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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Judge Dismisses ACLA PAMA Lawsuit

On September 21, the U.S. District Court for Washington, DC, dismissed the American Clinical Laboratory Association's (ACLA's) lawsuit challenging CMS's methodology in determining payment rates for Medicare Part B's 2018 Clinical Laboratory Fee Schedule (CLFS).

U.S. District Judge Amy Berman Jackson never scheduled or heard oral arguments and refused to consider the merits of ACLA's case. Instead Judge Jackson ruled that the court does not have "subject matter jurisdiction" because Section 216 of the PAMA statute prohibits administrative or judicial review. Judge Jackson ruled, in effect, that PAMA's prohibition against judicial review covers the entire statute and that CMS's determination of payment rates cannot be challenged regardless of the reasonableness, or fairness, of CMS's methodology.

ACLA says it is considering an appeal and has 60 days to file a notice of appeal with the U.S. Court of Appeals for the DC Circuit. Barring a legislative miracle, Medicare rates for most CLFS tests will be cut by another 10% on January 1, 2019. *Continued on page 3.*

Keep Us Out! Says American Hospital Association

The American Hospital Association (AHA) has come out against proposals that would require hospital labs to report their private-payer payment rates to CMS under PAMA. "The increased data reporting burden that would be imposed on hospital laboratories newly meeting the 'applicable laboratory' definition would not be justified by what CMS itself expects to be a minimal impact on the CLFS rates," wrote AHA in its comments to CMS on the Proposed Medicare Physician Fee Schedule Rule for 2019.

The AHA represents some 5,000 health systems and hospitals across the country. Its board of directors is stacked with CEOs from some of the largest health systems including Atlantic Health System, Carilion Clinic, Henry Ford Health System, ProMedica and Stanford Health Care. AHA spends more than $20 million per year on lobbying, making it one of the nation's most influential trade organizations.
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During the last PAMA reporting period, applicable labs were required to receive >50% of their Medicare revenue from the CLFS as recorded under their national provider identifier (NPI) number. The vast majority of hospital outreach labs do not have their own NPI number and use their parent hospital's NPI. As a result, nearly all hospital outreach labs were excluded from the 2017 data collection period.

In the last PAMA cycle, CMS collected private-payer information from a total of 1,942 labs—658 independent labs, 1,106 physician offices, 157 other entities, and only 21 hospital labs.

The AHA's comments focused on two new approaches that CMS is considering implementing with the goal of obtaining more data from which to base future CLFS payment rates.

A Proposed Change to the Majority of Medicare Revenues Threshold

CMS has proposed changing its definition of applicable laboratory to remove Part C Medicare Advantage payments from the denominator of the majority of Medicare revenues threshold in order to increase the number and type of reporting labs. CMS estimates that this proposed change would add 835 reporting labs and increase the number of data points reported by 5%.

The AHA has concluded that the costs associated with having hospital outreach labs collect and report PAMA data outweigh any potential improvement in CLFS rates.

In its comments, AHA stated, "Increasing the number of laboratories qualifying for applicable laboratory status and imposing an additional data reporting burden with no perceptible impact expected in the CLFS rates is in direct conflict with the Administration's goal of reducing regulatory burden."

Solicitation of Comments on using Bill Type 14X or CLIA Certificates

In its Proposed MPFS Rule for 2019, CMS asked for comments on whether it should allow labs to use Form CMS-1450 bill type 14x or CLIA certificate numbers to determine if they are an applicable lab. Doing so would require most hospital outreach labs to report their private-payer data.

AHA said that most hospital outreach labs do not have the systems in place needed to report their private-payer data at the CPT/HCPCS code level, as CMS requires. "The additional work-arounds necessary to report private-payer data for hospital outreach laboratories would pose a significant operational burden on hospitals," according to AHA.

Furthermore AHA said, "Even if every hospital outreach laboratory were to be required to report their private-payer data, it is highly unlikely that this would result in a significant change in the weighted median rates calculated by CMS due to the massive amount of private-payer data reported by the large independent laboratories.

AMA Opposes Requiring More POLs To Report PAMA Data

The American Medical Assn. (AMA) says that although it has serious concerns regarding the PAMA-directed CLFS rate cuts, it does not support any potential expansion of the number of physician-office labs (POLs) required to report their private-payer data. In its comments to CMS on the Proposed MPFS Rule for 2019, AMA said the initial PAMA reporting period proved to be unduly resource-intensive for the practices that participated, with the data reported likely having significant inaccuracies due to the difficulty of the process. "We strongly urge CMS to explore alternative methods for validating and enhancing clinical laboratory payment data instead of overburdening physician practices with requests for data that will not meaningfully impact the bottom line," according to AMA's comments.

Judge Dismisses ACLA PAMA Lawsuit (*cont'd from page 1*)

ACLA's lawsuit argued that CMS wrongly defined the term "applicable laboratory" which excluded more than 99% of hospital laboratories from PAMA's data-reporting requirements. As a result, ACLA says CMS did not get a fair representation of the lab market and relied too much on private-payer data from Quest Diagnostics and LabCorp.

Judge Jackson said that ACLA's 'arguments on the merits raise important questions,' but she refused to consider those arguments, because the PAMA law gave her no jurisdiction to do so.

In her decision, Judge Jackson cited PAMA statute (§ 1395m-1(h)(1)), which bars any "administrative or judicial review" to the "establishment of payment amounts" in the new private-payer-rate-based CLFS.

"The decision of which laboratories must report data is 'indispensable' and 'integral' to, and 'inextricably intertwined' with, the agency action's calculation of payment amounts based on that data and 'the establishment of payment amounts.' Therefore, it is not subject to judicial review," wrote Judge Jackson.

The Appeal Process Could Take Another 6 to 12 Months

"The Court's decision that it is powerless to require HHS to comply with the statutory requirements sets a harmful precedent that allows agencies to circumvent Congress' express directions at the expense of patient care," according to ACLA President Julie Khani. She says that ACLA and its members are reviewing further legal options. However, *Laboratory Economics* notes that if an appeal is filed, it would likely take between 6 to 12 months before a decision was rendered.

In the meantime, nearly all high-volume CPT codes on Medicare's CLFS are set to be cut by another 10% on January 1, 2019. In addition, the next PAMA rate-setting cycle will cover private-payer pricing data for the period January 1 to June 30, 2019, reported by applicable labs to CMS in early 2020, with new rates effective January 1, 2021.

A Legislative Solution Is Needed

Meanwhile ACLA, CAP and the National Independent Laboratory Assn. (NILA) continue to lobby Congressional leaders to amend the PAMA law so that more labs (especially hospital outreach labs) are required to report their private-payer data to CMS.

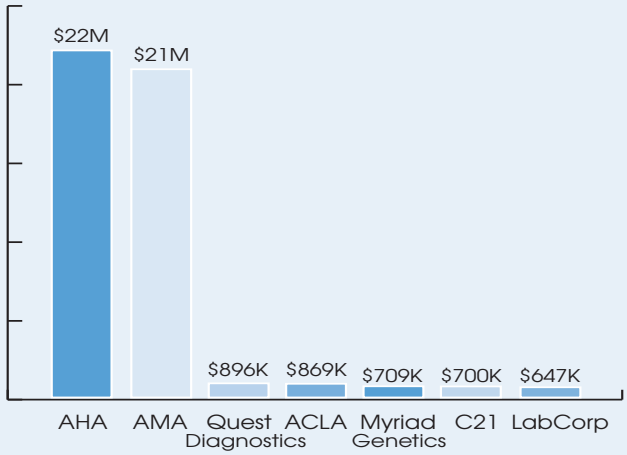
NILA President Mark Birenbaum, PhD, says that ideally new legislation would be passed that would delay the scheduled 10% cuts to the CLFS and revert back to 2017 rates until CMS can collect data that accurately reflects the laboratory market. "It's up to the lab industry to increase the noise level in Congress," says Birenbaum.

Unfortunately, the chances of getting PAMA amended before year's end are slim, according to long-time lab policy analyst Dennis Weissman, President of Dennis Weissman & Associates LLC (Falls Church, VA). He notes that there are few legislative vehicles available to get anything through Congress until after the midterm elections take place on November 6. That leaves only a few weeks before a lame-duck Congress preoccupied with staving off a partial government shutdown in early December struggles to adjourn prior to the holidays. "This year's 10% rate cut was difficult, but a second 10% cut will be devastating for smaller community labs," notes Weissman.

Influential Healthcare Trade Groups are Pulling in the Opposite Direction

However, there are other influential trade groups lobbying Congressional leaders in the opposite direction. For example, the Coalition for 21st Century Medicine (C21) has strongly supported

Average Annual Lobby Spending by Key Trade Groups in the PAMA Reporting Debate*



*Average annual lobby spending for January 2014 through June 2018
Source: Center for Responsive Politics

CMS's implementation of PAMA and Medicare's new CLFS rates. C21 is comprised of a small group of genetic testing labs, including Foundation Medicine, Genomic Health and Myriad Genetics, that have received Medicare rate hikes for their high-priced proprietary tests (see *LE*, October 2017).

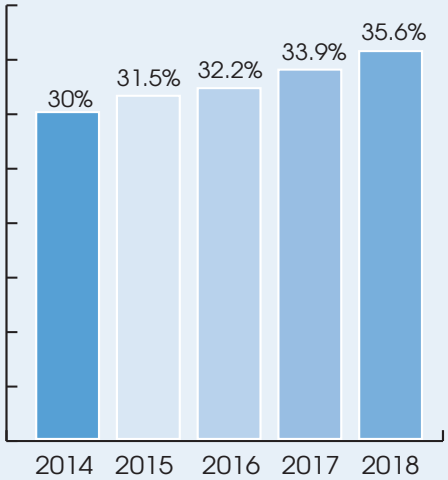
In addition, the highly influential American Hospital Association (AHA) and American Medical Association (AMA) have each come out in opposition to proposals that would require hospital labs and more physician groups to report their private-payer lab test payment data to CMS.

OIG Report Shows Molecular And Drug Testing Growing Fastest

The Medicare Part B program spent $7.1 billion on clinical lab tests last year, according to the latest OIG review of CLFS payments. Total payments for CLFS tests increased slightly from the totals from 2014 ($7.0 billion), 2015 ($7.0 billion) and 2016 ($6.8 billion).

Part B lab spending has been constrained over the past few years partly as a result of an enrollment shift of beneficiaries toward Part C Medicare Advantage plans offered through private insurance companies. Approximately 35% of the nation's 60 million Medicare beneficiaries is currently enrolled in a private health plan, up from 30% in 2014.

Percentage of Medicare Recipients in Private Health Plans



Source: Medicare Trustees Report for 2018

Part B lab spending is expected to drop by $670 million this year as a result of the first round of 10% PAMA rate cuts to the CLFS that went into effect January 1, 2018.

The OIG report highlighted the top 25 tests in 2017, which represented 64% of Medicare payments for all lab tests paid under the CLFS. Of the total $4.545 billion that Medicare spent on the top 25 tests in 2017, carrier payments to independent labs and POLs totaled $3.445 billion, or 76%, and payments to hospital labs totaled $1.1 billion, or 24%.

Spending grew the fastest for CPT 81528 (gene analysis for colorectal cancer), a proprietary test for colorectal cancer performed by Exact Sciences. Medicare payments for CPT 81528 grew by 47% to $117 million in 2017.

Spending also increased rapidly for several drug testing codes, including G0480 (drug test, definitive, 1-7 classes), up 38% to $110 million; G0481 (drug test, definitive, 8-14 classes), up 27% to $101 million; and G0482 (drug test, definitive, 15-21 classes), up 22% to $162 million.

Top 25 Lab Tests Based on Medicare Part B Payments in 2017 ($ millions)

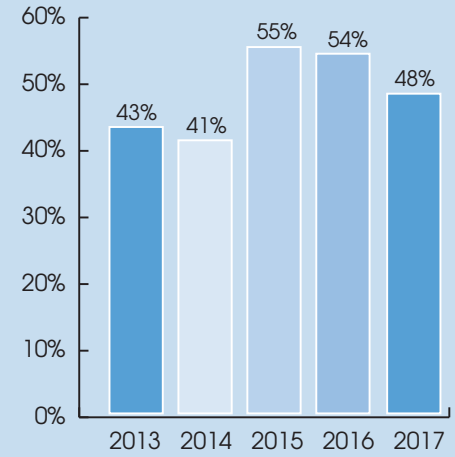
Code	Description	Medicare Payments to Independents & POLs	Medicare Payments to Hospitals	Grand Total	2016-2017 % Change
84443	Thyroid-stimulating hormone (TSH)	$340	$144	$484	0.3%
80053	Comprehensive metabolic panel	315	158	473	0.6%
85025	Complete CBC with auto diff wbc	306	126	432	-0.3%
80061	Lipid panel	276	139	415	1.1%
82306	Vitamin D level	251	97	348	-0.5%
G0483	Drug test def 22+ classes	302	5	307	21.3%
83036	Hemoglobin; glycosylated (A1C)	191	66	257	2.4%
80307	Testing for presence of drug	226	14	240	New Code
G0482	Drug test def 15-21 classes	159	3	162	22.1%
80048	Basic metabolic panel	71	59	130	-2.8%
83970	Parathyroid hormone level	80	45	125	3.9%
81528	Gene analysis for colorectal cancer	116	1	117	47.3%
82607	Vitamin B-12	81	33	114	0.9%
G0480	Drug test def 1-7 classes	99	11	110	37.7%
84153	PSA total	80	25	105	1.8%
G0481	Drug test def 8-14 classes	98	3	101	27.3%
85610	Prothrombin time	61	31	92	-14.0%
84439	Thyroxine measurement	61	25	86	1.7%
87086	Urine culture count	56	26	82	0.2%
83880	Natriuretic peptide level	42	28	70	1.9%
82728	Ferritin level	50	20	70	3.6%
81519	Breast cancer gene expression profile	60	0	60	-0.3%
85027	CBC automated	30	27	57	-1.1%
82746	Folic acid level	43	13	56	-0.7%
81162	BRCA 1&2 sequence & full dup/del	51	1	52	21.0%
	Totals for top 25 tests	***$3,445***	***$1,100***	***$4,545***	***5.4%***

Source: OIG analysis of Medicare Part B payments, September 2018

MDx Test Claim Denials Still Hover Near 50%

Forty-eight-percent of molecular diagnostic (MDx) test claims were denied by Medicare Part B contractors in 2017, according to an exclusive analysis of the latest available Part B data by *Laboratory Economics*. That compares with an average 54% denied MDx test claims in 2016 and 55% in 2015, and it greatly exceeds the average 5% to 10% denial rate for routine lab tests.

Medicare Part B Claims Denial Rates on Molecular Diagnostic Tests ($ millions)



Source: Medicare Part B aggregate denied claims vs. submitted claims for CPT codes 81162, 81200-81599, and G0452

The introduction of more specific codes in 2013 has allowed both Medicare Administrative Contractors (MACs) to deny claims for tests that they say lack medical necessity or do not have adequate evidence of clinical utility.

Deb Larson

For more insight into MDx claim denial trends, *Laboratory Economics* queried Deb Larson, Executive Vice President at the billing and revenue-cycle-management firm TELCOR Inc. (Lincoln, NE).

Are claims denials for MDx tests similarly high from private health insurance companies?

Our experience has been that commercial payers deny these claims at a higher rate. There appears to be a higher need for documentation and letters of medical necessity when submitting these codes to commercial payers such as United, Cigna, and Aetna.

There are probably less than 100 labs nationwide actually doing MDx tests in the CPT 81200 to 81407 code range. So is the MDx denial problem only affecting a small number of specialized labs performing these tests?

Roughly 5% of our customers are esoteric labs that have predominant submissions of these CPT codes. However, we have seen some of our hospital labs and pathology groups also perform this testing and submit these services, so they have been impacted as well.

What is the most common reason why a MDx test claim is denied?

Labs who have not registered for their Z-codes will typically see the following denial - CO 252 (an attachment/other documentation is required to adjudicate this claim/service). This will be accompanied by an N706 (missing documentation) and MA130 (claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable).

For those labs that perform this testing in jurisdictions that are not subject to the Z-code program, they will still receive similar denials requesting medical records or additional documentation.

What can labs do to reduce their claims denials for molecular diagnostic tests?

The best thing a lab can do is verify if their jurisdiction is subject to the Palmetto program and if so, it is paramount that they register for their Z-codes as soon as possible. Once they have registered with the program it is important that they speak with their software vendor to assure the Z-code is being transmitted in the correct loop and segment on their electronic claims.

Additionally with commercial payers it's effective to submit the claims with medical records and a letter of medical necessity signed by the provider with the original submission. What our customers do for these types of payers is automatically hold the charges and automatically by e-mail, fax or client portal, request the required documentation up front.

Then once the necessary documentation is received, they release the charges and submit claims. Payers are alerted in the electronic claim submission that an attachment is coming and our customers utilize an RCM Workqueue to track that the attachments are sent. This process reduces claim denials and allows for faster payment with less labor.

Denied Claims for 10 High-Volume Molecular Diagnostic Tests in 2017

CPT	Short Description	Submitted Claims	Denied Claims	Percent Denied	Allowed Charges
81479	Unlisted molecular pathology procedure	378,606	303,949	80.3%	$115,586,444
81528	Oncology (colorectal) screening	243,133	11,107	4.6%	118,892,527
81401	Molecular pathology procedure, Level 2	189,769	87,891	46.3%	13,813,243
81291	MTHFR gene analysis	121,578	78,210	64.3%	2,595,441
G0452	Molecular pathology interpretation	119,602	21,652	18.1%	1,860,693
81241	Factor V gene analysis	97,395	51,733	53.1%	3,824,996
81400	Molecular pathology procedure, Level 1	95,209	38,779	40.7%	6,678,376
81240	Factor II gene analysis	90,680	45,805	50.5%	3,026,972
81225	CYP2C19 genotype	77,732	59,423	76.4%	5,361,343
81226	CYP2D6 genotype	73,902	47,526	64.3%	$11,960,821

Source: *Laboratory Economics* from CMS

House Passes Weakened Version of LCD Transparency Bill

The House passed legislation September 12 that aims to improve accountability and transparency in the process Medicare contractors use to make local coverage decisions, but at least one lab group believes the legislation does not go far enough.

The Local Coverage Determination Clarification Act (HR 3635) mandates open and recorded Medicare Administrative Contractor (MAC) Carrier Advisory Committee meetings; upfront disclosure of evidence the MACs consider when drafting an LCD, as well as the rationale they are relying on to deny coverage; additional options for challenging an LCD; and annual reports to Congress on the number of LCD appeals and actions taken in lieu of the creation of an ombudsman.

Lâle White, Executive Chairman and CEO of XIFIN Inc. (San Diego), praised the bill, noting that it will help to re-establish a formal process with greater transparency and appears to provide greater flexibility in conducting coverage assessments.

"From a high level, the revisions to the LCD process would require notice and comment on any non-administrative change, including an expansion of coverage, which currently does not require notice and comment," she tells *Laboratory Economics*. "Even though this would delay coverage expansion, I think this is a welcome process change that clarifies the importance of the 'notice and comment' provision which had been losing some of its relevance in recent years."

The College of American Pathologists (CAP), which drafted the measure, believes that the House Ways and Means Committee weakened the bill when it removed a provision in the original text that would have prohibited MACs from adopting LCDs made by other contractors without prop-

erly considering them. This carbon copy adoption of LCDS by other MACs without independent assessment of comments and concerns from the public or medical community of the adopting MAC has the practical effect of establishing national coverage policies without having followed the more rigorous national coverage determination (NCD) requirements.

"We are disappointed that the committee, at the request of the Centers for Medicare and Medicaid Services, has removed one of the bill's cornerstone provisions to stop Medicare contractors from rubberstamping coverage decisions and using the LCD program to circumvent the more rigorous requirements of the National Coverage Determination process," said CAP President Bruce Williams, MD, FCAP, in a statement.

The bill is now in the Senate for consideration; the CAP is urging the Senate to preserve the bill's original provisions that were removed by the House committee.

Quest Announces Three Lab Acquisitions

Quest Diagnostics announced three lab acquisitions in September. The common thread was that each is a fast-growing specialty reference lab with limited exposure to the Medicare CLFS.

Quest To Buy Oxford Immunotec's U.S. Lab Business

Quest Diagnostics has agreed to acquire the U.S. laboratory service business of Oxford Immunotec (United Kingdom) for $170 million in cash. In the United States, Oxford Immunotec performs its latent tuberculosis (T-SPOT) and tick-borne disease (Accutix) tests at its CAP-accredited labs in Memphis, TN and Norwood, MA, respectively. Oxford's 35,000-square-foot laboratory in Memphis is expected to become a dedicated site for TB testing, assuming the close of the acquisition. Oxford's 58,000-square-foot lab in Norwood is likely be consolidated into Quest's regional lab in Marlborough, MA.

Oxford's U.S. lab business is on pace to reach roughly $66 million of revenue in 2018, up 10% from $60 million in 2017. This implies that Quest is paying a purchase price of 2.6 times estimated 2018 revenue. The acquisition is expected to close by year's end.

Medicare CLFS reimbursement for latent tuberculosis testing (CPT 86481) received a PAMA cut of only 2.7% this year to $100, and will remain at this level for 2019 and 2020.

Following completion of the sale, Oxford Immunotec will focus on its IVD kit business. Quest and Oxford have negotiated a long-term reagent supply agreement and expect to enter a strategic collaboration to increase T-SPOT testing in the U.S.

Quest Buys PhenoPath Labs

Quest acquired PhenoPath Laboratories (Seattle, WA) in September for an undisclosed amount PhenoPath is a national provider of molecular oncology testing services. The company has approximately 75 employees, including nine pathologists, and estimated annual revenue of $20-$30 million. PhenoPath had been owned by its pathologists including its Medical Director, Allen Gown, MD, who founded the company in 1998. The main PhenoPath laboratory in Seattle will remain in operation as part of Quest's AmeriPath division.

Quest Buys ReproSource

In mid-September, Quest purchased ReproSource (Woburn, MA), which operates a reference laboratory for infertility diagnostics just north of Boston. The company has more than 50 employees and estimated annual revenue of $10-$20 million. Quest says that it may transition ReproSource into its regional lab in Marlborough, MA.

Spotlight Interview with ProPath President Cory A. Roberts, MD


Cory A. Roberts, MD

ProPath, a large anatomic pathology and clinical laboratory located near Love Field in Dallas, employs more than 400 workers, including 50 pathologists. The lab serves more than 1,000 clients throughout the United States and internationally, although 75% of its work comes from Texas. *Laboratory Economics* recently spoke with ProPath's Chairman, President and CEO Cory A. Roberts, MD.

How many hospitals does ProPath provide laboratory medical directorships to?
We have directorships at 26 hospitals and 38 total facilities. Our most recent directorship is at Baylor Scott & White Medical Center in Sunnyvale. The largest hospital we serve is John Peter Smith Hospital in Fort Worth, which is a publicly funded hospital. We have five pathologists there. Other large hospitals include Texas Health Harris Methodist Hospital Southwest in Fort Worth and the Texas Health Harris Methodist Hurst-Euless-Bedford (HEB) Hospital in Bedford.

Are you still 100% owned by pathologists?
We are. We're very proud of that. We feel that having 100% physician ownership really validates our core values of placing the patient first. It makes us unique. We have been approached by potential investors, but we feel good about maintaining our position as is.

What is ProPath's current volume and annual revenue? Are you seeing growth?
Our revenue will be between $80 and $90 million this year. We do about 250,000 Pap smears a year. We process over 2,000 tissue blocks a day just in our lab. We've grown consistently both in volumes and in revenues. Since 2000, we've more than tripled in revenue. Our annual growth rate is 5% to 7%, and we expect that to continue, if not increase. We are targeting even more aggressive growth in the coming years. As everyone experienced, our Pap volume did decline slightly with the change in screening guidelines, but we've added more clients to mitigate that. In addition to our anatomic lab, we also recently expanded and built a clinical lab, which opened in September 2017.

Have the changes to the Clinical Laboratory Fee Schedule impacted ProPath?
Yes. However we were planning our business model for opening a clinical lab at the same time discussions about PAMA were happening. We built the PAMA pricing into our model.

What are your specialties?
Women's health, dermatology and gastroenterology are the top three although we have about 20 subspecialties represented by our pathologists. We are expanding our clinical lab menu to accommodate additional specialties as well.

Do you use digital pathology?
We are currently devising our plan to implement whole-slide imaging in 2019. We have a significant amount of immunohistochemistry technical work, for example, and we think we can apply an imaging solution there and decrease our shipping costs and improve delivery and care. We also think we can use the same platform to do more computer-assisted analysis. The vast majority of slides produced in our lab still come to pathologists who are on site, so I don't see utility in using digital pathology in that instance.

Have you added any new molecular tests to your menu recently?
Yes, in the last few months we implemented an expanded bacterial vaginosis panel. We also have implemented genetic screening for cystic fibrosis and Fragile X syndrome. We are currently validating tests for c-KIT mutations and antibiotic resistance markers. We plan to add more – our physicians and scientists are excellent at keeping up with the literature and keeping in touch with our partner clients to see what they need to best care for their patients.

Is ProPath experiencing any shortages in med techs, phlebotomists and histotechs given the low unemployment rate?
It's always a challenge. We do partner with a local university to provide opportunities for training and rotations for medical technology and histotechnology students. We're actually pursuing having our own in-house cytotechnologist program here. We trade opportunities for advanced training and a career path for a commitment to work with us for a certain period of time.

What are your biggest opportunities? Challenges?
The biggest opportunity is to take our message of being a physician-owned quality-driven practice to other physicians around the country who want top quality over all else. In terms of challenges, unlike in other businesses, we do not get to set our prices. If our expenses go up, we don't get more reimbursement. I expect the downward pressure on reimbursement to continue. Healthcare is always going to evolve, and there will be challenges we can't even contemplate right now. We pursue strategies that position us well for nimble reactions to all the pressures and challenges that will come. The key is adaptability to circumstance and not predictability of the future.

Guardant Health Raises $273 Million From IPO

Guardant Health (Redwood City, CA) raised gross proceeds of $273 million from its initial public offering on October 3. The company sold 14.375 million shares at $19 each, well above its anticipated price range of $15 to $17. Furthermore, shares of Guardant have since jumped to $31.60, giving the company an enterprise valuation of nearly $2.4 billion, an amount equal to 48 times the company's current annual revenue of $50 million (*see page 12*).

Guardant plans to use proceeds for working capital, sales, marketing, administrative and other corporate purposes, according to its IPO filing with the U.S. Securities and Exchange Commission. It may also use some proceeds to acquire or invest in products and businesses.

Guardant markets "liquid biopsy" cancer test panels that it claims are a less invasive — and often less costly — than traditional tissue biopsies. The company's primary product is Guardant360, a laboratory-developed test panel that analyzes 73 cancer-related genes to help match solid-tumor cancer patients with targeted therapies. The test is performed at Guardant's CLIA-certified laboratory in northern California and has a list price of $7,800.

Japan's SoftBank is Guardant's biggest holder with a 33% stake after the IPO, and Sequoia Capital is its second-largest backer, with a 9% stake.

Caris Raises $150 Million In Debt/Convertible Note Financing

Caris Life Sciences (CLS-Irving, TX) has raised $150 million through the sale of a combination of secured debt and convertible notes to TPG Sixth Street Partners (Fort Worth, TX and San Francisco).

CLS has a total of approximately 300 employees at its headquarters in the Dallas area and its 66,000-square-foot genomic testing laboratory in Phoenix. CLS intends to use the proceeds from this financing to launch new cancer profiling services, expand its commercial organization, and increase the capacity of its clinical and R&D laboratory.

The financing represents the first external capital to be raised by CLS since it sold its anatomic pathology business (Caris Diagnostics) to Miraca Holdings in 2011. Since then the company had been funded exclusively by its Chairman and CEO David Halbert.

Coding Change Will Slash BRCA1/BRCA2 Reimbursement

When the new PAMA market-based pricing system fails to reduce rates for a high-cost lab test, CMS can instead make coding changes to achieve a desired Medicare spending reduction. This is the strategy that CMS is using to cut spending on BRCA1/BRCA2 gene testing used to determine a woman's risk of hereditary breast and ovarian cancer.

The primary code currently used to bill Medicare for BRCA1/BRCA2 testing is CPT 81162.

- CPT 81162: BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis.

Medicare Part B spending on CPT 81162 totaled $52 million in 2017, up 21% from the previous year. This placed it among the top 25 lab tests for total Medicare spending and also makes it one the fastest-growing (see table on page 5).

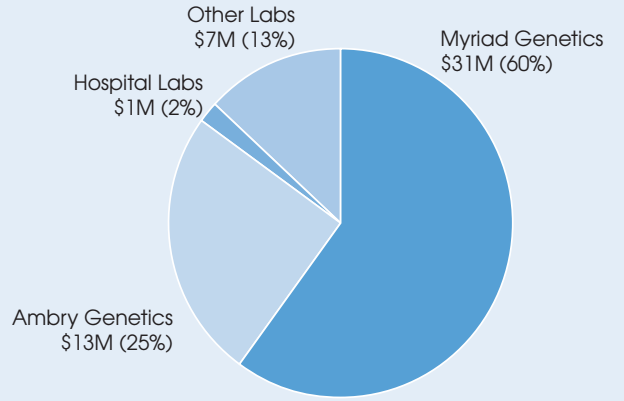
The PAMA repricing lowered the Medicare reimbursement rate for CPT 81162 by the maximum 10% to $2,253 in 2018, and another 10% cut was scheduled for 2019.

But the American Medical Association's CPT Editorial Panel has revised CPT 81162, so that starting January 1, 2019, it will be replaced by the following two new codes:

- 81X78 BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis.
- 81X79 BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements).

CMS received a number of recommendations on how to price these two new codes, but made a preliminary determination to reimburse 81X78 at $468 and 81X79 at $584. So next year, if these preliminary rates are finalized, labs will get $1,052 for doing the full gene sequencing and full duplication/deletion analysis of BRCA1 and BRCA2 versus the current rate of $2,253 when billed using CPT 81162—a decrease of 53%. The coding change will save CMS approximately $25 million next year.

Market Share of Medicare Spending on BRCA1/BRCA2 Gene Testing, 2017



Source: *Laboratory Economics* from CMS Part B Utilization Data

"Current market-based research of available BRCA test codes suggest rates that are consistent with our payment methodology and recommended crosswalk codes. Lastly, we believe the comparable lower payment rate will support a more competitive landscape for these tests to be accessible to a greater Medicare beneficiary population," according to CMS.

Lower reimbursement for BRCA1/BRCA2 gene testing will only have a significant impact on the two lab companies that do the majority of this testing, Myriad Genetics (Salt Lake City) and Ambry Genetics Corp. (Aliso Viejo, CA). However, CMS's willingness to use coding changes to cut reimbursement for a high-priced molecular test is an ominous foreboding for other tests like Genomic Health's Oncotype DX (CPT 81519), Exact Sciences' Cologuard (CPT 81528) and others.

Lab Stocks Up 40% Year To Date

Prices for 18 publicly-traded lab stocks are up 40% on an unweighted average basis through October 11. In comparison, the S&P 500 Index is up 10.5% year to date.

Enzo Biochem is currently the least expensive lab company, in terms of valuation measured by enterprise value divided by trailing 12 month revenue. Enzo currently has an enterprise value of $121 million and annual revenue of $108.4 million for an EV/revenue ratio of 1.1.

The most expensive lab company is Guardant Health, which just came public (*see page 10*). Guardant currently has an enterprise value of $2.4 billion and annual revenue of $49.8 million for an EV/revenue ratio of 48.

Company (ticker)	Stock Price 10/11/18	Stock Price 12/29/17	2018 Price Change	Enterprise Value ($ millions)	Enterp Value/ Annual Revenue
Enzo Biochem (ENZ)	$3.75	$8.15	-54%	$121	1.1
Cancer Genetics Inc. (CGIX)	0.85	1.85	-54%	34	1.1
Interpace Diagnostics (IDXG)	1.28	1.02	25%	29	1.6
Opko Health (OPK)	3.54	4.90	-28%	2,060	2.0
LabCorp (LH)	168.25	159.51	5%	23,490	2.1
Quest Diagnostics (DGX)	100.44	98.49	2%	17,940	2.3
Psychemedics (PMD)	18.67	20.56	-9%	99	2.4
Sonic Healthcare (SHL.AX)	23.69	21.40	11%	13,270	2.4
Myriad Genetics (MYGN)	43.69	34.35	27%	2,960	3.8
Veracyte (VCYT)	10.20	6.53	56%	323	4.0
NeoGenomics (NEO)	13.87	8.57	62%	1,300	4.8
Natera (NTRA)	20.11	8.99	124%	1,340	5.7
Genomic Health (GHDX)	62.80	29.39	114%	2,240	6.2
Invitae (NVTA)	13.27	9.08	46%	961	8.9
CareDx (CDNA)	22.15	7.34	202%	861	15.2
Exact Sciences (EXAS)	66.41	52.54	26%	8,160	23.1
Foundation Medicine (FMI)*	137.00	68.20	101%	5,350	26.5
Guardant Health (GH)	31.60	19.00	66%	2,398	48.1
Unweighted Averages			40%	$82,936	9.0

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

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