Jondavid Klipp, Editor, labreporter@aol.com

Volume 11, No. 12 December 2016

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

LAB OUTREACH GROWING DESPITE CHALLENGES

Hospital laboratory outreach programs continue to grow, despite major challenges, with the average size program growing from $10.6 million in the early 2000s to $24.9 million in 2016, according to a recent survey by Chi Solutions Inc., an Accumen company. *Full details, pages 7-8.*

MDL FILES ANTITRUST SUIT AGAINST LABCORP AND INDEPENDENCE BC

Medical Diagnostic Laboratories (MDL-Hamilton, NJ) has filed an antitrust lawsuit alleging that Independence Blue Cross (IBC) and LabCorp have colluded to prevent MDL and other labs from becoming in-network providers to IBC members in the Philadelphia region. In addition, MDL alleges that IBC refuses to pay for services provided by out-of-network labs such as MDL, effectively excluding them from competing in Southeastern Pennsylvania. *Cont'd on page 9.*

QUEST, LABCORP WIN PARTIAL SUMMARY JUDGMENT IN FLORIDA MEDICAID LAWSUIT

On December 5, Judge John C. Cooper of the 2nd Judicial Circuit Court in Leon County, Florida, ruled that it was reasonable for Quest Diagnostics and LabCorp to bill their undiscounted list prices to Florida Medicaid and accept its fee schedule amounts as payment. The ruling threw out one of two major charges filed by Hunter Labs and its former owner Chris Riedel in a decade-long lawsuit against the two big commercial labs. *Cont'd on page 3.*

REGISTRIES CAN HELP WITH DATA REPORTING UNDER NEW QUALITY PAYMENT PROGRAMS

Pathologists should consider using a qualified registry to report performance data to the Centers for Medicare and Medicaid Services (CMS) under the new quality payment programs that begin Jan. 1, 2017.

Mick Raich, President of the consulting firm Vachette Pathology (Blissfield, MI), says registries can help streamline the reporting process, eliminate some guesswork and provide ongoing feedback on physician reporting before it's set in stone. Raich discussed the registries during a December 7 *Laboratory Economics* teleconference. *Cont'd on page 2.*

Contents

REGISTRIES CAN HELP WITH DATA REPORTING (*cont'd from page 1*)
Physicians may choose to start reporting performance data any time between Jan. 1 and Oct. 2, 2017. Whenever you choose to begin, you must send in your performance data by March 31, 2018. This information will be used to determine Medicare payment adjustments that take effect on Jan. 1, 2019. The data may be reported through a certified electronic health record, through Medicare claims or through a qualified clinical data registry.

A list of qualified registries is available at *http://www.vachettepathology.com/looking-registry-assist-mips-check-full-list/*.

The cost of using a registry is about $300 to $350 per physician, with minimal start-up fees, says Raich. The College of American Pathologists is working to develop a pathology-specific registry with additional quality measures, but it likely won't be available until sometime next year, he adds.

Under the Merit-based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (APMs), Medicare payment adjustments to physicians will range from +/-4% starting in 2019 to +/-9% in 2022 and beyond (*LE*, November 2016, p. 1).

MIPS Overview:
Initial performance period begins on January 1, 2017.
First MIPS payments adjustments will apply to Medicare Part B claims for services furnished on or after January 1, 2019.

- ❑ Medicare payment increases and decreases of up to 4% in 2019 to MIPS eligible clinicians based upon composite scores.
- ❑ Maximum percentage adjustment will increase annually from 4% until it reaches 9% in 2022.
- ❑ Maximum percentage may continue to increase in years beyond 2022.

Source: Ober|Kaler

Among other issues discussed during the teleconference:
How will CMS know if you are a non-patient-facing physician? CMS defines this category as physicians with 100 or fewer patient-facing encounters. The agency will post a list of encounter codes on its website that will provide guidance on which services qualify as non-patient-facing. In addition, CMS says in the final rule that it will notify pathologists about whether they meet the definition of non-patient-facing before the beginning of the MIPS performance period.

Does the 100 or fewer patient-facing encounters apply to each physician in a group or the entire group itself? CMS will first look at the individual physicians in a group. If 75 percent of the group's physicians meet the non-patient-facing criteria, then the entire group does as well, Kristen Carter, an attorney with Ober|Kaler (Baltimore), told teleconference listeners.

How should pathologists who have a group practice and a separate independent lab report quality measures? Reporting must be done by each tax identification number, according to Raich, so the group practice would need to report quality measures and the independent lab also would have to report quality measures. CMS may provide additional subregulatory guidance on how independent labs must report, adds Carter. Check for updates at https://qpp.cms.gov.

How would pathologists certify that they are providing 24/7 access to clinicians, which is one of the measures in the clinical practice improvement category? A call log should be sufficient to prove the on-call access was available, said Raich.

QUEST, LABCORP WIN PARTIAL SUMMARY JUDGMENT (*cont'd from p. 1*)
Riedel's lawsuit (case no. 2007-CA-003549) was filed in 2007 and the State of Florida intervened as a plaintiff in the lawsuit in 2013.

The lawsuit makes two allegations:

1. That Florida Medicaid rules require providers to bill the program their "usual and customary charge." The lawsuit claims that "usual and customary" means a provider's most frequent price or fee accepted as full payment from the provider's non-Medicaid Florida customers. The lawsuit alleges that Quest and LabCorp billed Florida Medicaid some of their highest rates, and were paid the maximum Florida Medicaid fee schedule amounts for lab tests.
2. The lower prices that Quest and LabCorp charged non-Medicaid customers were allegedly used as a kickback to "pull through" referrals for higher paid Medicaid business.

Judge Cooper ruled that the term "usual and customary charge" has never been precisely defined and that it was reasonable for Quest and LabCorp to bill their undiscounted list prices to Florida Medicaid. "At bottom, Plaintiffs have not submitted a scintilla of actual evidence to support their contended meaning of usual and customary charges," wrote Judge Cooper in his order granting the defendants' motions for partial summary judgment.

However, Reidel's kickback allegations are still alive and in the discovery phase. His attorney Niall McCarthy, a Principal at Cotchett, Pitre & McCarthy, LLP, has asked Judge Cooper to set a trial date as soon as possible. *Laboratory Economics* notes that Quest and Labcorp have one more shot to knock out the kickback allegations before trial.

Meanwhile, in addition to Florida, Riedel still has one more Medicaid whistleblower lawsuit alive in Georgia. His lawsuit versus LabCorp in Georgia is awaiting a ruling for a second motion to dismiss.

Status of 7 Medicaid Whistleblower Lawsuits Initiated by Chris Riedel

State	Medicaid Enrollment	Whistleblower Lawsuit Filed	State Intervene?	Defendants	Status
California	12.5M	2005	YES	Quest, LabCorp and 7 smaller labs	Settled in 2011. Quest paid $241M. LabCorp paid $49.5M.
Florida	3.5M	2007	YES	Quest, LabCorp	Florida AG intervened in November 2013; now in discovery phase.
Georgia	1.8M	2008	NO	Quest, LabCorp	Settled with Quest in March 2014. Lawsuit vs. LabCorp is awaiting ruling for second motion to dismiss.
Massachusetts	1.6M	2007	NO	Quest	Settled in 2013 for undisclosed amount.
Michigan	2.3M	2008	YES	Quest	Dismissed, then settled on appeal for an undisclosed amount in early 2015.
Nevada	563,000	2007	NO	Quest	Settled in 2013 for undisclosed amount.
Virginia	1.0M	2007	NO	Quest, LabCorp	Both lawsuits dismissed in 2014.

Source: *Laboratory Economics* from lawsuits

FOCUS ON LDT OVERSIGHT NOW SHIFTS TO CONGRESS

While the Food and Drug Administration (FDA) has decided not to finalize its draft guidance on laboratory developed tests (LDTs), expanded oversight of home-brew assays could still happen if Congress moves forward with proposed legislation.

"The LDT guidance is dead for now," says Dennis Weissman, President of Weissman and Associates, a laboratory consulting company. "There is more of a possibility that there will be a congressional approach on this, maybe expanding oversight through CLIA rather than the FDA."

Weissman adds that he expects President-Elect Trump to issue a freeze on new regulations shortly after taking office. The new administration is likely to be anti-government regulation.

Over the past year, FDA officials have said repeatedly that they intended to finalize draft guidance issued in October 2014 that would set forth a risk-based approach to regulating moderate- and high-risk LDTs. However, following the election, officials notified industry groups that the agency no longer plans to finalize its draft guidance on LDTs this year. Instead, the FDA stated that it intends to work with the new administration and Congress, as well as stakeholders, to update the LDT framework.

Lawmakers have taken a stab at the LDT oversight conundrum, with several different draft proposals being circulated in the House. One would have removed in vitro clinical tests from FDA's purview and placed them under a new center within the agency. Another would have created an entirely new regulatory agency to oversee LDTs.

The law firm of Ropes & Gray, in a regulatory alert published November 23, notes that "the politics of FDA oversight are complex, with some industry players traditionally allied with pro-business Republicans advocating increased regulation of LDTs, others arguing the FDA regulation would be undesirable and that the focus should be on improving regulation under CLIA, and yet others calling for hybrid or entirely new approaches."

The only certainty, says Ropes & Gray attorney Gregory Levine, is that the question of how LDTs should be regulated in the future will not go away.

"FDA's latest announcement may, however, have the effect of preserving the status quo for longer than might have been otherwise the case," Levine tells *Laboratory Economics*. "With the next round of Medical Device User Fee Amendments set to be enacted in 2017, it is possible that Congress could use that legislative vehicle to establish a new LDT scheme if consensus can be reached by then."

JULIE KHANI TO LEAD ACLA AS NEXT PRESIDENT

The American Clinical Laboratory Assn. (ACLA) has announced that Julie Khani will be its next President effective January 1, 2017. Khani will succeed long-time President Alan Mertz, who is retiring but will continue to serve the association in an advisory role. Khani joined ACLA in the newly created position of Senior Vice President in 2013 and was promoted earlier this year to Executive Vice President, taking on additional management responsibilities and leading policy initiatives such as the implementation of the Clinical Laboratory Fee Schedule (CLFS) provisions of the Protecting Access to Medicare Act (PAMA). Prior to joining ACLA, Khani served in senior roles at the National Association of Chain Drug Stores and Ford Motor Company.

SPOTLIGHT INTERVIEW WITH NEOGENOMICS' DOUGLAS VANOORT

NeoGenomics (Fort Myers, FL) acquired Clarient Inc. (Aliso Viejo, CA) in December 2015 for approximately $275 million. The acquisition doubled the size of NeoGenomics to more than $225 million in annual revenue and about 950 employees, including 30 pathologists. *Laboratory Economics* recently spoke with Douglas VanOort, Chief Executive Officer of NeoGenomics, for an update on the Clarient acquisition and other news.

Douglas VanOort

Has the Clarient acquisition met expectations?

It absolutely has. In fact, it has exceeded our expectations in many respects. Clarient had a strong clinical trials business, which is important to us because we wanted to build that business. Clarient also had strong immunohistochemistry and digital pathology platforms, which are a perfect complement to our services.

What was greatest benefit gained from buying Clarient?

It's scale, clearly. Pure size. We have a lot more significant national coverage and a more comprehensive test menu now. Financially, we've more than doubled the revenue of NeoGenomics and more than tripled our adjusted EBITDA in just the first year . We also picked up a lot of great people, including some of the top pathologists in the country. There are a lot of benefits.

What has been most challenging in terms of integrating Clarient?

Integration is always challenging in the lab business. We combined two clinical labs that were about the same size, but we both had different processes and strengths. We had to identify the best practices in both companies and create a single uniform service offering and do it very quickly. It was difficult because after we selected the best practices, we had to incorporate them into our laboratory information system. Clarient was doing a lot more immunohistochemistry than we were. They also had a strong digital pathology platform. Also, Clarient had a very good pharmaceutical services business, much bigger than NeoGenomics. On the other side, NeoGenomics had a deeper molecular test menu and a terrific FISH program. By combining all of that, we ended up with the best of the best.

NeoGenomics at a Glance

Est'd annual revenue 2016	$250M
Est'd patient requisitions 2016	360,000
Est'd avg. revenue per req 2016	$600
Average # tests per patient req	1.5
Total # employees	950
Employed pathologists	30
Main labs	Aliso Viejo, CA; Ft. Myers, FL; Irvine, CA; Houston, TX

Source: *Laboratory Economics'* estimates and NeoGenomics

Who is in charge of Clarient operations?

From the beginning we combined our management teams, so we have one single management team running the whole business. Clarient is not separately run; it's integrated. Our Clinical Services Division is run by Rob Shovlin, who has been with NeoGenomics for a few years.

Were any labs consolidated?

Not yet, but we will be consolidating NEO's Irvine laboratory into Clarient's main Aliso Viejo facility by the end of February. The two facilities are only eight miles from each other in Orange County, Calif. We are just finishing up renovating the Clarient lab now, and when we are done, we will have a state-of-the-art facility.

Is Clarient now completely integrated with NeoGenomics?
Almost. As of today, nearly all of the Clarient clients and NeoGenomics clients are on the same laboratory information and billing systems. The only remaining piece is the consolidation of the lab facilities.

NeoGenomics' consolidated revenues for the third quarter of 2016 increased by 142% over the same period last year while clinical genetic test volume grew 150%. Was this due entirely to your acquisition of Clarient?

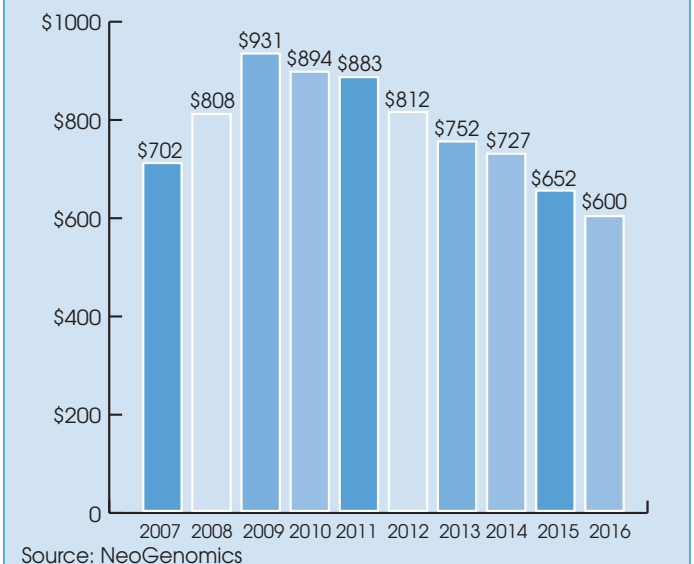
Not entirely. We continued to grow organically even as we were integrating the two companies. On an apples to apples comparison, if you included Clarient and NeoGenomics together last year, our volume increase would have been more like 15%. The rest of the 150% growth was a result of the Clarient acquisition.

What is your opinion on the outlook for digital pathology?
We think digital pathology will continue to grow. It should grow because it makes the workflow more efficient for pathologists. As pathologists grow more comfortable with digital images, there will be even more digital pathology. I think it is a good tool and we expect it to be used more broadly. This is one area where the regulation seems to be a bit behind the advances in technology.

Will NeoGenomics continue to focus on TC services, or do you have any plans to get more into professional reads?
We do both, but we offer them separately because we believe that having a partnership with pathologists is important. A lot of pathologists like to be involved in the diagnostic process. It's probably about half TC and half PC now. We do a lot of molecular testing and cytogenetics, and that's all global, and our pathologists are always there to consult on the most complex cases.

What are your thoughts on gastro, dermatology and urology groups insourcing pathology? Has this trend run its course?
I think that there will always be some insourcing if a client is large enough, and if it's cost effective and if they can duplicate the quality, but I think it's changing a lot. For one, the reimbursement rate for many of these tests are now quite low. There's just not a lot of incentive to insource anymore unless you have real scale.

NeoGenomics' Average Revenue per Patient Requisition



Source: NeoGenomics

Describe how NeoGenomics is working with pharmaceutical companies to develop new drugs.
We're very excited about the pharmaceutical business. Today it's about $25 million in revenue or about 10% of our business. It keeps us at the leading edge of advances in cancer care. We work with almost all of the top pharmaceutical companies. In total, we have more than 100 pharmaceutical clients, and almost 400 active projects. In the last nine months we've introduced about 25 new tests. The tests that are generating a lot of excitement are liquid biopsy tests, most of which are for hematologic cancers. We believe the liquid biopsy market will be one of the fastest growing markets we serve over the next five years.

HOSPITAL LAB OUTREACH GROWING (*cont'd from page 1*)

Kathleen Murphy, PhD

More lab outreach programs are now based out of multiple-hospital core laboratories as compared to single hospital laboratories, concludes Chi's 15th annual outreach survey, which was completed by approximately 150 hospital labs. Weaknesses are that only 44% of these programs have in-office phlebotomists, 43% report not having full-time sales representatives and nearly half have ineffective IT connectivity to physician offices. "In spite of these shortcomings, hospital-based laboratory outreach has continued to compete and grow in the open marketplace," Chi's survey report concludes (the survey's findings are available at http://www.chisolutionsinc.com/knowledge-center/laboratory-white-papers/).

One of the most surprising results of the survey is that only 26% of study participants indicated that their laboratory outreach program's profitability is analyzed, while 39% are unsure if it has been analyzed, and 35% know for certain it hasn't been analyzed, says Chi. But for those multi-facility core laboratory-based outreach programs that have analyzed their profitability, the median contribution margin is 20.3%, while the average contribution margin is 30.9%. Single hospital lab outreach is even more profitable, with a median contribution margin of 24% and an average contribution margin of 34.6%.

Kathleen Murphy, PhD, a senior growth advisor with Accumen, is passionate about laboratory outreach but acknowledges the challenges these programs face. "As pressure increases, you have to get better at what you do, or you won't be able to maintain the kind of margins you need to be viable long term," she tells *Laboratory Economics*. "Many outreach programs are run like mom and pop operations. These won't survive. Outreach programs need to be run like a for-profit business, with better billing and collections and a monthly profit and loss statement (P&L). The average lab outreach program brings in $20 million – what other $20 million business would be run without a P&L? That's the problem, but it's also the opportunity."

Key Characteristics of Hospital Lab Outreach Programs

Characteristic	% Respondents	Average Number	Median Number
Have freestanding PSCs	54%	11.0	7.0
Have in-office phlebotomists	4%	8.0	.5
Have full-time sales reps	57%	3.5	1.5
Have full-time field sales reps	25%	3.0	2.0

Source: Fifteenth Comprehensive National Laboratory Outreach Survey, Chi Solutions Inc.

Sales of lab outreach programs to national independent labs such as Quest Diagnostics are likely to continue in the coming years, says Murphy, who believes such sales are a natural part of the business cycle. "I think we'll see more sales of major hospital clinical laboratories with outreach under PAMA [Protecting Access to Medicare Act]," she says. "Hospitals might think the reimbursement is at its peak and choose to monetize. But other hospitals might think they can grow another 30% to 40%, thereby increasing the value, and choose to wait."

Impact of PAMA

Under regulations implementing PAMA's lab repricing initiative, almost all hospital outreach laboratories will be excluded from reporting their private payer data, which will have a negative impact on final payment rates. Under the final rule, only labs billing with their own National

Provider Identifier (NPI) are to submit payment data. Since almost all hospital outreach programs bill under the hospital-wide NPI, most will be excluded from providing information used to determine final pricing (though they will be affected by the final payment amounts). Chi projects that there will be an overall laboratory outreach revenue reduction of 3% per test, collectively from all payers.

Jeff Myers

Jeff Myers, Accumen's Vice President of Consulting, believes that PAMA was designed specifically to exclude hospital data. "The Centers for Medicare and Medicaid Services (CMS) argues that most hospital lab tests are paid under the outpatient prospective payment system, which isn't necessarily true," he tells *LE*. "I believe CMS deliberately avoided getting data from hospitals because hospitals get paid about 20% more than commercial labs."

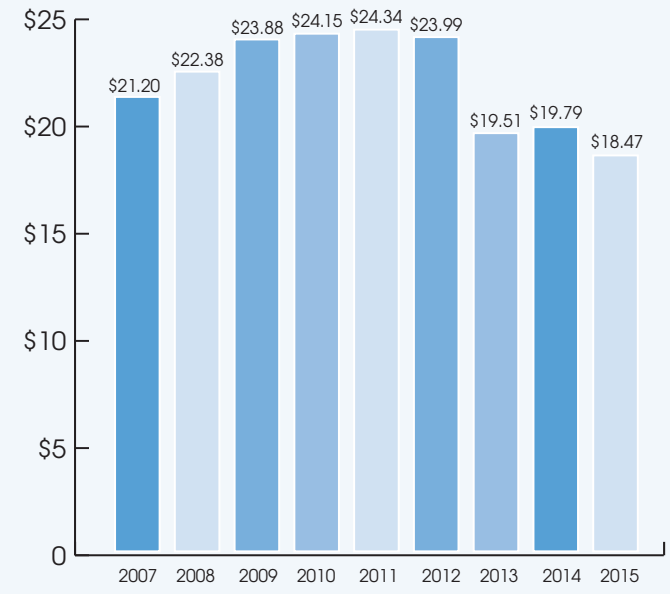
Murphy believes that eventually all labs will be paid under one fee schedule, regardless of where the testing is done. "There's no reason why hospitals should be paid more," she says. "We've been predicting this for years."

Outpatient Lab Testing

Beginning in January 2014, Medicare began bundling reimbursement for outpatient clinical laboratory tests under the Hospital Outpatient Prospective Payment System (OPPS). Previously, clinical lab tests performed on outpatients were paid separately under the Clinical Laboratory Fee Schedule (CLFS). While it's unclear just exactly what impact this has had on payment for hospital outpatient lab tests, Myers believes there was some shift from CLFS payment to OPPS payment.

Between 2013 and 2014, CMS paid $2.7 billion less under the CLFS while OPPS spending increased by $4.8 billion, notes Myers. "It's hard to say how much of the OPPS increase is lab testing, but there would have been some modest decline in reimbursement to hospitals under OPPS, and test utilization now becomes a bigger factor as blended outpatient services are no longer reimbursed under fee-for-service," he explains.

Average Hospital Lab Outreach Net Revenue Per Test



Source: Fifteenth Comprehensive National Laboratory Outreach Survey, Chi Solutions Inc.

Because hospital outreach services are still paid separately under the CLFS, hospital outpatient bundling could actually give outreach labs an advantage, though Murphy notes that not all hospitals do a good job of distinguishing between outpatient and outreach. "It's not always tracked as well as it should be resulting in lost opportunity," she notes.

Lab Outreach Net Revenue Per Test

The Chi survey showed that average net revenue per lab outreach test increased from 2007 through 2011, but has diminished since. The average net revenue per lab outreach test was $18.47 in 2015, according to the survey.

MDL FILES ANTITRUST SUIT AGAINST LABCORP AND IBC (*cont'd from page 1*)
MDL, which was founded in 1997 and employs approximately 670 people, is an independent lab specializing in testing for sexually-transmitted diseases.

IBC is the largest health insurer in the Philadelphia region, covering 2.5 million members or approximately 67.5% of the private healthcare market in Southeastern Pennsylvania, according to the lawsuit.

Prior to July 1, 2014, IBC had lab contracts with both Quest Diagnostics and LabCorp. Thereafter Quest lost its contract with IBC and LabCorp became its exclusive national lab provider (see *LE*, April 2014, p. 10).

MDL's lawsuit (case 2:16-cv-05855-GJP) was filed on November 10 in U.S. District Court for the Eastern District of Pennsylvania. MDL claims that all of IBC's in-network labs within 200 miles of Philadelphia are owned by LabCorp. In addition, MDL says that IBC and LabCorp have threatened and coerced physicians to direct all of their lab tests to LabCorp, and IBC has refused to reimburse for tests referred to MDL.

MDL says that its volume from IBC's in-network physicians began to decline in 2014, and then declined at a more dramatic rate in 2015 and 2016 after LabCorp and IBC increased efforts to coerce in-network physicians from using MDL.

For example, the lawsuit says:

> "In May 2016, IBC called an Ob-Gyn group with multiple offices in Southeastern Pennsylvania threatening to cut the offices' reimbursements if they continued to use out-of-network laboratories. The offices initially chose to ignore IBC's threats and stated they were going to continue using MDL. On or around August 1, 2016, the offices in the group received a directive from the group's hospital stating that all out-of-network laboratory use must cease because IBC claimed that the hospital was breaching its contract by having work done by out-of-network laboratories. As a direct result of IBC's actions, this medical practice so substantially reduced its use of MDL that it in essence ceased using MDL's services."

The lawsuit says that in-network IBC physicians also have stopped sending tests to MDL for patients not insured with IBC.

MDL says that it repeatedly has tried to become an in-network lab for IBC, but IBC has informed MDL that it needs approval from LabCorp before being granted in-network status.

Pennsylvania does not have an "any willing provider" law in place. However, MDL contends, "This does not provide IBC and LabCorp with a license to engage in unlawful threats and intimidation to push MDL and other laboratories out of the market by effectively preventing doctors from exercising independent medical judgment in the interests of their patients."

MDL claims it has lost millions of dollars in revenue as a result of IBC's and LabCorp anticompetitive conduct. MDL is seeking a jury trial to enjoin IBC and LabCorp from engaging in alleged anticompetitive behavior and to recover damages in excess of $75,000.

LabCorp has not yet filed its response.

NEW LAB FORMATIONS BOOM LED BY GENETIC TESTING AND TOXICOLOGY

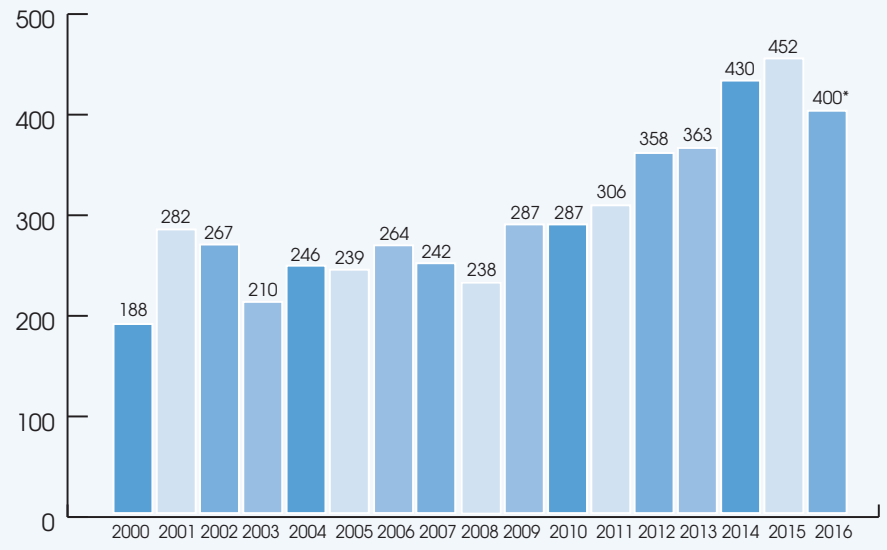
CMS instituted more specific coding and major Medicare reimbursement cuts for molecular diagnostics in 2013. However, despite the rate cuts and high claims denials associated with more specific coding, the number of new genetic testing labs being formed is booming.

The latest data from CMS shows that approximately 400 new independent labs were issued CLIA certificates in 2016. This marks the third year in a row that new independent lab formations have numbered 400 or more. New genetic testing and personalized medicine labs are leading the growth. More than 40 new genetic testing labs were issued CLIA certificates in 2016.

Examples of new genetic testing labs opened in 2016 include Eurofins Genomics (Louisville, KY), GeneMed Management (Blanco, TX), Ingenious Personalized Medicine (North Miami, FL), Pacific Genomics (Irvine, CA), Personalized Genetic Testing, Inc. (Miami, FL) and Precision Genetics (Greenville, SC).

Pain management and toxicology labs were another specialty that has added to the growth in new independent lab formations, according to the CMS data. More than 25 new independent toxicology labs were issued CLIA certificates in 2016. Once again, the growth came despite new bundled codes for drugs-of-abuse testing that resulted in severe Medicare rate cuts that became effective January 1, 2016.

Number of New CLIA-Certified Independent Labs



*Projected based on CMS data through September 30, 2016 (excludes waived-testing-only labs)

Source: *Laboratory Economics* from CMS CLIA data Sept. 30, 2016

Examples of new toxicology lab companies formed in 2016 include AZTox LLC (Gilbert, AZ), Gene Tox Worldwide (Lyndhurst, NJ), Matsunaga Pain Management (Columbia, MD) and Sunset Toxicology (Torrance, CA).

Top 30 CLIA-Certified Labs by Test Volume

On the next page, we rank the top 30 lab facilities by reported annual test volume (excluding those owned by or partnered with Quest Diagnostics and LabCorp), according to the latest CMS CLIA reports as of September 30, 2016. As you can see, the list is dominated by donor screening, toxicology, and labs affiliated with the integrated managed care organization Kaiser Permanente (Oakland, CA).

TOP 30 CLIA-CERTIFIED LABS BY ANNUAL TEST VOLUME (excl. Quest and LabCorp)

NAME	CITY	STATE	LABORATORY TYPE	ANNUAL TEST VOLUME
CSL PLASMA INC.	KNOXVILLE	TN	PLASMA DONOR SCREENING	75,730,500
BIOLIFE PLASMA SERVICES	HOOVER	AL	PLASMA DONOR SCREENING	59,241,220
MILLENNIUM HEALTH	SAN DIEGO	CA	TOXICOLOGY	57,384,720
DAVITA LABS	DELAND	FL	DIALYSIS PATIENT TESTING	23,852,797
SO. CAL PERMANENTE MED GROUP LAB	NORTH HOLLYWOOD	CA	HMO	22,109,424
SONIC/SUNRISE MEDICAL LABS	HICKSVILLE	NY	ROUTINE	21,964,502
QUALTEX LABORATORIES	SAN ANTONIO	TX	PLASMA DONOR SCREENING	20,286,240
GRIFOLS BIOMAT USA, INC.	SAN MARCOS	TX	PLASMA DONOR SCREENING	20,085,144
KAISER FOUNDATION HEALTH PLAN	LARGO	MD	HMO	18,605,340
CREATIVE TESTING SOLUTIONS	TEMPE	AZ	BLOOD BANK TESTING	18,250,000
SPECTRA/SHIEL MEDICAL LAB	BROOKLYN	NY	ROUTINE	18,101,045
FLORIDA HOSPITAL LABORATORIES	ORLANDO	FL	HOSPITAL LAB	17,325,686
PERMANENTE MED GROUP REGIONAL LAB	RICHMOND	CA	HMO	16,243,000
CREATIVE TESTING SOLUTIONS	BEDFORD	TX	BLOOD BANK TESTING	16,095,500
PRECISION TOXICOLOGY, LLC.	SAN DIEGO	CA	TOXICOLOGY	16,080,600
ASCEND CLINICAL, LLC.	REDWOOD CITY	CA	DIALYSIS PATIENT TESTING	15,427,347
ALERE TOXICOLOGY/AVEE LABS	CLEARWATER	FL	TOXICOLOGY	15,319,600
NORTHWELL HEALTH LABORATORIES	LAKE SUCCESS	NY	HOSPITAL LAB	14,872,567
CREATIVE TESTING SOLUTIONS	SAINT PETERSBURG	FL	BLOOD BANK TESTING	14,836,711
SONIC/CLINICAL PATHOLOGY LABS	AUSTIN	TX	ROUTINE	14,363,784
PATHOLOGY ASSOCIATES MEDICAL LABS (PAML)	SPOKANE	WA	REFERENCE LAB	14,206,035
MAYO CLINIC LABS - ROCHESTER MAIN CAMPUS	ROCHESTER	MN	HOSPITAL LAB	13,729,878
ST JOHN HOSPITAL & MEDICAL CENTER	DETROIT	MI	HOSPITAL LAB	13,724,256
CORDANT HEALTH SOLUTIONS	TACOMA	WA	TOXICOLOGY	13,486,358
US BIOTEK LABORATORIES	SEATTLE	WA	REFERENCE LAB	12,080,890
SPECTRA EAST INC.	ROCKLEIGH	NJ	DIALYSIS PATIENT TESTING	11,847,472
DEPT. OF HEALTH-PUBLIC HEALTH LABS	SHORELINE	WA	PUBLIC HEALTH LAB	11,443,355
UNIVERSITY OF MICHIGAN HOSPITALS	ANN ARBOR	MI	HOSPITAL LAB	11,008,392
WADSWORTH CENTER - AXELROD INSTITUTE	ALBANY	NY	PUBLIC HEALTH LAB	10,694,928
OSU WEXNER MEDICAL CENTER CLINICAL LABS	COLUMBUS	OH	HOSPITAL LAB	10,420,005

Source: *Laboratory Economics* from CMS CLIA data Sept. 30, 2016

LAB STOCKS UP 3% YTD

Sixteen lab stocks have risen by an unweighted average of 3% year to date through December 13. In comparison, the S&P 500 Index is up 10%. The top-performing lab stocks so far this year are Psychemedics, up 123%, Enzo Biochem, up 53% and Exact Sciences, up 50%. At the big two commercial labs, Quest Diagnostics is up 29% and LabCorp is up 5%.

Company (ticker)	Stock Price 12/13/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	1.40	3.30	-58%	26	NA	1.0	1.0
CombiMatrix (CBMX)	3.30	10.95	-70%	8	NA	0.7	1.2
Enzo Biochem (ENZ)	6.90	4.50	53%	319	7.1	3.1	3.6
Exact Sciences (EXAS)	13.88	9.23	50%	1,500	NA	19.2	4.2
Foundation Medicine (FMI)	20.10	21.06	-5%	705	NA	6.2	3.6
Genomic Health (GHDX)	30.80	35.20	-13%	1,030	NA	3.2	7.1
Invitae (NVTA)	7.49	8.21	-9%	298	NA	15.7	3.4
LabCorp (LH)	129.61	123.64	5%	13,350	20.6	1.4	2.4
Myriad Genetics (MYGN)	17.93	43.16	-58%	1,230	13.1	1.6	1.7
NeoGenomics (NEO)	9.17	7.87	17%	720	NA	3.4	9.0
Opko Health (OPK)	11.91	10.05	19%	6,640	49.8	5.4	3.2
Psychemedics (PMD)	22.66	10.14	123%	124	27.8	3.6	8.9
Quest Diagnostics (DGX)	91.95	71.14	29%	12,750	19.5	1.7	2.7
Rosetta Genomics (ROSG)	0.58	1.23	-53%	13	NA	1.2	1.0
Sonic Healthcare (SHL.AX)	21.61	17.87	21%	9,110	19.8	1.8	2.5
Veracyte (VCYT)	7.39	7.20	3%	243	NA	4.0	6.9
Unweighted Averages			3%		22.5	4.6	3.9

Source: Capital IQ

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Kimberly Scott, Associate Editor