinai deal).

LabCorp Hospital Lab Outreach Acquisitions

Health System	*Location*	*Transaction Date*
Mount Sinai Health System	New York City	Pending
Henry Mayo Newhall Hospital	southern California	April 2016
John Muir Health/MuirLab	northern California	November 2013
Dignity Health	Arizona	August 2013
McNeal Hospital/Genesis Clinical Lab	Illinois	August 2013
Faxton-St. Luke's Healthcare/Centrex Lab	upstate New York	November 2009
Stanford Outreach Lab	northern California	August 2008
NCH Healthcare/DSI Laboratories	Florida	August 2007

Source: *Laboratory Economics*

THERANOS FIRES ANOTHER 155 EMPLOYEES

Theranos Inc. (Palo Alto, CA) has announced that it has fired 155 employees. These layoffs follow 340 job cuts made in October after the company closed its lab operations in Arizona, California and Pennsylvania. As a result, Theranos is left with 220 employees who are working on getting FDA clearance and commercialization of the company's miniLab testing system. The company is facing lawsuits from patients, investors and its former partner Walgreens that allege that Theranos lied about the accuracy of its blood testing technology.

TEXAS PATHOLOGISTS SEEK TO DELAY BeaconLBS (*cont'd from page 1*)

BeaconLBS (Montvale, NJ) is a lab benefit management program owned by LabCorp. UHC has used the system in Florida for the past two years and plans to expand its use to all fully-insured UHC commercial members in Texas effective March 1, 2017.

The program requires physicians to file advance notification using BeaconLBS's Physician Decision Support software when ordering approximately 80 high-cost lab tests and most pathology services (Pap tests, biopsies, IHC, thyroid panels, et al). UHC says that ordering physicians must use the program when ordering these tests as a prerequisite for payment to the performing lab or pathologist.

However, Homer says TSP has identified a number of concerns with the system and is asking UHC to delay implementation until after they are addressed. Among TSP's many concerns and requests are:

- BeaconLBS currently interfaces with a limited number of EMRs. TSP says implementation should be delayed until at least 80% of EMRs used by UHC-contracted physicians are interfaced with the program.
- BeaconLBS has told several large Texas labs that it does not provide electronic payment remittances. Implementation should be delayed until UHC can assure the uninterrupted flow of electronic payments.
- BeaconLBS requires pre-notification by ordering physicians, but failure to do so results in payment denials to the performing laboratory. Therefore, labs working with non-compliant physicians will be forced to either antagonize their own clients or perform testing for free. Homer says that talks with his colleagues at the Florida Society of Pathologists indicate that referring physicians are commonly non-compliant with BeaconLBS and that labs are simply not being paid for tests on UHC patients in those cases. TSP wants the program redesigned so that labs are not penalized for omissions which are not under their control.
- Redirection of anatomic pathology referrals to anonymous pathologists at a large reference lab will break existing physician-to-pathologist relationships to the detriment of care. Anatomic pathology tests (CPT 88000-88999) should not be characterized as "decision support tests."

Homer says that, as far as he can tell, BeaconLBS provides little or no guidance that helps physicians identify and order the correct test. "It's more focused on where to send the test [to LabCorp], rather than which test to order." He notes that by denying payment to performing labs, UHC and BeaconLBS may violate the Texas Department of Insurance's "prompt payment of clean claims" law. "We're considering all our options if our talks with UHC are not fruitful," says Homer.

2017 OUTLOOK FOR LABS: 10 EXECUTIVE PERSPECTIVES (*cont'd from p. 1*)

Barbara Bigler, President of **ACL Laboratories** (West Allis, WI and Rosemont, IL), anticipates that rate reductions resulting from Medicare's PAMA repricing of the CLFS, effective in 2018, will push more partnerships among hospital outreach labs. "Size and scale will matter even more."

Hospital outreach labs will be under more pressure than ever to lower cost structures. "That's difficult to do unless you understand your cost structure and manage your own outreach billing independent of the hospital outpatient department," notes Bigler.

Over time, Bigler expects the difference between hospital outpatient lab test rates and more competitive outreach lab test rates to disappear. "Higher out-of-pocket costs are driving patients to shop for labs."

ACL Laboratories is jointly operated by Wisconsin-based Aurora Health Care and Chicago-based Advocate Health Care. It operates a central laboratory in the Milwaukee area and another in the Chicago area. In addition, ACL manages 27 hospital-based labs and provides service to 110 owned clinics and more than 5,000 outreach physician accounts. Total annual volume is 25.5 million tests (54% from hospitals/31% owned clinics/15% outreach clients).

Bigler says outreach volumes are growing by approximately 8-10% annually. She notes that both systems have been acquiring physician practices over the past few years, which has added to outreach test volume growth, although in many cases acquired groups have been existing ACL outreach clients.

Peter Fisher, MD, President and CEO of **Health Network Laboratories** (Allentown, PA), says HNL's test volumes are growing by approximately 8-10% per year. HNL is an independent lab owned by the hospitals of Lehigh Valley Health Network, Good Shepherd Rehabilitation and Phoebe Ministries. Its nearly 1,000 employees perform more than 50 million tests per year, including roughly 30 million for non-hospital patients and another 20 million for 12 hospital labs it manages.

Fisher says growth is being driven by its molecular diagnostic reference testing services as well as toxicology and pain management testing. In early 2016, HNL also acquired two forensic DNA and paternity testing labs—Fairfax Identity Laboratories and Mitotyping Technologies—based in State College, Pennsylvania. Finally, Fisher notes that HNL introduced a direct-access testing service, branded Milestone Health Direct, about one year ago. "Demand is good and increasing."

Regarding Medicare's PAMA repricing, Fisher says, "It has got a misguided focus on unit test cost. The value of appropriate test utilization and of onsite 24/7 labs hasn't come into this conversation at all."

Fisher says HNL is investing in predictive and value analytics research that can give quantified answers to questions such as "What is the value of a $10 lab test that can help avoid an unnecessary patient admission or reduce a length of stay?" In the future, he believes some private insurance companies might actually acquire labs to gain control of lab testing data.

Stan Schofield, President of **NorDx** (Scarborough, ME), says his lab outreach test volumes are growing by approximately 3% per year. "We're growing but it's not the double-digit growth from 10 years ago." The NorDx outreach market includes Maine and New Hampshire. Its primary competitor is Quest Diagnostics and its large new laboratory in Massachusetts.

NorDx operates a 36,000-square-foot freestanding core lab in Scarborough (just south of Portland) that, in addition to outreach testing, performs all esoteric and pathology TC services for the nine hospitals that make up MaineHealth. NorDx and its 550 employees also manage the inpatient labs at all MaineHealth hospitals. Total volume is six million tests per year (70% hospital/30% outreach).

Schofield estimates that lab and pathology reimbursement has been reduced by an overall average of roughly 12% over the last three to four years, including cuts to 88305-TC, immunohistochemistry and the MDx codes. But he says Medicare's PAMA repricing initiative will potentially be more devastating. He anticipates the first year cut, effective in 2018, will average 7% to Medicare's CLFS, and that private insurers will match it. "Only the very strong, very cost-effective will survive."

Schofield says that NorDx has survived and thrived since being formed in 1997 because of its ability to contain costs. For example, he says that the average cost per test at MaineHealth's flagship hospital, MaineMed (700 beds) has increased a total of less than 5% over the past 20 years. "Hospital management understands this and it would be difficult for any commercial lab to match."

Mauro Guerra, Chief Executive at **Pathology Associates of San Antonio** and its technical lab, **Pathology Reference Laboratory** (PRL-San Antonio, TX), says his seven client service reps visit every client at least once every six months, with their largest clients visited once per month. PRL and its 27 pathologists serve more than 40 hospitals and ambulatory surgery centers and 1,000 physician practices in Central and South Texas. "A personal client relationship means physician office staff are more likely to call us when a problem occurs, rather than keep quiet and switch to a competitor."

Guerra believes the in-office pathology lab trend peaked a few years ago. His group currently provides professional services to six gastro groups, one derm practice and a urology group. "We recognized the in-office lab trend and made a decision to participate."

Guerra's biggest immediate worry is UnitedHealthcare's decision to expand BeaconLBS into Texas. "I'm not sure this was created to improve quality standards or as a means to stop out-of-network testing, or as a way for LabCorp [which owns BeaconLBS] to simply get rid of competition. I am pleased that the Texas Society of Pathologists has expressed concern. The biggest problem is getting physicians to cooperate and use the system. I know our clients are upset that they are being forced to do more."

Pathology Associates of San Antonio was started in 1944 at Santa Rosa Hospital (San Antonio) and formed PRL in 2000. PRL is a specialty lab performing surgical, cytology, flow, in-house FNA's and some molecular testing specific to cytology/pathology.

David Bostwick, MD, returned as Chief Executive of **Bostwick Laboratories** (Glen Allen, VA) about six months ago. He had resigned as CEO in 2012 after the company was sold to the private investment firm Metalmark Capital (New York City). In between, Dr. Bostwick started another lab company, Granger Genetics (see *LE*, January 2016), which his wife owns and helps manage.

At its peak Bostwick Labs had more than 1,000 employees, including 32 pathologists, and operated labs in Tennessee, Arizona, Florida, Virginia and New York. Dr. Bostwick says a perfect storm of reimbursement cuts, insourcing by urologists and a reduction in PSA screening and resulting biopsies forced Bostwick Labs to restructure. Presently Bostwick Labs operates a single lab in Long Island, New York and has 200 employees, including 10 pathologists.

Over the past six months, Dr. Bostwick and new CFO Tammy Hunt have focused on billing improvements, including: 1) no longer accepting certain out-of-network specimens that had little chance of being reimbursed; and 2) optimizing the company's appeal process for denied claims.

Bostwick Labs has also refocused its attention on its core business of prostate and kidney biopsies. Dr. Bostwick says turnaround times have been lowered from an average of 3-4 days to 24 hours over the past six months.

The company also changed its sales leadership by promoting Vedran Pipinic to Vice President of Sales and Marketing and added 100 new clients last year, according to Dr. Bostwick.

Goals for 2017 include continued billing improvements, consolidation of administrative functions at its Virginia offices, and hiring more sales reps. "We're in the late stages of our turnaround," says Dr. Bostwick.

Sonora Quest Laboratories (SQL-Tempe, AZ), a joint venture between Banner Health and Quest Diagnostics, anticipates 2017 revenue growth to be in the range of 4% to 4.5%, a slightly slower rate from 2016's growth of 5.9%, says Chief Executive **David Dexter**. The decline, he says, is due primarily to managed care contract changes. For 2016, revenues were about $300 million, with approximately 6.3 million laboratory requisitions.

SQL is experiencing rapid growth in its direct access testing business – 15% per month. My Lab ReQuest, launched in July 2015 after the state passed legislation allowed consumers to order lab tests, has exceeded all expectations, according to Dexter, and has led to a partnership with Safeway's Wellness Clinics. Currently, SQL operates nine patient service centers at Safeway stores throughout Arizona and expects to add additional PSCs in 2017. [Note: Quest Diagnostics now offers diagnostic testing in dozens of Safeway locations in addition to the two operating through SQL. Quest officials have said they expect to expand to 200 locations by the end of 2017.]

Dexter attributes the success of My Lab ReQuest in part to high-deductible health plans that encourage consumers to take more responsibility for their own health care. Results are not sent to physicians, which alleviates liability concerns, and payment is made up front so there are no billing costs on the back end.

While about 80% of SQL's business is still fee-for-service, Dexter says the lab is in the process of pilot testing alternative payment programs with insurers and accountable care organizations (ACOs). He sees bundled payment as a cost-savings opportunity, noting that it could reduce or eliminate billing inefficiencies that cost the organization $1 million per month. "We have to embrace the future," he says. "The fee-for-service model is not sustainable."

The biggest challenge for Sonora Quest and for the lab industry is transforming the business model from one based on fee-for-service to one based on value, says Dexter. SQL has developed data analytics tools that use data in real-time to help support the health of specific populations. Dexter says he could eventually see selling these data analytics tools to insurers to help them manage the health of their members.

SQL is participating in Medicare's data collection efforts under the lab test repricing initiative. The exercise is expected to reduce Medicare payments for clinical lab services starting as early as 2018. However, Dexter notes that because Arizona is already one of the lower paying markets, the decline may not be felt as acutely as in other parts of the country.

Mark McDonough, President and CEO of **CombiMatrix Corp.** (Irvine, CA), says the company is on track to reach its goal of positive cash flow from operations by the end of 2017. CombiMatrix operates a 13,000-square-foot laboratory and office in Irvine, California, that is focused on prenatal genetic testing.

Since being promoted to Chief Executive in early 2013, McDonough has refocused CombiMatrix on prenatal genetic testing and de-emphasized oncology testing. The company's primary service is a micro-array miscarriage analysis test that allows women to make more informed decisions on future pregnancies. CombiMatrix's revenue from miscarriage analysis grew by 36% to $4.7 million in the nine months ended Sept. 30, 2016; average collected revenue per case was approximately $1,600. McDonough says CombiMatrix is also seeing strong growth from preimplantation genetic testing for women undergoing in vitro fertilization (IVF) where payment is received (average $1,400 per case) prior to results being sent.

In addition, McDonough says CombiMatrix's billing and collections team has focused on increasing cash collections by asking patients and physicians to serve as advocates for reimbursement with the payers. For example, CombiMatrix will contact its patients by mail and telephone and request they sign letters of attestation that confirm that they ordered a test and the test was useful. These letters are used to appeal denied claims. "It requires a lot of sweat equity but it has improved our appeal times and success rates," notes McDonough.

CombiMatrix's current bad-debt expense is less than 5% with a DSO of approximately 90 days. Overall, CombiMatrix reported total revenue of $9.3 million (up 26%) and an operating loss of $3.5 million in the first nine months of 2016.

Joint Venture Hospital Laboratories (JVHL), a hospital-based lab outreach network based in Michigan, expects 5% growth in billable tests and revenues in 2017, as opposed to over 6% in 2016, according to Chief Executive **John Kolozsvary**.

JVHL, which was established in 1992, is owned by six health systems—Univer-

sity of Michigan, Beaumont Health, Trinity, St. John Providence, McLaren Health Care and Sparrow Health System. In total, JVHL has 127 hospitals participating in its network, which includes the Great Lakes Laboratory Network.

JVHL serves as a single administrative resource for outreach lab service contracting and payer relation activities for members (with the exception of agreements with Medicare, traditional Blue Cross Blue Shield and a handful of other health plans, which are handled by the hospitals directly). Currently, the network has agreements with 30 health plans representing more than 5.4 million lives.

JVHL volume on average represents about 40% of the member hospital total outreach laboratory testing. In 2016, through the JVHL health plan agreements, network members performed 15 million tests with revenues of about $136 million, an increase of about 7% over 2015, according to Kolozsvary

JVHL reports core HEDIS measures for all participating health plan partners with the exception of one. Test utilization data reports generated by JVHL include genetic test utilization and cost tracking, high user/low user physician tracking, medical care group leakage reports, referring physician leakage reports, hospital leakage reports, physician compliance and other custom reports.

Kolozsvary says that less than 5% of member hospital labs are required to report their managed care payment and volume information to Medicare under the CLFS repricing initiative. However, JVHL is encouraging members who meet the applicable lab criteria otherwise but do not currently have a lab-specific national provider identifier to get one and participate in the next data collection period.

The repricing initiative will have a material effect on member lab outreach revenues, says Kolozsvary. "In the long run, I believe it will have some negative impact on any outreach laboratory reimbursements based on the CLFS for certain CPT codes beginning in 2018, with the real impact coming after the adjustment period ends in 2023."

While there has been a great deal of banter about repeal of the Affordable Care Act, Kolozsvary believes that a wholesale repeal would be political suicide for any party enacting that radical a change (which would negatively impact millions of Americans who receive insurance through Medicaid expansion and the healthcare exchanges). "There is opportunity for overhaul, though, and some surgical strikes on the ACA through reconciliation would, hopefully, cause a more calculated phased-in approach to fixing what's wrong," he says.

Significant improvements in turnaround times, productivity, and injury reduction lead key metrics at **PCL Alverno Laboratories** (Hammond, IN) where Chief Executive **Sam Terese** has focused the organization on continuous improvement and laboratory efficiency. PCL Alverno owns and operates 26 hospital labs as well as one central laboratory that serves thousands of physician offices in the Midwest.

Terese expects PCL Alverno's 2017 internal growth rate to be in the single digits, repeating single digit growth from 2016, down from a peak growth rate of 20% in 2015. The influx of physician practices acquired by the two parent systems, Franciscan Alliance and Presence

Health, leveled off in 2016, reflecting consolidation within the market and a slowdown in growth. "The commercial side of the business is growing", says Terese, "while the hospital side is contracting."

In 2016 PCL Alverno performed approximately 15 million billable tests. Fee-for-service work accounted for the vast majority of the lab's testing revenue in contrast to non-fee-for-service business, which accounted for less than 10% of revenues. Terese recognizes that the lab needs to offer more value-added services and the decision to add more value-added services is taking shape.

"We need to provide something more predictive," says Terese. "We're not there yet, we're building connectivity to enter the value-added market place. We expect these efforts to be completed in 2017 and to request feedback from our partners this year."

PCL Alverno forecasts a likely 10% reduction in Medicare revenues once the new CLFS rates go into effect in 2018. The repricing of the CLFS requires PCL Alverno's central lab to submit data to Medicare during 2017. The hospital labs under Alverno management do not have to submit their data.

Ray Sukumar, MD, Chief Executive of **Doctors Pathology Services** (DPS-Dover, DE), says his expansion into ultrasound-guided fine needle aspiration (FNA) biopsies helped his lab offset losses caused by the double whammy of insourcing by urology, gastroenterology and derm groups and the reduction in 88305-TC rates. "I'm not sure we could have survived without it."

Sukumar says DPS began doing ultrasound-guided biopsies in early 2011. DPS operates several mobile pathology CLIA-certified lab vans that visit physician offices and ambulatory surgery centers throughout Delaware, New Jersey, Maryland and Pennsylvania. Sukumar and his staff carry ultrasound equipment into the doctor's office, perform scheduled ultrasound-guided biopsies, and then prepare and analyze the specimens from inside their specially equipped van in the parking lot. In addition to mobile ultrasound-guided biopsies, DPS recently opened a fixed site office in Lewes, Delaware, that also performs ultrasound-guided biopsies.

Sukumar says that his reimbursement from ultrasound-guided biopsies (including radiology and pathology services) averages about $1,500 per patient case—about double the amount he receives when doing only the pathology service. Ultrasound-guided biopsies now comprise about 50% of DPS's revenue.

"Most office-based radiologists don't want to be bothered with doing ultrasound FNAs and it can take three or four weeks before a patient gets scheduled for an ultrasound at a hospital," notes Sukumar. Pathologist-performed ultrasound biopsies provide quicker and more-specific results that reduce repeat visits and unnecessary surgeries, according to Sukumar.

After losing about one-third of its clients to in-office pathology labs, Sukumar says DPS is growing again. DPS, which currently has two full-time pathologists and 25 other employees, is in the process of hiring another pathologist. Sukumar says DPS is also rolling out a digital pathology system from Leica Biosystems and is contracting with two former AFIP (Armed Forces Institute of Pathology) pathologists from Washington, DC, to do primary diagnosis on routine cases and second opinions on more complex cases.

Could Lab Copay Issue Re-emerge in 2017? (*cont'd from page 1*)
"Laboratory is one of the only Part B services that doesn't have a copay," notes Weissman. "That makes it stick out like a sore thumb when lawmakers are looking for savings. It could come up."

Weissman made his prediction during a January 11 teleconference hosted by *Laboratory Economics*, during which he and Julie Khani, President of the American Clinical Laboratory Association (ACLA), discussed the potential financial impact of the Trump era on labs and pathologists.

ACA repeal could result in less comprehensive policies and less certain funding mechanisms that could leave providers contending with higher copays and deductibles, says Weissman. Replacing the current Medicaid funding mechanism with block grants is likely to create downward pressure on provider reimbursement, and the market uncertainty along with emerging headwinds will likely drive consolidation as weaker providers seek scale to reduce costs, he believes.

Trump and GOP leaders have also said that changes to Medicare could be included in the ACA repeal. House Speaker Paul Ryan supports turning Medicare into a "premium support" system that pays private plans and traditional fee-for-service programs a fixed amount per beneficiary, notes Weissman. Rep. Tom Price (R-GA), an orthopedic surgeon who is Trump's pick for secretary of Health and Human Services, also supports repeal of the ACA and a Medicare premium support system. What's more, says Weissman, Price supports balance billing and is hostile to the shift away from fee-for-service to quality-based methods of provider payment.

Seema Verma, an Indiana health policy consultant who is Trump's pick to head the Centers for Medicare and Medicaid (CMS), has also been praised by conservatives interested in phasing out government healthcare programs. Verma worked with Vice President-elect Mike Pence in designing Indiana's alternative approach to ACA's Medicaid expansion.

Private Payer Data Reporting Underway
As Congress grapples with repeal of the ACA and confirming Trump's Cabinet picks, CMS has begun collecting private payer rate and volume information from applicable laboratories (primarily independent labs with their own National Provider Identifier), as required by the Protecting Access to Medicare Act (PAMA). The first data reporting period runs from January 1 through March 31, 2017 (for data collected January 1 – June 30, 2016).

Labs Required to Report Data

Labs must report their private payer rate and volume data to CMS if they:

- Receive more than $12,500 in Medicare revenues from laboratory services on the CLFS
- Receive more than 50% of their Medicare revenues under the CLFS or Physician Fee Schedule
- Have their own National Provider Identifier

Khani advises labs not to wait until the last minute to report their data, noting that there were some problems with the reporting portal during the testing period. "There are multiple steps to this process," she notes. "Plan a lot of time for this effort."

CMS issued a detailed user guide on how to access and use CMS's reporting portal on January 4, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Data-Collection-System-User-Guide.pdf. CMS notes that laboratories that expect to submit more than 100,000 lines of data in the .csv template should contact the CMS/CLFS help desk at clfshelpdesk@dcca.com. Additional guidance, including applicable HCPCS codes and the data reporting template, are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

MEDICARE CLFS RAISED 0.7% FOR 2017

The new CLFS payments resulting from repricing are slated to begin Jan. 1, 2018. For 2017, labs will receive a 0.70% update under the CLFS. This includes a 1% CPI inflation increase minus a 0.3% productivity adjustment. The annual update to payments made on a reasonable charge basis for all other lab services is 1.00%. There is no payment change in 2017 for specimen collection fees (codes 36415, P9612 and P9615). CMS will issue the 2017 trip fee update to the standard mileage rate later in the year.

For 2017, the national minimum payment for a cervical or vaginal test (pap smear) is $14.49. Affected codes include 88142-43, 88148, 88150, 88152-54, 88164-67, 88174-75, G0123, G0143-45, G0147, G0476 and P3000. The automatic Part B Medicare payment cuts of 2% that have been in place since 2013 remain in effect for 2017. Under the Medicare Access and CHIP Reauthorization Act of 2015, pathologists and other physicians will receive a 0.5% increase in Medicare payment in 2017 and 2018.

ESTIMATED $1.7 BILLION OF LAB ACQUISITIONS IN 2016

A total of 21 lab acquisitions valued at an estimated $1.7 billion were completed in 2016, estimates Laboratory Economics. LabCorp was the most active with six deals valued at more than $500 million, including its purchase of Sequenom (San Diego, TX) in September for $379 million and the Center for Disease Detection (San Antonio, TX) for $115 million in October.

Lab Acquisition Summary for 2016 ($ millions)

Lab Type	Date	Buyer	Target	Purchase Price	Acquired Revenue	Price/ Revenue
Routine	Pending	LabCorp	Mount Sinai outreach lab	NA	NA	NA
Pathology	Pending	CellNetix	Puget Sound Institute of Pathology	NA	NA	NA
Esoteric	Dec-16	DNA Diagnostics Center	Identigene	NA	NA	NA
Pathology	Nov-16	P4 Diagnostix	Metamark Laboratories	NA	NA	NA
Esoteric	Oct-16	LabCorp	Center for Disease Detection	$115	NA	NA
Pathology	Oct-16	LabCorp	ClearPath Diagnostics	NA	NA	NA
Esoteric	Sep-16	LabCorp	Sequenom	379	115	3.3
Esoteric	Sep-16	Eurofins Scientific	VRL Laboratories	NA	NA	NA
Pathology	Aug-16	Pritzker Group Private Capital	PathGroup	NA	250	NA
Routine	Aug-16	Schryver Medical	Professional Clinical Laboratory	NA	NA	NA
Routine	Aug-16	Internist Laboratory	West Pacific Medical Laboratory	NA	NA	NA
Esoteric	Jul-16	Oxford Immunotec	Imugen	22.2	NA	NA
Esoteric	Jun-16	Ningbo MedicalSystem	Atherotech	19.6	NA	NA
Esoteric	May-16	The Cooper Companies	Recombine Inc.	85.0	20	4.3
Pathology	May-16	Advanced Dermatology	Skin Pathology Associates	NA	NA	NA
Routine	Apr-16	LabCorp	Nebraska LabLinc	NA	NA	NA
Routine	Apr-16	LabCorp	Henry Newhall Mayo outreach labs	NA	NA	NA
Pathology	Apr-16	Aurora Diagnostics	Pathology Associates of Sebring	250K	NA	NA
Pathology	Mar-16	Aurora Diagnostics	Pacific Pathology Associates	7	NA	NA
Routine	Feb-16	Quest Diagnostics	Clinical Laboratory Partners	135	NA	NA
Pathology	Jan-16	LabCorp	Pathology Inc.	NA	NA	NA
Esoteric	Jan-16	Health Network Labs	Fairfax Identity/ Mitotyping Technologies	NA	NA	NA
Pathology	Jan-16	Consonance Capital Partners	Bako Integrated Physician Solutions	NA	NA	NA

Source: *Laboratory Economics*

LAB STOCKS UP 1% IN 2016

Sixteen lab stocks rose by an unweighted average of 1% last year. In comparison, the total return for the S&P 500 Index was 12%. The top-performing lab stocks in 2016 were Psychemedics, up 147% (including dividends), Enzo Biochem, up 54% and Exact Sciences, up 45%. At the big two commercial labs, Quest Diagnostics was up 30% (including dividends) and LabCorp was up 4%

Company (ticker)	Stock Price 12/30/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	1.35	3.30	-59%	32	NA	1.3	1.2
CombiMatrix (CBMX)	2.65	10.95	-76%	9	NA	0.7	1.2
Enzo Biochem (ENZ)	6.94	4.50	54%	329	7.3	3.2	3.7
Exact Sciences (EXAS)	13.36	9.23	45%	2,060	NA	26.3	5.7
Foundation Medicine (FMI)	17.70	21.06	-16%	678	NA	6.0	3.5
Genomic Health (GHDX)	29.39	35.20	-17%	979	NA	3.1	6.8
Invitae (NVTA)	7.94	8.21	-3%	350	NA	18.5	4.0
LabCorp (LH)	128.38	123.64	4%	13,840	21.3	1.5	2.5
Myriad Genetics (MYGN)	16.67	43.16	-61%	1,120	12.6	1.5	1.5
NeoGenomics (NEO)	8.57	7.87	9%	675	NA	3.2	8.4
Opko Health (OPK)	9.30	10.05	-7%	5,100	49.8	4.1	2.5
Psychemedics (PMD)	24.99	10.14	147%	132	50.7	3.9	11.2
Quest Diagnostics (DGX)	91.90	71.14	30%	12,850	19.7	1.7	2.8
Rosetta Genomics (ROSG)	0.42	1.23	-66%	12	NA	1.2	0.9
Sonic Healthcare (SHL.AX)	21.40	17.87	20%	8,820	19.4	1.8	2.4
Veracyte (VCYT)	7.74	7.20	8%	253	NA	4.2	7.2
Unweighted Averages			1%		25.8	5.1	4.1

Source: Capital IQ

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