

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

LABS EXPECT CMS'S PRIVATE-PAYER ANALYSIS WILL LEAD TO 5-10% CLFS RATE CUTS

Thirty-three percent of labs anticipate that CMS's analysis of private-payer rates will lead to the maximum allowed 10% cut to Medicare reimbursement for clinical lab tests in 2018, while another 12% anticipate a 5% reduction, according to an exclusive survey of 170 lab executives and pathologists conducted by *Laboratory Economics* in early September. Zero percent anticipate it will increase rates, while a significant portion (40%) said they did not have enough information to make a good prediction.

On a more cheerful note, *LE's* survey showed most labs are experiencing solid volume growth this year for both anatomic pathology tests (avg. 6% growth) as well as for clinical lab tests (avg. 8% growth). However, for the third year in a row, survey participants reported declining Pap test volumes (avg. -1% decrease). For a full summary of *LE's Anatomic Pathology & Clinical Lab Trends Survey 2016*, see pages 5-7.

How will CMS's private-payer-rate analysis impact lab test rates in 2018?

It will increase rates	0%
Anticipate little change	15%
Anticipate an average 5% reduction	12%
Anticipate an average 10% reduction	33%
Not enough info to make a good prediction	40%
Source: <i>LE</i> Survey, September 2016; n=170 labs	

SALES REPS GET COCKERELL IN TROUBLE

An expansion into genetic testing and toxicology and a couple of rogue sales reps have gotten Cockerell Dermatopathology Laboratory (Dallas, TX) and its respected owner Clay Cockerell, MD, into hot water for allegedly billing the Tricare military healthcare system for millions of dollars of unnecessary tests. The story was first reported by *CBS News* on June 8, 2016, and within days the Department of Defense Inspector General's office confirmed it was investigating Cockerell Dermatopathology for potential Tricare billing fraud. *Laboratory Economics* provides a timeline and additional details about the controversy on page 3.

KNOWLEDGE IS POWER IN SEND-OUT TEST NEGOTIATIONS

Hospital labs may think they are getting a good deal for send-out tests when they use a group purchasing organization (GPO) for contracts with reference labs, but they are not, according to Jack Mattice, President of the hospital lab consulting firm J.A. Mattice & Associates (Vancouver, WA). He says the major reference labs, Quest Diagnostics, LabCorp, Mayo and ARUP, simply can't afford to give the large GPOs their best prices. *Continued on page 2.*

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KNOWLEDGE IS POWER IN SEND-OUT TEST NEGOTIATIONS (*cont'd from p. 1*)

If a large GPO has 3,000 hospital members, and each hospital sends out 30,000 tests per year, then the GPO is negotiating for an annual total of 90 million tests, explains Mattice. If the GPO were able to negotiate an average reduction of \$10 per test, then the combined 3,000 hospitals would save a total of \$900 million per year (90 million tests x \$10 = \$900 million). No reference lab can absorb that kind of a financial hit, says Mattice.

He says a single hospital, or small group of hospitals, is capable of obtaining significantly better prices than a GPO because the big reference labs are willing to take a small hit to win or maintain a contract. The key is knowing the lowest price that the major reference labs are willing to provide for each specific send-out test.

Since Mattice founded his eponymous firm in 1974, he has helped negotiate reference lab contracts for more than 100 hospitals and health systems. And from the beginning, he says his firm has kept track of the lowest prices it has found from the four largest reference labs: Quest Diagnostics (including different fees from five acquired labs), LabCorp, ARUP, Mayo, as well as for a few regional labs. “Our database includes 7,984 unique line items and is updated whenever we negotiate a new reference lab contract. Every time we find a lower price for the same test code, we keep track of it, and it becomes our new standard price for negotiations.”

Mattice says that his reference lab contracts are typically three years. “We help with the transition to the new vendor or fees, and then audit every test performed for the period of our relationship with our client. I want to emphasize that we do not focus only on price.” However, Mattice says that in his experience, all of the major reference labs provide excellent service, although there may be regional or local differences in perceived quality.

A typical client is a network of five hospitals. If they average 30,000 send-outs a year per hospital, a total of 150,000 tests are performed by their reference lab. “If I can save them \$10 a test, the system saves \$1.5 million per year. Conversely the reference lab stands to lose that same amount, but will accept lower pricing for a number of strategic reasons.”

What about using an auction-style RFP for selecting a reference lab? “Like relying on a GPO fee schedule for keeping prices low, using any form of RFP doesn’t usually favor the hospital. The key is knowing exactly which prices to demand for each test. Vendors respond well to precise pricing requests,” answers Mattice.

Meanwhile, information supplied by Mattice show that there is a wide variation in what hospitals pay for common send-out tests. For example, Mattice has found that some hospitals pay their reference lab as little as \$11 for Vitamin D tests, while others pay as high as \$29. Meanwhile, Medicare’s Clinical Laboratory Fee Schedule reimburses Vitamin D at a national rate of \$37.

Pricing Comparison for Common Send-Out Tests

Test	CPT Code	Low Price	Mid Price	High Price
Vitamin D	82306	\$11	\$25	\$29
Cystic fibrosis screen	81220	68	82	121
HIV viral load	87536	38	57	226
Lyme disease antibody	86618	85	130	153
Lead (blood)	83655	4	5	10
JAK2 gene analysis	81270	169	225	345

Source: J.A. Mattice & Associates

CONTRACTED SALES REPS GET COCKERELL IN BIG TROUBLE (*cont'd from p. 1*)

Dr. Cockerell resigned from his position as Managing Director for Quest's DermPath Diagnostics division in late 2012 to start his own dermatopathology lab company. Dr. Cockerell purchased and renovated a 78,000-square-foot medical office building in Dallas and began processing specimens in mid-2013. Cockerell Dermatopathology grew quickly and currently processes more than 1,000 cases per day for more than 1,300 referring physicians.

In early 2015, Cockerell Dermatopathology expanded into genetic testing and toxicology using the brand name Origen Laboratories. Origen is owned by Dr. Cockerell, located in the same building as Cockerell Dermatopathology, and uses the same CLIA certificate as Cockerell Dermatopathology.

Origen's business operations, including its sales and marketing, are managed by a separate company named Progen Lab Systems LLC. Progen was formed in late 2014 by Dr. Cockerell's entrepreneurial nephew Quinton Cockerell. Progen is headquartered at the same address as Cockerell Dermatopathology and Origen Laboratories.

Sometime in early 2015, Progen contracted with two outside sales reps who are allegedly responsible for the scheme targeting military individuals covered by Tricare. The two individuals apparently set up sham patient service centers in Killeen, Texas (about 50 miles south of Dallas), that gave military personnel and their family members \$50 Walmart gift cards in exchange for a photocopy of their military ID and urine and cheek swab samples. The sales reps then allegedly obtained, or forged, physician signatures for lab test orders which were sent to Origen Laboratories for testing.

The lab orders typically included molecular tests for cancer and/or drugs-of-abuse tests and often totaled several thousand dollars per patient. The scam went on for about six months from mid-2015 to at least late 2015. *CBS News* estimates that about 2,000 soldiers and their family members were lured in by the \$50 gift cards and that Cockerell Dermatopathology billed Tricare more than \$5 million last year for unnecessary tests.

In a statement, Dr. Cockerell said that Progen became aware of the scam in late 2015 and immediately terminated all relationships with those involved. "Tricare was notified and an arrangement was made to pay back revenue generated by the scheme." He said that he found out about the situation only after corrective actions were taken. "I was not involved in dealing with the issues as I am not an operator of the lab [Origen Laboratories]," according to Dr. Cockerell. "I am outraged and appalled that my good reputation and honest laboratory operations were used in this fashion."

A spokesperson for Dr. Cockerell says Cockerell Dermatopathology has not been contacted by the Department of Defense, but will cooperate fully if it is.

Who will be held responsible for HIPAA violations?

Meanwhile, in addition to having to contend with a DoD Inspector General's office investigation, Cockerell Dermatopathology may also potentially be liable for major HIPAA violations, notes *Laboratory Economics*. That's because *CBS News* reporters found an unlocked shed outside one of the abandoned specimen collection offices in Killeen that included personnel information from dozens of soldiers including Social Security numbers, medical information, DNA specimens and more than 60 photocopies of military IDs. Apparently, no one has secured this sensitive information. It's unclear who will ultimately be held responsible for it, the physicians that ordered the tests, the two rogue sales reps, Progen Lab Systems, or Cockerell Dermatopathology.

PUBLICLY-TRADED LABS GROW 4.9% IN FIRST-HALF 2016

On a combined basis, 18 publicly-traded labs saw their revenue increase by 4.9% to \$8.8 billion during the first six months of 2016 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 16 publicly-traded labs grew by 10.4% in first-half 2016 (after adjusting for acquisitions).

Pro forma revenue growth was fastest at Invitae Corp., up 215%; Exact Sciences, up 191%; and Cancer Genetics Inc., up 53%.

Acquisition-adjusted revenue for Quest Diagnostics increased by 2.3% in first-half 2016, while LabCorp's revenue was up 4.7%. The third largest U.S. lab company, Bio-Reference Labs (now part of Opko Health) had estimated revenue growth of 15.2%.

Revenue Growth at 18 Publicly-Traded Lab Companies (\$'000)

Company	First-Half 2016	First-Half 2015	Reported Change	Pro Forma Change*
Quest Diagnostics (lab testing only)	\$3,565,000	\$3,463,000	2.9%	2.3%
LabCorp (lab testing only)	3,250,000	3,047,000	6.7%	4.7%
Opko/Bio-Reference ¹	518,534	450,000	15.2%	15.2%
Sonic Healthcare USA ²	420,500	412,700	1.9%	1.9%
Myriad Genetics ³	377,000	369,000	2.2%	2.2%
Genomic Health	162,868	138,771	17.4%	17.4%
Aurora Diagnostics	141,541	124,039	14.1%	4.0%
NeoGenomics	122,832	47,396	159.2%	32.0%
Foundation Medicine	58,615	41,753	40.4%	40.4%
Sequenom Laboratories	56,857	70,572	-19.4%	-19.4%
Exact Sciences	36,020	12,385	190.8%	190.8%
Enzo Clinical Labs (lab testing only) ⁴	35,685	30,382	17.5%	17.5%
Veracyte	28,225	23,126	22.0%	22.0%
CareDx	17,297	14,344	20.6%	20.6%
Psychemedics	16,367	13,757	19.0%	19.0%
Cancer Genetics Inc.	13,069	8,555	52.8%	52.8%
Invitae Corp.	9,536	3,030	214.7%	214.7%
Combimatrix	6,079	4,878	24.6%	24.6%
Total, 18 companies	\$8,836,025	\$8,274,689	6.8%	4.9%
Total, 16 companies (excluding Quest and LabCorp)	\$2,021,025	\$1,764,689	14.5%	10.4%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

¹Bio-Reference's revenue is for the six months ended June 30, 2015 estimated by *Laboratory Economics*; ²Sonic Healthcare USA's revenue is for six months ended June 30, 2016; ³Myriad Genetics' revenue is for six months ended June 30, 2016; ⁴Enzo's revenue is for lab services only for six months ended April 30, 2016.

Source: *Laboratory Economics* from company reports

LE SURVEY SPOTLIGHTS GROWING CONCERN OVER REIMBURSEMENT

Declining reimbursement has consistently been the top concern for labs and pathologists since LE conducted its first survey in 2007. However, this year it hit an all-time high with 32% of survey respondents citing it as the biggest challenge that labs and pathology groups will face in the next five years. Anecdotally, LE notes that the tone of the comments received from survey participants was noticeably more pessimistic than past surveys.

“The push for pricing transparency, even though I believe it is a good thing, will ultimately emphasize low price and convenience over quality. Ultimately, I believe that pathology work is going to go to the lowest price bidder, likely the large commercial labs, unless small independents can adapt,” according to a pathologist from Virginia.

“Declining reimbursement and exclusion of generally excellent local independent labs from payer panels is going to eventually lead to the complete Walmartization of American pathology. I’ve seen that big box lab work product in the dermatopathology realm, and I hope everyone likes crap,” lamented a pathologist from North Carolina.

“Hospitals will increasingly look to outsourcing to lower their bottom-line expenses,” according to a pathologist from Idaho.

“With Medicare proposing more severe cuts to 88305, reimbursement pressure is clearly continuing. So far we have managed to control costs and grow test volume to offset the reimbursement declines, but that will only be sustainable up to a certain point,” said a lab executive from Kentucky.

The next most frequently cited challenge was “exclusion from managed care contracts,” which was cited by 15%, the same percentage as our 2015 survey. And “competition from large commercial labs” was the third highest ranked challenge at 12%.

What is the biggest challenge that labs and pathology groups will face over the next 5 years?

	2016	2015	2014	2013	2011	2010	2009	2008	2007
Declining reimbursement.....	32%	28%	31%	31%	26%	29%	25%	27%	23%
Exclusion from managed care contracts.....	15%	15%	10%	9%	9%	8%	10%	NA	NA
Competition from large commercial labs	12%	14%	12%	13%	16%	15%	15%	19%	20%
Bundled payment for outpatient tests.....	11%	11%	NA	NA	NA	NA	NA	NA	NA
Staffing shortages	9%	5%	6%	6%	7%	8%	13%	19%	15%
Technical staff shortages	7%	4%	4%	5%	5%	7%	12%	13%	NA
Pathologist shortages.....	2%	1%	2%	1%	2%	1%	1%	6%	NA
Specialty physician groups insourcing pathology	8%	12%	11%	15%	19%	17%	18%	14%	15%
Difficulty/expense of adding new molecular diagnostics.....	4%	5%	4%	6%	5%	5%	7%	9%	NA
Increased expenses for information technology.....	4%	6%	7%	6%	8%	9%	10%	6%	NA
Increased utilization mgt. leading to lower test volume	4%	2%	11%	3%	NA	NA	NA	NA	NA
Weak economy	1%	2%	6%	6%	8%	8%	NA	NA	NA
Other.....	0%	0%	2%	5%	2%	1%	1%	2%	16%

Note: No survey was conducted in 2012

Source: LE’s Anatomic Pathology & Clinical Lab Trends Surveys, 2007-September 2016

Dealing with Lower Medicare Reimbursement

Medicare reimbursement for the technical component of CPT 88305 is facing a proposed 10% reduction next year. In addition, Medicare's repricing of clinical lab tests based on private-payer rates looms for 2018. In terms of adapting to lower reimbursement, the most popular response was "put pressure on reagent suppliers and other vendors to lower costs" cited by 59% of survey takers. Fifty-three percent said they are "growing their way out of it" and 45% said "improve billing and collection efficiency."

How is your pathology group/lab adapting to lower Medicare rates?*	2016	2015
Put pressure on reagent suppliers and other vendors to lower costs.....	59%	38%
We will grow our way out of it.....	53%	35%
Improve billing and collection efficiency	45%	40%
We will delay new instrument/equipment purchases	25%	26%
We will hold or reduce employee compensation.....	23%	35%
We will reduce staff.....	23%	23%
We will consolidate offices/labs	12%	10%
We will sell our technical lab	7%	2%

*Survey respondents were allowed to select multiple answers

Source: *LE's Anatomic Pathology & Clinical Lab Trends Surveys*, July 2015 and September 2016

Which Subspecialty is Growing Fastest?

Twenty-three percent of survey respondents said they were seeing their fastest growth in molecular test volumes. The second fastest area of growth was dermatopathology. The slowest area of growth was urologic pathology, which was each cited by only 7% of survey takers.

In which subspecialty is your path group/lab seeing its fastest growth?	2016	2015
Molecular diagnostics.....	23%	20%
Dermatopathology.....	20%	19%
Surgical pathology.....	16%	17%
Gastrointestinal pathology	10%	16%
Routine clinical lab testing.....	10%	9%
Cytopathology	8%	11%
Hematopathology	8%	5%
Urologic pathology	5%	3%

Source: *LE's Anatomic Pathology & Clinical Lab Trends Surveys*, July 2015 and September 2016

Market Share for Reference Lab Cancer Testing

NeoGenomics, which acquired Clariant Inc. in December 2015, is the primary reference lab for cancer testing to 28% of surveyed pathology groups/labs. LabCorp follows with 20% and ARUP Labs has 13%.

Who is your primary reference lab for cancer testing?	2016	2015
NeoGenomics/Clariant	28%	27%
LabCorp/Integrated Oncology.....	20%	17%
ARUP Labs.....	13%	6%
Quest Diagnostics/AmeriPath	8%	14%
Bio-Reference/GenPath.....	6%	3%
Mayo Medical Labs.....	6%	9%
CSI Laboratories	5%	1%
Genoptix.....	4%	0%
Other.....	10%	23%

Source: *LE's Anatomic Pathology & Clinical Lab Trends Surveys*, July 2015 and September 2016

Survey Demographics: The survey was e-mailed to approximately 6,000 pathology groups, independent labs and hospitals in early September 2016. A total of 170 surveys were judged usable, yielding a response rate of 3%. Among the respondents, 47 were from hospital-based pathology groups or labs, 79 from local or regional independent pathology groups and labs, 21 from academic medical center-based pathology groups, 15 from national pathology or lab companies and 8 from in-office pathology labs.

In-Office Pathology Labs Remain a Problem

The percentage of pathology groups and labs that say they have lost significant business during the past year to specialty groups that have built in-office histology labs is down from the all-time high shown in *LE's* 2013 survey. But that's only because most big urology, gastroenterology and dermatology groups have already built in-office labs. And while the insourcing trend may have slowed down, it has not gone away. Thirteen percent of respondents to our latest survey said they had lost "significant business" over the past year and 31% said they lost "some business" to a new in-house histology lab.

Has your pathology group/lab lost business in the past year because a physician group client created its own histology lab?

	2016	2015	2014	2013	2011	2010	2009	2008	2007
Yes, we've lost significant business ...	13%	17%	15%	27%	11%	17%	15%	8%	5%
Yes, we've lost some business	31%	34%	31%	32%	36%	29%	37%	28%	28%
No, we have not been affected.....	56%	49%	54%	41%	53%	54%	48%	64%	67%

Note: No survey was conducted in 2012; Source: *LE's Anatomic Pathology & Clinical Lab Trends Surveys, 2007-2016*

Currently, the insourcing trend seems to be strongest at dermatology and gastroenterology groups. In addition, it looks like it's spreading to big ob/gyn practices. Nine percent of survey respondents said that an ob/gyn group had insourced pathology in their area. Among the states where pathologists reported insourcing by ob/gyn groups were Connecticut, Florida, Illinois, New York, North Carolina and Tennessee.

Another 9% of survey respondents reported that an oncology group had insourced testing in their area. Among the states where pathologists reported insourcing by oncologists were California, Florida, Georgia, New York, South Carolina, Tennessee, Texas and Utah.

What types of groups have in-sourced pathology services in your area?

	2016	2015	2014	2013	2011
Dermatology.....	70%	55%	63%	65%	64%
Gastroenterology.....	64%	62%	66%	64%	68%
Urology.....	44%	51%	59%	62%	61%
Ob/Gyn.....	9%	8%	3%	2%	0%
Oncology.....	9%	16%	0%	2%	1%

Note: No survey was conducted in 2012; Source: *LE's Anatomic Pathology & Clinical Lab Trends Surveys, 2011- 2016*

"We are seeing newer lab companies selling equity interests to referring physicians—particularly dermatologists. The dermatologists then refer to the lab in which they have an ownership interest and receive remuneration from the lab in the form of equity distributions. It is a new way to make money from referrals without the effort of client billing," described a lab executive from Texas.

"Even with decreased reimbursements, our biggest challenge seems to be new in-office histology labs," according to a pathologist in Arizona.

"Corporations like Dermatology Solutions Group, Integrated Dermatology Group and Forefront Dermatology, et al., are buying practices from older retiring dermatologists all over the country and redirecting dermatopathology referrals to in-house labs. This situation will get worse if PIMA doesn't get passed,"* noted a lab executive from Georgia.

*Earlier this year, congresswoman Jackie Speier (D-CA), Jim McDermott (D-WA) and Dina Titus (D-NV) re-introduced legislation to close the in-office ancillary services exception to the Stark Law. The Promoting Integrity in Medicare Act (PIMA), or H.R. 5088, would prevent physicians in certain specialties from referring patients to ancillary medical services in which they have an ownership interest and are offered in their offices (see *LE*, May 2016, p. 10).

SPOTLIGHT INTERVIEW WITH PAML's DR. VELAZQUEZ

Pathology Associates Medical Laboratories (PAML), based in Spokane, Washington, is a reference laboratory owned by Providence Health & Services and Catholic Health Initiatives. PAML has laboratories in Washington, Idaho, Montana and Oregon, and joint ventures with hospital labs in several other states. *Laboratory Economics* recently spoke with PAML's CEO, Francisco R. Velázquez, MD, about his company and changes in the laboratory industry. Here's a summary of our discussion:



*Francisco R.
Velázquez, MD*

With the new lab payment system scheduled to take effect Jan. 1, 2018, do you have any concerns about how new payment rates for lab tests will be determined?

It makes sense for Medicare to look at the laboratory industry or any other provider to make sure patients are getting the best value, but they need to look at the industry in its totality. By just looking at aggregated reimbursement data for a fraction of the providers, key aspects such as community-centric valued-added services may be lost. As an example, we are one of the few laboratories in our region that does home draws for homebound patients. I am concerned that CMS might not adequately identify and value that service appropriately.

I also have some concerns about sharing so much detailed proprietary data with Medicare or any agency given that there are so many cybersecurity threats.

It seems plausible to think that labs that aren't larger in size may see their reimbursement go down, while those who are larger may go up. Those that have large volumes will benefit because of their overrepresentation in the book of business. They also have economies of scale.

Has PAML put in place a system to capture the data that will need to be transmitted to CMS as part of the data collection process for this new payment system?

We're pretty good at leveraging our information technology expertise and collating whatever information we need to gather and submit. The detail that we are going to have to look at is different than what we've had to look at before, but we have a lot of expertise in mining line-item financial data. The downside is that it's one more project that we have to do with added costs.

How is your direct-to-consumer product – Cinch – performing?

We have seen between two and three thousand patients in the past year ordering from our consumer products. Adoption is a little slower for us than for others, and that's because we still rely on blood draws. We did look at a self-collection kit, but the extraction process was too complicated. We are looking at using saliva, which would increase the adoption rate.

What is your view of hospital outreach labs?

We think there is value in hospital outreach, and PAML has eight outreach joint ventures right now. We also have a couple of different partnerships, such as with Franklin Healthcare in Tennessee. We also manage three inpatient hospital labs as part of one of our joint ventures. We have a couple of other joint ventures and partnerships in various stages of development as well.

How has bundled payment for laboratory outpatient tests affected hospital outreach labs?

It has prompted a conversation about what is the value of lab services and how do we pay for it. I think we'll see a lot of impact over the next 18 months. We are having conversations with our partners about the value proposition of lab testing and what's an appropriate line item reimbursement for different services.

Please update us on your planned expansion into California.

In California, we continue to grow organically. We expanded into Orange County more recently. We don't own any facilities in the state, it's all through our joint ventures. We have a joint venture and partnership with St. Joseph's in Burbank. California is not our fastest growing market segment. We're growing faster in Colorado and Kentucky.

What kind of overall revenue growth has PAML experienced in the past year?

Our organic growth was 8.6% year over year. The previous year was about 8.8%. We're projecting similar growth for this year.

What are the biggest challenges facing PAML and the lab industry right now?

There are a number of challenges. One is the need for us to articulate our value proposition in the overall healthcare system. Another is the rapid consolidation of the industry where the large number of mergers and acquisitions places a strain on the local/regional services, and the overall availability of services and options for patients and consumers.

PATHOLOGY GROUPS CALL FOR TRANSPARENCY IN LCD PROCESS

A number of pathology groups, including the College of American Pathologists and the Association of Molecular Pathology (AMP), are calling for increased transparency in Medicare's local coverage determination (LCD) process.

The organizations are calling for passage of the Local Coverage Determination Clarification Act (HR 5721), introduced by Reps. Lynn Jenkins (R-KS) and Ron Kind (D-WI). The legislation would improve the LCD process through a number of methods:

1. Open meetings—Require that the Medicare Administrative Contractors' (MACS) Carrier Advisory Committee (CAC) meetings be open, public, and on the record, with minutes taken and posted to the MAC's website for public inspections.
2. Upfront disclosure—Require MACs to include—at the outset of the process—a description of the evidence the MAC considered when drafting an LCD, as well as the rationale they are relying on to deny coverage.
3. Meaningful reconsideration and options for appeal—Create an appeals process for providers and suppliers to appeal a MAC's decision to the Centers for Medicare & Medicaid Services (CMS). Under current CMS rules, MAC LCDs are essentially unreviewable once they become final.
4. Stop the use of LCDs as a backdoor to NCDs—Prohibit CMS from appointing a single MAC, either expressly or in practice, from making determinations to be used on a nationwide basis in a given specialty.
5. Ombudsman position—Create an ombudsman to provide providers and suppliers with administrative and technical assistance in filing appeals, making publicly available information about the number of appeals filed with the MAC and with CMS each year, the actions by the MACs with respect to appeals filed, and recommendations to CMS on ways to improve the efficiency of the appeals process.

“Too often the current coverage process takes place in the dark and neglects the input of physicians,” says Samuel Caughron, MD, chair of AMP's Economics Affairs Committee. “AMP believes HR 5721 will improve the coverage determination process by ensuring transparency and accountability.”

QUEST TO OUTSOURCE BILLING TO UNITEDHEALTH'S OPTUM

In a move designed to reduce billing costs and bad debt, Quest Diagnostics has announced a 10-year deal to outsource its billing operations to UnitedHealth Group subsidiary Optum. Quest's 2,400 revenue-cycle employees are being hired by Optum (although these employees will remain in the same physical location). Optum will begin managing Quest's billing operations on November 13, 2016.

Optum already manages \$50 billion in healthcare billings covering 100 million lives for a number of large clients, including Dignity Health, Northwell Health (formerly North Shore – LIJ) and the Mayo Clinic.

As part of the deal, Optum will make Quest its primary vendor for biometric screening services (wellness screenings) that Optum provides to its own employees and other employer/health plans.

But the big question is whether or not this deal will increase Quest's chances of regaining a national lab contract with UnitedHealth Group. LabCorp became UnitedHealth's exclusive national lab provider back in 2007; however, this contract is up for renewal at the end of 2018.

PRITZKER INVESTS IN PATHGROUP

PathGroup (Brentwood, TN) has raised additional capital through a majority leveraged recapitalization led by Pritzker Group Private Capital (Chicago and Los Angeles). Details of the transaction were not disclosed.

Current owners of PathGroup now include Pritzker Group Private Capital, Vesey Street Capital (New York City), and PathGroup management and pathologists, who continue to hold a significant ownership stake. Primus Capital, which had led a minority equity investment in PathGroup in 2009, is no longer a shareholder.

PathGroup says the new capital will help the company expand in current and future geographies.

PathGroup's board of directors includes members of Pritzker Group Private Capital, Vesey Street Capital, and management including Ben Davis, MD, who remains Chairman and CEO.

PathGroup has 1,200 employees, including 80 pathologists, and operates a major central lab in Nashville. The company grew its revenue by 15% to reach \$225 million in 2015.

MYRIAD GENETICS BUYS ASSUREX HEALTH

Myriad Genetics closed on its acquisition of Assurex Health (Mason, OH) effective August 31. Myriad paid \$225 million upfront plus the potential for an additional \$185 million based on Assurex achieving certain performance-based milestones.

Assurex operates a CAP-accredited lab in suburban Cincinnati that performs a proprietary test named GeneSight Psychotropic. GeneSight is a cheek swab test that analyzes a panel of genetic markers that can be used to personalize patients' antipsychotic and antidepressant medicines. The test is based on patented technology licensed from Mayo Clinic and Cincinnati Children's Hospital Medical Center.

GeneSight has a list price of \$3,800 and an average selling price of approximately \$400 after discounts. Assurex generated revenue of more than \$60 million and tested more than 150,000 patients in the 12 months ended June 30, 2016, according to Myriad.

LABCORP COMPLETES ACQUISITION OF SEQUENOM

LabCorp (Burlington, NC) has completed its acquisition of Sequenom (San Diego), which specializes in prenatal genetic testing, for \$302 million, or \$2.40 per share of Sequenom stock. Including Sequenom's outstanding debt, the total enterprise value of the acquisition was approximately \$371 million. Sequenom recorded a net loss of \$19.8 million in the six months ended June 30, 2016; revenue fell by 19% to \$56.9 million.

SONORA QUEST OPENS SIX MORE SAFEWAY PSCs

Sonora Quest Laboratories (Tempe, AZ) has opened six new patient service centers (PSCs) inside Safeway supermarket stores in Arizona. The new locations follow the two pilot PSCs that opened in Safeway stores in Scottsdale and Phoenix in November 2015 (see *LE*, December 2015, p. 8). The Safeway PSCs serve patients ordering their own lab tests as well as those with physician orders. Sonora Quest, a joint venture laboratory between Quest Diagnostics and Banner Health, is the largest independent lab in Arizona.

THERANOS TO APPEAL CLIA PENALTIES

Theranos (Newark, CA) has filed a notice of intent to appeal the sanctions that the Centers for Medicare and Medicaid Services (CMS) announced in July. The sanctions included a two-year ban on lab ownership by CEO Elizabeth Holmes and revocation of CLIA certification for the company's lab in Newark, California, where major quality control lapses allegedly occurred.

The appeal will delay the sanctions which had been scheduled to take effect on September 5.

CMS had previously said Theranos could "begin negotiations" with the agency. Any agreement would be based on the ability of Theranos to "remove immediate jeopardy" to patients, the agency said, as well as other factors, such as the severity of the lab's deficiencies and "the overall compliance history of the laboratory."

Theranos has already voluntarily stopped patient testing at its Newark lab. The company continues to operate a lab in Scottsdale, Arizona and five PSCs in the Phoenix area.

California Lawsuits Combined

Separately, California U.S. District Judge Yvonne Gonzalez Rogers has ordered that six class actions lawsuits against Theranos and Walgreens be consolidated to "save time and effort." The lawsuits allege fraud and false advertising over the accuracy of the company's lab tests. Theranos is also facing four similar lawsuits in Arizona.

CMS POSTS PAMA CLFS DATA REPORTING GUIDE

CMS has issued a Clinical Laboratory Fee Schedule Data Reporting Template and a "Quick User Guide" to assist clinical labs in meeting private-payer payment data reporting requirements under the Protecting Access to Medicare Act of 2014 (PAMA). In the Quick User Guide, CMS notes that "applicable" laboratories [i.e., independent labs and large POLs] must collect private-payer payment rates and associated volume for lab test codes on the CLFS for the period beginning January 1, 2016 through June 30, 2016. Labs must report this data to CMS beginning January 1, 2017, through March 31, 2017. CMS will use the data to calculate lab test rates for calendar-year 2018. The fields included in the template are: National Provider Identifier, HCPCS Code, Payment Rate and Volume.

LAB STOCKS UP 2% YTD

Sixteen lab stocks have risen by an unweighted average of 2% year to date through September 14. In comparison, the S&P 500 Index is up 7.8%. The top-performing lab stocks so far this year are Exact Sciences, up 104%, Psychomedics, up 97%, and Enzo Biochem, up 22%. Meanwhile, LabCorp is up 8% and Quest Diagnostics is up 15%.

Company (ticker)	Stock Price 9/14/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/Sales	Price/Book
Cancer Genetics Inc. (CGIX)	\$1.90	\$3.30	-42%	\$31	NA	1.4	1.1
CombiMatrix (CBMX)	2.79	10.95	-75%	7	NA	0.6	0.6
Enzo Biochem (ENZ)	5.47	4.50	22%	253	14.3	2.5	4.8
Exact Sciences (EXAS)	18.83	9.23	104%	2,030	NA	32.3	7.4
Foundation Medicine (FMI)	21.76	21.06	3%	760	NA	6.9	3.5
Genomic Health (GHDX)	27.44	35.20	-22%	916	NA	2.9	6.6
Invitae (NVTA)	7.74	8.21	-6%	250	NA	16.8	2.7
LabCorp (LH)	132.99	123.64	8%	13,605	18.7	1.4	2.6
Myriad Genetics (MYGN)	21.90	43.16	-49%	1,510	15.1	2.0	2.0
NeoGenomics (NEO)	7.86	7.87	0%	612	NA	3.5	3.0
Opko Health (OPK)	10.19	10.05	1%	5,670	39.1	5.3	2.8
Psychomedics (PMD)	19.99	10.14	97%	109	41.9	3.7	9.2
Quest Diagnostics (DGX)	82.09	71.14	15%	11,412	18.0	1.6	2.5
Rosetta Genomics (ROSG)	0.88	1.23	-28%	18	NA	1.7	1.2
Sonic Healthcare (SHL.AX)	20.66	17.87	16%	8,591	18.8	1.7	2.3
Veracyte (VCYT)	6.75	7.20	-6%	188	NA	3.4	5.6
Unweighted Averages			2%		23.7	5.5	3.6

Source: Capital IQ

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