Jondavid Klipp, Editor, labreporter@aol.com

Volume 13, No. 12 December 2018

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Sonic Buying Aurora Diagnostics For $540 Million

Sonic Healthcare has agreed to purchase Aurora Diagnostics (Palm Beach Gardens, FL) in a cash deal valued at $540 million, including roughly $420 million in assumed debt. The buyout saves Aurora from having to make scheduled debt principle payments due July 2019 and January 2020.

Australian-based Sonic Healthcare, with U.S. headquarters in Austin, TX, said part of the deal rationale was to reduce Sonic's exposure to Medicare CLFS cuts, noting that in excess of 98% of Aurora's revenue is not exposed to fee changes by PAMA.

Aurora has 1,200 employees, including 220 pathologists, at 32 pathology practices in 19 states. The company recorded pro forma revenue of $310 million and EBITDA of $59 million in the 12 months ended September 30, 2018. Aurora's pathology practices process approximately 2.5 million patient requisitions per year at an average collected revenue of about $124 per req. *More details on page 2.*

Hospital Outreach Labs Face Daunting Task Of Reporting Private-Payer Rates To CMS

Hospitals are in a state of shock regarding CMS's decision to require nearly all hospital outreach labs to collect and report their private-payer test prices in the next PAMA reporting cycle, which starts January 1, 2019.

In the first PAMA reporting cycle in 2016, only hospital outreach labs that had their own NPI were required to report. And only 21 such hospital outreach labs actually wound up reporting. The new rule expands the reporting requirement to include hospital outreach labs that bill through their hospital's NPI under bill type 14x on the Form CMS-1450, which is used to bill Medicare for non-patient outreach testing.

As a result, any hospital outreach lab (irrespective of their NPI status) that receives $12,500 or more of Medicare CLFS payments during the first six months of 2019 must now report their private-payer volume and rates to CMS. Failing to do so could lead to significant monetary penalties. *Continued on page 3.*

Contents

Sonic Buying Aurora Diagnostics For $540 Million (*cont'd from page 1*)
Aurora is being sold by its private-equity owners Summit Partners and KRG Capital. Its largest lender is Cerberus Business Finance (New York City).

To fund the acquisition, which is expected to close in early 2019, Sonic plans to raise $432 million by selling shares to intuitional investors plus up to $72 million more from retail shareholders in Australia and New Zealand.

The $540 million purchase price is equal to 1.7 times Aurora's annual revenue and 9.2 times its EBITDA (earnings before interest, taxes, depreciation and amortization).

Sonic Healthcare CEO Colin Goldschmidt, MD, said that Sonic had conducted "very, very intensive due diligence and is quite convinced the revenue and earnings are what we will be getting."

Laboratory Economics notes that the challenge for Sonic will be in managing Aurora's 220 pathologists located at 32 practices across the United States. Aurora's largest practices include LMC Pathology Services (Las Vegas, NV), with 28 pathologists; University Pathologists (Warwick, RI), 17 pathologists; GPA Laboratories (Greensboro, NC), 14 pathologists; and Cunningham Pathology (Birmingham, AL), 12 pathologists.

Sonic's primary pathology laboratory, CBLPath (Ryebrook, NY), was acquired for $124 million in December 2010. As a result of Medicare rate cuts and physician insourcing, CBLPath restructured its entire operation in 2015, which included changes of management, staffing and certain clients.

On the positive side, the wave of reimbursement pressure that hit the anatomic pathology market between 2013 and 2017 appears to be over. In addition, most large specialty practices (urology, gastroenterology and dermatology) that were going to insource histology, have already done so.

Finally, *Laboratory Economics* notes that the 1.7x revenue multiple for the Sonic-Aurora deal is well below the average 2.6x multiple for large pathology lab transactions made over the past 20 years.

Comparison of Pathology Lab Acquisition Valuations Based on Annual Revenue ($ millions)

Closing Date	Buyer	Target	Purchase Price	Acquired Revenue	Price/ Revenue
Nov-10	GE Healthcare	Clarient Inc.	$585	$117	5.0
Oct-07	Aurora Diagnostics	Greensboro Pathology (now GPA Labs)	145	35	4.1
Nov-11	Miraca Holdings	Caris Diagnostics	725	207	3.5
Nov-01	Dianon	UroCor	202	62	3.3
Jan-03	LabCorp	Dianon	600	190	3.2
May-07	Quest Diagnostics	AmeriPath	2,000	752	2.7
Dec-10	LabCorp	Genzyme Genetics	925	370	2.5
Dec-15	NeoGenomics	Clarient Inc.	310	124	2.5
May-05	Caris Ltd.	Pathology Partners	120	50	2.4
Feb-05	LabCorp	US Labs	155	73	2.1
Mar-03	Welsh Carson	AmeriPath	839	480	1.7
Pending	Sonic Healthcare	Aurora Diagnostics	540	310	1.7
May-04	Genzyme Genetics	Impath	215	125	1.7
Feb-11	Novartis	Genoptix	330	195	1.7
Dec-10	Sonic Healthcare	CBLPath	124	85	1.5
Dec-18	NeoGenomics	Genoptix	140	100	1.4
Overall	Average				2.6

Source: *Laboratory Economics* from company reports and SEC filings

Hospital Outreach Labs Face Daunting Task Of Reporting (*cont'd from page 1*)

What information needs to be reported to CMS?

The PAMA regulations require applicable reporting labs, now including hospital outreach labs, to report:

- The specific HCPCS code for each test on their test menu, excluding unlisted/NOC codes.
- The private-payer rates received by all private payers, including commercial plans, Medicare Advantage and Medicaid Managed Care, after all price concessions and discounts are applied.
- The volume of tests for each code paid at each private-payer rate.
- Non-reportable tests including those subject to an unresolved appeal and tests with final payment of zero dollars (e.g., because payer refused to pay).

The data collection period covers tests performed from Jan. 1, 2019 to June 30, 2019. Labs will report this data to CMS in the first quarter of 2020. CMS will calculate new rates based on this data that will take effect with the Medicare CLFS for 2021.

What challenges will hospital outreach labs face in reporting PAMA data?

To start with, hospital outreach labs will need to properly identify and separate their non-patient outreach tests from their outpatient tests. The definition for outreach varies among hospitals. For example, most hospitals register patients visiting their owned clinics and physician practices as outpatients when billing commercial insurance for lab tests. This provides higher reimbursement as well as certain tax benefits. Hospitals will need to create new computerized systems that can identify their 14x bill-type-equivalent patients on the private-payer side.

Next, they will have to develop new systems that give them access to private payer reimbursement rates at the CPT code level. Most hospitals bill outreach tests through their main billing department with bulk payment posting that does not provide payment details for lab tests at the CPT level.

Lâle White

But essentially one of the big hurdles for a lot of these hospital labs is that they have bulk payment posting and lack the detail to do the CPT level reporting that's necessary for this exercise at the payer level.

Hospital labs will need to retain their electronic remittances and download them into a searchable database from which they can extract the necessary PAMA data, according to Lâle White, Executive Chairman and CEO of XIFIN Inc. (San Diego).

Meanwhile, *Laboratory Economics* recently conducted an informal survey of three dozen hospital lab outreach administrators, asking them, "On a scale of 1-10, how would you rate the difficulty of PAMA reporting for the average hospital lab outreach program (1=easy, 10=impossible)?" The overall average response was 7.7 with everyone ranking the task at between 5 and 9.

Finally, the American Clinical Laboratory Association (ACLA) has reported that even the nation's largest commercial lab companies had great difficulty gathering the required data in the first PAMA round. "The initial data collection process cost at least one of ACLA's members [presumably Quest or LabCorp] almost $2 million, and included at just one stage of the production "approximately 240 people work[ing] 6 days a week for approximately 8 weeks," according to ACLA.

What impact will the inclusion of hospital lab outreach data have in CLFS rate calculations?
The participation of hospital outreach labs does have the potential to improve Medicare rates, or at least lessen future rate reductions, according to White. The key is their ability to overcome the data collection challenges so they can actually participate.

Laboratory Economics notes that during the first PAMA data collection cycle in 2016, the Department of Health and Human Services Office of the Inspector General (OIG) had estimated that 12,547 labs would report, but only 1,942 labs actually did report. Many smaller labs were simply unaware of their need to report, while others refused to commit the administrative and IT resources necessary to report. As a result, pricing data from Quest Diagnostics and LabCorp dominated the data pool.

White estimates that Medicare CLFS rates would have had a minimal change, if all required labs had actually participated in the first PAMA round.

"The real issue is participation, and if all applicable reporting labs participate, we could anticipate a significant difference in the next PAMA round," says White.

Laboratory Economics estimates that there are well over 1,000 hospital outreach labs that will meet the minimum $12,500 Medicare CLFS revenue threshold and be required to report in the next round.

Will non-reporting labs be held accountable?
The OIG has the authority to bring civil money penalty actions against labs who are required to report, but who do not report, notes attorney Hope Foster, Chair of the Health Care Enforcement Defense Practice at Mintz Levin (Washington, DC).


Hope Foster

Foster says that the OIG would generally take action after receiving a referral from CMS. "So the key question is will CMS make reports of such laboratories to the OIG for enforcement action?" She says that's difficult to predict. "To the extent that CMS means what they say, and they want to make sure that labs comply, then it's very likely at some point in the future that they will bring enforcement against those who don't comply….The authority is there."

The PAMA law authorizes CMS to impose civil monetary penalties of up to $10,000 per day on applicable laboratories that fail to report, or for each misrepresentation or omission in reporting.

"Any laboratory that is subject to the requirement to report this data should be reporting it. They're in violation of the law if they don't. And civil money penalties are not actions that one wants to be in the position of having to defend," adds Foster.

Where can labs go for additional details on PAMA reporting requirements?
CMS has a website where you can get specific details on the data that needs to be collected and the format for submitting it. Go to: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html

In addition, CMS is expected to release additional guidance specific to data reporting for hospital outreach labs based on the 14x bill type sometime in the next few weeks.

How have private-payers responded to the Medicare CLFS rate cuts?
As expected, private payers are using the lowered Medicare CLFS rates that became effective this

year as leverage to reduce their lab fee schedules. The surprise has been that the largest commercial insurers are demanding the entire three-year phased-in Medicare CLFS 30% cut to be made to their fee schedules upfront immediately.

"We're seeing some of the majors, like Aetna, Cigna, United Healthcare, et al., offering new entrants into their network and contracts coming up for renewal, a 20-25% discount below the 2018 published Medicare CLFS which saw most codes cut by 10%. So they are trying to get the entire 30% of Medicare CLFS cuts in advance," notes XIFIN's White.

At the same time, White says that labs have gotten a little more sophisticated in the way that they're negotiating their contracts with private payers, and they are seeking fee schedules that are not tied to Medicare rates anymore.

In addition, some labs have gotten to a point where they are sophisticated enough to negotiate pricing on specific CPT codes outside of an across-the-board percentage rate based on Medicare. White says these labs are negotiating separate rates for specific CPT codes whose costs justify higher reimbursement.

"I think everyone understands that it is extremely problematic to continue to reference their private payer contracts to Medicare fees and I think the industry needs to do a lot to push back," adds White.

ACLA Files Opening Brief In PAMA Lawsuit Appeal Case

On December 4, the American Clinical Laboratory Association (ACLA) filed its opening brief with the U.S. District Court of Appeals for the District of Columbia Circuit (DDC) for its lawsuit challenging CMS's implementation of PAMA.

The lawsuit had been dismissed by U.S. District Judge Amy Berman Jackson on September 21 on the grounds that PAMA statute (§ 1395m-1(h)(1)) bars any "administrative or judicial review" to the "establishment of payment amounts."

ACLA's opening brief argued that Judge Jackson incorrectly ruled that PAMA's limited jurisdiction-stripping provision, which precludes review "of the establishment of payment amounts," should be interpreted broadly to bar review of the Secretary's final rule exempting hospital outreach laboratories from PAMA's data-reporting requirements.

The DDC Appeals Court briefing schedule calls for the Department of Health and Human Services (HHS) to submit its response brief by January 25, and for ACLA to reply by February 15.

Appeal Briefing Schedule

ACLA's Opening Brief	December 4, 2018
HHS/CMS's Response Brief	January 25, 2019
ACLA's Reply Brief	February 15, 2018
Oral arguments	not yet scheduled

"We anticipate having our day in court. Because, unlike the District Court, at this level [Appeals Court] you typically do have the opportunity to present oral arguments," according to ACLA President Julie Khani.

Khani says that while CMS will now require hospital outreach labs to report in the next PAMA survey, this does nothing to stop the drastic cuts that have already taken place this year and the


Julie Khani

impending cuts in 2019 and 2020, which are based on a skewed initial survey of private-payer rates.

If the DDC Appeals Court rules in favor of ACLA's appeal, then the case will most likely go back to Judge Jackson to hear arguments and make a ruling.

On the other hand, if the DDC Appeals Court denies ACLA's appeal, then ACLA could seek an *en banc* review by the entire circuit court, notes attorney Hope Foster from Mintz Levin. "A three-judge court will hear this appeal, but if the three-judge court rules against ACLA, then ACLA could seek either an *en banc* review or review by the Supreme Court," explains Foster.

In the meantime, Khani says ACLA continues to lobby Congress for a legislative fix to PAMA. She says it's unlikely that any future policy change would take the Medicare CLFS back to the pre-PAMA implementation 2017 rates. However, she says ACLA is currently lobbying for a short-term fix that would either reduce or delay upcoming cuts to the Medicare CLFS, as well as delay the next data collection and reporting period so that labs have more time to prepare.

GAO Warns Of Increased Costs From Unbundling Panel Tests

A new report from the U.S. Government Accountability Office (GAO) has zeroed in on the unbundling of common panel tests as a practice that could cause Medicare to overpay billions under PAMA's new market-based CLFS.

The potential for overpayment stems from a loophole that enables labs to charge significantly more for common panel tests by billing for each component test individually (see *LE*, December 2017). Previously, Medicare had paid a lower bundled rate for routine panel tests such as Comprehensive Metabolic Panel (CPT 80053) and Lipid Panel (CPT 80061).

But starting January 1, 2018, PAMA limited CMS's ability to automatically combine individual component tests into groups for bundled payment. Labs now have the ability to game the system for higher reimbursement by billing individually for tests in a panel. The GAO report has estimated that this practice could potentially increase Medicare expenditures by as much as $10.3 billion from 2018 through 2020.

The Department of Health and Human Services (HHS) commented that it is taking steps to address this issue. More specifically, HHS is developing an automated process to identify claims for panel tests that should receive bundled payments and anticipates implementing this change by the summer of 2019. In addition, HHS posted guidance on November 14, 2018, stating that for panel tests with billing codes, laboratories should submit claims using the corresponding code rather than the codes for the separate component tests beginning in 2019 (see *CMS National Correct Coding Initiative Policy Manual for Medicare Services for 2019*, https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html).

In addition, CMS says that it has been monitoring changes in panel test utilization, payment rates, and expenditures. CMS says that preliminary data indicates that Medicare payments for individual component tests of panel tests have, in fact, increased substantially in 2018.

Spotlight Interview With Indiana University Health's Joe Meyer

Indiana University Health is an 18-hospital integrated health system serving central Indiana. IU Health Laboratories, which perform more than 19 million tests per year, serves the system's academic health center, which includes a pediatric hospital and two adult hospitals, as well as supports reference testing throughout the system. *Laboratory Economics* recently spoke to Joe Meyer, Vice President of System Laboratory Services for IU Health.

Joe Meyer

How many employees does IUH Laboratories have?
We have about 950 non-medical employees, plus about 70 medical personnel, including 53 pathologists.

Can you explain how IUH Laboratories differs from the Department of Pathology and Laboratory Medicine at Indiana University?
The Department of Pathology and Laboratory Medicine is a department within Indiana University School of Medicine, which is an independent entity. That department staffs most of the hospital labs…they are essentially the medical directors. The School of Medicine at one time ran University Hospital but then realized it could not run a single hospital profitably, so University Hospital was merged with two other hospitals to form what has become IU Health. The system today includes two urban adult hospitals, University Hospital and Methodist Hospital, Simon Cancer Center, and a pediatric hospital, Riley Hospital. In addition, the system has five large community hospitals and nine smaller hospitals. IUH Laboratories is independent of the university, although we work very closely together.

Are lab revenues and volumes growing? If so, could you share by how much?
Our anatomic pathology specimen volumes have been growing in the high-single digits, and our chemistry volumes have been growing in the low-single digits. We would prefer not to share revenue figures.

To what do you attribute your volume growth?
Mainly to the growth of the health system. We've acquired several large multi-specialty provider practices, so we're getting new work. I think our growth rates will continue about the same as they have been.

Did IU Health Laboratories participate in the data collection and reporting for the new Medicare payment system for lab tests? How was the process?
We did. It was not onerous. My colleagues in managed care handled that work.

How much has the new Medicare CLFS impacted IU Health Labs' bottom line?
We've been fortunate in this regard because much of our lab work is inside the health system, so we've been shielded from the full brunt of the first-year changes. We do have an outreach lab with about 400 external clients. Much of that work is direct bill. Our billing system is very old, so we don't have very good data. We do have a plan to modernize our billing system.

Have you seen cuts from private payers?
It's indirect for the lab. Anthem is the dominant commercial provider in our market. There has been some pressure to reprice our outpatient lab fee schedule so that it is more in line

with that of the national labs. Inpatient is approximately half of our work, outpatient about 40%, and outreach is about 10%. Our outreach has shrunk considerably over the last seven years because we've bought many of the formerly independent practices as we grew our provider base to more than 3,000 physicians.

What initiatives have you implemented to reduce expenses and control costs?
We have looked at this across three broad categories. The first is people. We're working on improving productivity so our teams can be more efficient. We've also made a lot of investment in automation in our core laboratory.

The second area is supplies. For large contracts, we're ensuring that we're negotiating favorable contracts that leverage the size of our health system today. We're also working on supply management to reduce waste and inventory levels.

The third area is contracted services. We've had two big projects: one with clinical engineering support and one with send-out work. The goal with send-outs was to reduce the number of third-party labs we use, build electronic interfaces and renegotiate contracts. Our primary reference lab is now ARUP. Our goal with clinical engineering was to find a third-party partner to provide a single source for instrument service, which historically was contracted to a large number of instrument providers.

In the last two years we've generated $7 million in annualized savings. This far exceeds what our reimbursement cuts were. We have more work planned for next year with an emphasis on workforce productivity and supply management. Both of these streams of work will be multi-year efforts. We're setting a $3 million savings target for 2019.

What do you see as the biggest challenges faced by IU Health Laboratories?
There's been lots of discussion about value-based pricing and the pressure on health systems to offer value-based services. Regardless of how the health system is paid, we have to be efficient and competitive. My main concern is to be a top-quartile performing lab financially. We will be benchmarking in 2019 to set clear metrics to help guide our targets.

What are your biggest opportunities?
One area we're eager to participate with the health system in is improving outcomes and proving the value of the diagnostic work we do so it's not looked at as a cost but as a benefit. This is building upon our very strong test and service quality to demonstrate our relevance to clinical outcomes and operational flow in our facilities.

Quest Survey Reveals That Most Hospitals Don't Understand PAMA

Nearly 80% of hospital executives surveyed lacked significant knowledge of the Protecting Access to Medicare Act (PAMA) and its impact on hospitals: 45% of executives responded that they are "not at all familiar" with PAMA, and 33% said they are only "somewhat familiar."

The survey was conducted by Modern Healthcare Custom Media on behalf of Quest Diagnostics.

The survey was sent by email between July-August 2018 to a sample of 27,618 healthcare professionals who subscribe to *Modern Healthcare*. The 287 respondents included senior management (29%), operations management (16%), financial management (15%), clinical management (15%), lab administrators (4%) and other healthcare professionals (21%).

Will your lab change strategy to adapt to PAMA?

No plans to change	51%
Expect to change lab strategy in 3+ years	2%
Expect to change lab strategy within 2-3 years	20%
Expect to change lab strategy within 1 year	16%
Expect to change lab strategy within 6 months	10%

Source: Quest Diagnostics Survey, July-August 2018; n=287

Roughly half of survey respondents said their organization has an outreach lab, and most have a positive outlook on their labs' performance: 60% say their hospital or health system's outreach lab is currently profitable, 20% reported a lack of profitability, and 11% said their lab is a loss leader.

Due in part to a lack of awareness of PAMA, over half of respondents (51%) said they have no intention of changing their lab strategy to respond to PAMA. Only 10% expect change within six months, 16% within one year and 20% expect to shift lab strategy within two to three years. Two percent say it will take over three years for them to take action.

"The data presented here support what we've experienced in the health care marketplace," according to Quest's Chairman and CEO Steve Rusckowski. "Many C-suite executives of hospital health systems aren't aware of the impact of PAMA on the profitability of their outreach laboratories, especially when the PAMA cuts were first enacted."

Quest To Acquire Boyce And Bynum's Clinical Laboratory

Quest Diagnostics has signed an agreement to acquire the clinical lab business of Boyce and Bynum Pathology Laboratories (Columbia, MO). Boyce and Bynum will keep control of its anatomic pathology division, Boyce and Bynum Pathology Professional Services, Inc., and its nursing home lab division. The anatomic pathology services division, which includes 20 pathologists, will become the exclusive pathology provider for Quest Diagnostics clients in Missouri and a preferred pathology provider in the greater Midwestern region.

The transaction is expected to close in the first quarter of 2019. Based on its number of employees, *Laboratory Economics* estimates that Boyce and Bynum's clinical lab generates annual revenue of $30-$50 million.

Boyce and Bynum plans to lay off 177 workers next year as a result of the sale, according to a notice filed with the Missouri Department of Economic Development. The notice says the layoffs will begin in February and continue through April. Boyce & Bynum said in a statement that it realizes the layoffs will be "painful" and only made the decision after reviewing its options in a "challenging healthcare landscape." The laid-off employees will have a chance to apply for jobs with Quest.

Quest Completes Purchase of Marin General Hospital Outreach Lab

Quest completed its purchase of the clinical lab outreach operations at Marin General Hospital (Greenbrae, CA) effective November 26. The sale included four outpatient lab draw stations in the San Francisco area. *Laboratory Economics* estimates the outreach lab business at Marin General (235 beds) at <$15 million in revenue per year.

Jon Friedenberg, Marin General's chief operating officer, said Marin General's decision to sell its outreach lab business came in response to a change in government policy, Friedenberg said. "In 2014, the federal government let the hospital industry know that they want us to get out of the outpatient lab business, and they were going to give us several years to do this," Friedenberg reportedly said at a Marin General board meeting held November 13, according to the *Marin Independent Journal*.

Friedenberg said the outreach lab did not have a high profit margin, so its sale won't have a significant effect on the hospital's revenue stream. He said the sale will result in lower out-of-pocket costs for patients because Quest's rates are lower.

The Outlook for Consolidation

Speaking at Quest's Investor Day conference on November 29, Quest CFO Mark Guinan, noted that smaller labs, including hospital outreach, POLs and independent labs, are being disproportionately hurt by the PAMA rate cuts because their profit margins are lower than the biggest commercial labs and smaller labs get a higher percentage of their revenue from the Medicare CLFS.

"It's gonna wipe out the profit of the rest of the industry. As people are waking up to this, they're getting on board with the lobbying effort, but they're also realizing that it may be time to exit. It's not happening as quickly as many of us would have anticipated, but certainly this is starting to give some traction to consolidation," said Guinan.

He said that Quest has as much as $4 billion of "dry powder" to spend on acquisitions and still maintain its investment grade rating for its debt.

Does New Far-Reaching Anti-Kickback Law Apply To All Labs?

Hastily passed opioid legislation, signed into law by President Trump on October 24, outlaws the use of volume-based compensation for laboratory sales reps, regardless of the type of testing involved. The new law, Section 8122 of the "Eliminating Kickbacks in Recovery Act of 2018" (EKRA), authorizes criminal penalties for some conduct that is currently permissible under anti-kickback statute safe harbors.

The new law prohibits commission payments based on the number of patients referred to a laboratory, the number of tests performed, or the amount billed to or received from a "health care benefit program" (which includes commercial insurers as well as Medicare and Medicaid).

As written, Section 8122 of EKRA applies to all laboratories, not merely labs that perform testing for recovery homes and clinical treatment facilities, and to all services covered by all payers, rather than only services covered by Federal healthcare programs.

Karen Lovitch, attorney at Mintz Levin, notes that Senators Marco Rubio (R-FL) and Amy Klobuchar (D-MN) introduced this provision in an effort to target patient brokers who recruit patients for addiction treatment centers and allegedly receive financial kickbacks in return. Brokers have reportedly paid for patients' travel, rent, or other expenses to make it easier for them to seek treatment, and even helped uninsured patients obtain private insurance coverage by paying their premiums while in treatment.

Lovitch says the EKRA fails to carve out lab testing that has nothing to do with opioid or drug abuse. Furthermore, it applies to all labs when doing business with all payers. The legislative history fails to clarify whether Congress intended to construct this anti-kickback provision so broadly with respect to laboratories and, if so, whether Congress had any rationale for doing so, according to Lovitch.

Lovitch believes that it's unlikely that Congress will remove laboratories from the new law entirely, but expects that there will be significant pressure on Congress to limit its applicability to services related to opioid use and treatment. See: https://www.mintz.com/insights-center/viewpoints/2146/2018-11-all-payor-kickback-statute-included-recently-passed-opioid

In-Office Pathology Opens Six New Labs

In-Office Pathology LLC (Lake Forest, IL) and its affiliate In-Office Cytometry (Woodstock, GA) helped open a total of six new labs at specialty group practices between October and mid-December, according to IOP President Joe Plandowski. "After taking a lot of heat five or ten years ago, in-office pathology has become an accepted practice with most pathology groups now taking part by providing professional services."


Joe Plandowski

Over the past 13 years, IOP has opened a total of 83 in-office labs at specialty groups, with the majority (>60) at gastroenterology practices. Plandowski says IOP generates leads from online advertising and its website, direct mail and word of mouth. The most common concern stopping specialty practices from opening their own lab is unwarranted worries about the regulatory issues involved with operating their own laboratory, according to Plandowski.

Gastroenterology

IOP recently opened new histology labs at three small gastroenterology practices (2-3 doctors each) all located in Virginia. All three groups bill globally and have contracted with a large independent pathology lab in Virginia for professional services.

Contracted rates for an 88305-26 typically average between $20 and $24 per read, according to Plandowski. He notes that although the gastro groups do the billing and keep part of the 88305-26 rate, the contracted pathologists get paid for every read irregardless of denials or non-collections.

Plandowski says that most large gastro groups (>5 doctors) already operate their own histology lab or profit from a client billing arrangement with an independent pathology lab.

Allergy & ENT

Allergy groups are the newest physician specialty that IOP—through its IOC division—is targeting. The company recently helped open in-office flow cytometry labs at three allergy/ENT practices in Ohio, Maryland and Virginia, each with five doctors. Allergy groups most frequently use flow cytometry to perform immunophenotyping to discriminate between peanut allergy and tolerance, according to Plandowski.

He says that an in-office flow cytometry lab can be installed for a total investment of $300,000 to $350,000, with the largest cost being a flow cytometer at roughly $250,000. Each patient tested can bring in between $1,000 and $1,200 of lab revenue; contracted pathologists are paid $50 to $100 per patient depending on the number of markers read, says Plandowski. In addition, he says a medical technologist with flow cytometry experience must be hired by the practice at an average annual salary of about $75,000.

Plandowski says that IOP/IOC has partnered with Oral Alpan, MD and his specialty laboratory Ammerimmune LLC (Fairfax, VA) to provide medical/technical advice and reference testing services.

Dermatology

IOP has opened several histology labs at dermatology practices over the past few years, but none recently. Plandowski says most dermatologists want their slides read by a dermatopathologist at a commercial lab or academic medical center. "Finding and hiring dermpaths is difficult and they're less flexible on their rates," notes Plandowski.

Urology

"Urology labs are dead." Plandowski says bundled reimbursement (G0416) introduced in 2015 has killed the profitability of in-office histology labs at all but the largest urology groups.

Lab Stocks Up 41% Year To Date

Prices for 18 publicly-traded lab stocks are up 41% on an unweighted average basis through December 12. In comparison, the S&P 500 Index is up 5% year to date. Cancer Genetics Inc. is currently the least expensive lab company, in terms of valuation measured by enterprise value divided by trailing 12 month revenue. CGI currently has an enterprise value of $18 million and annual revenue of $28 million for an EV/revenue ratio of 0.6. The most expensive lab company is Guardant Health, which has an enterprise value of $3.5 billion and annual revenue of $78 million for an EV/revenue ratio of 44.7.

Company (ticker)	Stock Price 12/12/18	Stock Price 12/29/17	2018 Price Change	Enterprise Value ($ millions)	Enterp Value/ Annual Revenue
Cancer Genetics Inc. (CGIX)	$0.24	$1.85	-87%	18	0.6
Enzo Biochem (ENZ)	2.99	8.15	-63%	$93	0.9
Interpace Diagnostics (IDXG)	1.01	1.02	-1%	21	1.0
LabCorp (LH)	140.85	159.51	-12%	19,910	1.8
Opko Health (OPK)	3.34	4.90	-32%	2,000	1.9
Quest Diagnostics (DGX)	88.28	98.49	-10%	15,610	2.0
Psychemedics (PMD)	16.27	20.56	-21%	86	2.0
Sonic Healthcare (SHL.AX)	21.83	21.40	2%	11,780	2.1
Myriad Genetics (MYGN)	31.30	34.35	-9%	2,450	3.1
Natera (NTRA)	16.90	8.99	88%	1,010	4.1
NeoGenomics (NEO)	13.26	8.57	55%	1,310	4.7
Veracyte (VCYT)	13.05	6.53	100%	430	5.0
Genomic Health (GHDX)	72.74	29.39	147%	2,450	6.5
Invitae (NVTA)	12.60	9.08	39%	855	6.7
CareDx (CDNA)	27.66	7.34	277%	1,030	15.6
Exact Sciences (EXAS)	71.79	52.54	37%	8,310	20.8
Foundation Medicine (FMI)*	137.00	68.20	101%	5,350	26.5
Guardant Health (GH)	42.44	19.00	123%	3,480	44.7
Unweighted Averages			41%	$76,193	8.3

*Foundation Medicine was acquired by Roche for $137 per share on July 31. Source: *Laboratory Economics* from Capital IQ

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