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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Most Pathology Services Will See Small Rate Cuts Under Final MPFS For 2019

The Final Medicare Physician Fee Schedule (MPFS) for 2019 includes a 1% increase to the technical component for CPT 88305, raising it to a national unadjusted rate of $30.63. Meanwhile, the final rate for the professional interpretation for CPT 88305 is being reduced by 1% to $39.64.

Overall, CMS estimates that Medicare technical service payments to independent pathology labs will decrease by 2% in 2019 due to changes to the technical component direct practice expense inputs. Meanwhile, overall Medicare payments to pathologists for professional services are also estimated to decrease by 2% next year.

Continued on page 4.

CMS Says Hospital Outreach Labs Must Report PAMA Pricing Data

In a surprise move, CMS has broadened the definition of "applicable laboratories" that must report their private-payer test prices under PAMA. Hospital outreach laboratories that receive at least $12,500 in Medicare CLFS revenues billed on CMS-1450 14X bill type during the next data collection period (Jan. 1, 2019 to June 30, 2019) must now report private-payer test prices to CMS in early 2020.

The broadened definition was contained in the Final Medicare Physician Fee Schedule Rule for 2019 released by CMS on November 1. It means that nearly every hospital outreach lab is required to report its private-payer test prices.

The rule change will not stop the scheduled 10% rate cuts for most CLFS tests in 2019 and again in 2020. However, the addition of pricing data from hospital outreach labs could have a dramatic positive effect on CLFS rate adjustments in 2021 and thereafter. But this will only happen if a large majority of hospital outreach labs are actually able to retrieve and report detailed private-payer payment data from their main hospital billing departments.

Continued on page 2.

Contents

CMS Says Hospital Outreach Labs Must Report (*cont'd from page 1*)

The American Hospital Association had opposed the inclusion of hospital outreach labs on the grounds that it would be a huge administrative burden that would have little impact on CLFS rates (see *Laboratory Economics*, October 2018).

The PAMA law requires applicable laboratories to report private-payer data for each 6-month data collection period including: (1) the Healthcare Common Procedure Code System (HCPCS) code for the test; (2) each private-payer rate for the test described by that HCPCS code for which final payment has been made (after all contractual adjustments and discounts); and (3) the associated volume of tests performed corresponding to each private-payer rate.

Many hospital systems do not post or have data at a CPT/HCPCS code level required to report payments by test. As a result, AHA has said that many hospital outreach labs will not be able to report their private-payer data at the CPT/HCPCS code level, as CMS requires.

Furthermore, AHA has argued that many hospital outreach labs will not have sufficient time to make the necessary systems changes needed prior to the start of the next data collection period on January 1.

Potential Severe Monetary Penalties for Labs that Skip Reporting

So now it seems hospital outreach labs are faced with the choice of 1) complying with the law at a major billing and information technology department expense, or 2) taking the risk of incurring severe monetary penalties for not reporting.

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.

Thousands of independent labs and POLs failed to report their private-payer data during the first PAMA data collection (January 1 - June 30, 2016) and reporting period (January 1 - May 30, 2017). However, CMS did not hunt down these offenders or issue any monetary penalties.

CMS may not be as forgiving during the next round of data collection (January 1 - June 30, 2019) and reporting (January 1 - March 31, 2020). In a report issued earlier this year, the Office of Inspector General suggested that CMS threaten the use of monetary penalties to encourage more applicable labs to report (see *Laboratory Economics*, August 2018). In addition, ACLA has urged CMS to take enforcement action against labs that are required to report, but fail to do so.

Next PAMA Private-Payer Data Collection and Report Schedule

Data collection period	January 1, 2019 through June 30, 2019
Data reporting period	January 1, 2020 through March 31, 2020
Preliminary CLFS rates announced	Fall 2020
Final CLFS rates become effective	January 1, 2021

Source: CMS

Finalized Change to the Majority of Medicare Revenue Threshold

CMS has also finalized 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 has estimated that this proposed change would add 835 reporting labs and increase the number of data points reported by 5%.

The Impact of Hospital Outreach Lab Pricing Data
The inclusion of hospital outreach labs, as well as the threshold adjustment to exclude Medicare Advantage revenue from the denominator to determine Medicare percentage, are welcome news, says Lâle White, Executive Chairman and CEO at XIFIN Inc. (San Diego). These changes will certainly increase the number of labs reporting in the next data collection, according to White.

White estimates that for the highest-volume CLFS tests, hospital outreach labs get paid an average of roughly 30% more than independent labs by private payers. And on other CPT codes they get 60-90% more and, for some payers, as much as 3-4 times more than independent labs.

"Hospitals have been the recipient of generous lab reimbursement over the last two decades, using their ability to leverage their existing hospital-based outpatient contracts," adds Jeff Myers, CPA, Vice President of Consulting at Accumen Inc. (San Diego). He estimates that private insurance rates for hospital outreach labs average in the range of between 140% and 180% over the Medicare CLFS. In addition to avoiding penalties and fines, the inclusion of hospital outreach lab data will favorably impact Medicare rates in the next rate-setting cycle, so hospitals should have a strong incentive to report this information, according to Myers.

However, White says it is not clear if CMS will receive sufficient data at each CPT code level to have a significant effect on the Median rate calculations. She notes that CMS still expects that the large labs will dominate the data it collects.

How Ready are Hospital Outreach Labs to Report Required Pricing Data?
Hospital outreach labs that have their own tax identifier and use either their own inhouse billing system or a billing service are in the best position to collect the required data, according to Deb Larson, Executive Vice President at TELCOR Inc. (Lincoln, NE).

On the other hand, Larson notes that outreach labs using the hospital's tax identifier and therefore doing institutional billing will have a bigger challenge. In this case, which represents the majority of outreach lab programs, payments are often received at a claim level and may not be allocated to each specific service line.

If the required data is not going to be readily available, then it is better to know before the data collection period starts, notes Larson. "They need to put a process in place, even if it's manual, to get the required data and avoid potential penalties."

What Should Hospital Outreach Labs Be Doing Right Now to Prepare?
First, outreach lab leadership needs to assign a project manager to focus on the new reporting requirement, according to Jim Sundberg, President of LabMetrics Laboratory Consulting (Ishpeming, MI). For example, Sundberg notes that independent labs that reported during the first PAMA cycle typically selected either their billing manager, CIO or compliance department head as project manager.

He says that outreach lab leadership and the project manager need to quickly notify and work closely with their central billing office (CBO) or lab billing vendor to communicate and ensure all parties recognize the new CMS reporting requirement. "Everyone needs to understand the reporting challenges that may exist in acquiring and submitting the required data."

Finally, Sundberg says that the project manager needs to develop a plan to obtain the data required by CMS, including any system changes that may be necessary.

How Many Hospital Outreach Labs Will Actually Report?
Basically, any hospital outreach lab that receives $12,500 or more of Medicare CLFS payments

during January 1 through June 30, 2019 will be required to report. As a result, Tom Hirsch, President of Laboratory Billing Solutions (Portsmouth, NH), estimates that over 90% of the hospitals in the country that have an outreach program will be required to report.

This means that there are easily 1,000+ hospital outreach labs that will be required to report, observes *Laboratory Economics*.

However, Hirsch says reporting will be a somewhat manual and tedious process for most outreach labs since they lack basic reporting at the CPT code level as well as any custom software needed to handle the reporting requirements electronically.

During the last PAMA reporting cycle, approximately 100 hospital-owned labs with their own NPI were required to report, but only 20 actually did. Next year's PAMA reporting cycle greatly broadens the pool of hospital outreach labs required to report, but these labs are ill-prepared and there is no guarantee that they will follow through on the arduous reporting process.

ACLA Files Notice to Appeal Lawsuit Dismissal

On October 19, the American Clinical Laboratory Association (ACLA) filed its notice to appeal with U.S. District Court for the District of Columbia (DDC) in its lawsuit challenging CMS's implementation of PAMA, which requires CMS to establish a market-based payment system for Medicare CLFS tests.

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." If DDC 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.

Meanwhile, ACLA President Julie Khani says that while ACLA appreciates CMS making changes in its final rule to increase representation of hospital outreach labs in the next round of data collection, ACLA will continue with its lawsuit appeal and lobbying for legislative action on PAMA reform.

Most Pathology Services Will See Small Rate Cuts (*cont'd from p. 1*)

The final MPFS rates released by CMS represent a minor disappointment from the small rate hikes that were indicated in the proposed rule that CMS issued in July (see *Laboratory Economics*, July 2018).

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) will decrease by 3% to $108.48; professional interpretation down 1% to $37.12; technical component down 4% to $71.36.

The global rate for CPT 88341 (IHC, additional slide) is essentially unchanged at $94.42; professional interpretation gets a tiny increase to $29.91; technical component gets a tiny reduction to $64.51.

Prostate Biopsies

Global reimbursement for G0416 has been cut by 11% to $386.34, including a 19% cut to the technical component. Reimbursement for G0416-TC should stabilize following a final phase-in reduction of 16% scheduled for 2020.

Flow Cytometry

Following significant cuts made in 2017 and 2018, another round of cuts for key flow cytometry codes is scheduled for 2019. CPT 88185 (flow cytometry, TC, add on) will decrease by 19% to $24.87. Reimbursement for CPT 88185 should stabilize following a final phase-in reduction of 10% in 2020.

Final Medicare Rate Changes for Key Pathology Codes for 2019

CPT/HCPCS	Short Description	Final 2019[1]	Final 2018[2]	% Change
88184-TC only	Flow cytometry/1st marker	$67.75	$68.04	0%
88185-TC only	Flow cytometry/each add'l marker	24.87	30.60	-19%
88187-26 only	Flow cytometry, read 2-8	38.92	48.24	-19%
88189-26 only	Flow cytometry, read 16+	88.30	88.92	-1%
88305-Global	Level IV, Tissue exam by pathologist	70.28	70.20	0%
88305-26	Level IV, Tissue exam by pathologist	39.64	39.96	-1%
88305-TC	Level IV, Tissue exam by pathologist	30.63	30.24	1%
88307-Global	Level V, tissue exam by pathologist	273.54	270.00	1%
88307-26	Level V, tissue exam by pathologist	86.85	87.84	-1%
88307-TC	Level V, tissue exam by pathologist	186.68	182.16	2%
88309-Global	Level VI, tissue exam by pathologist	415.53	410.04	1%
88309-26	Level VI, tissue exam by pathologist	153.53	155.88	-2%
88309-TC	Level VI, tissue exam by pathologist	262.00	254.16	3%
88112-Global	Cytopath cell enhance technique	68.47	70.20	-2%
88112-26	Cytopath cell enhance technique	29.19	29.52	-1%
88112-TC	Cytopath cell enhance technique	39.28	40.68	-3%
88120-Global	Cytopath urine 3-5 probes each spec	608.70	649.79	-6%
88120-26	Cytopath urine 3-5 probes each spec	60.19	60.84	-1%
88120-TC	Cytopath urine 3-5 probes each spec	548.52	588.95	-7%
88121-Global	Cytopath urine 3-5 probes by computer	488.33	541.79	-10%
88121-26	Cytopath urine 3-5 probes by computer	51.18	52.20	-2%
88121-TC	Cytopath urine 3-5 probes by computer	437.15	489.59	-11%
88312-Global	Special stains, group 1	101.99	99.36	3%
88312-26	Special stains, group 1	27.75	28.08	-1%
88312-TC	Special stains, group 1	74.24	71.28	4%
88313-Global	Special stains; group 2	73.88	72.00	3%
88313-26	Special stains; group 2	12.61	12.60	0%
88313-TC	Special stains; group 2	61.27	59.40	3%
88331-Global	Path consult intraop 1 block	99.11	99.72	-1%
88331-26	Path consult intraop 1 block	65.59	66.60	-2%
88331-TC	Path consult intraop 1 block	33.52	33.12	1%
88341-Global	Immunohistochemistry (Add'l stain)	94.42	94.68	0%
88341-26	Immunohistochemistry (Add'l stain)	29.91	29.88	0%
88341-TC	Immunohistochemistry (Add'l stain)	64.51	64.80	0%
88342-Global	Immunohistochemistry (1st stain)	108.48	111.60	-3%
88342-26	Immunohistochemistry (1st stain)	37.12	37.44	-1%
88342-TC	Immunohistochemistry (1st stain)	71.36	74.16	-4%
88360-Global	Tumor IHC/manual	129.74	136.44	-5%
88360-26	Tumor IHC/manual	44.33	46.80	-5%
88360-TC	Tumor IHC/manual	85.41	89.64	-5%
88361-Global	Tumor IHC/computer	134.07	148.32	-10%
88361-26	Tumor IHC/computer	47.57	49.68	-4%
88361-TC	Tumor IHC/computer	86.49	98.64	-12%
G0416-Global	Prostate biopsy, any method	386.34	434.52	-11%
G0416-26	Prostate biopsy, any method	185.60	186.84	-1%
G0416-TC	Prostate biopsy, any method	200.74	247.68	-19%

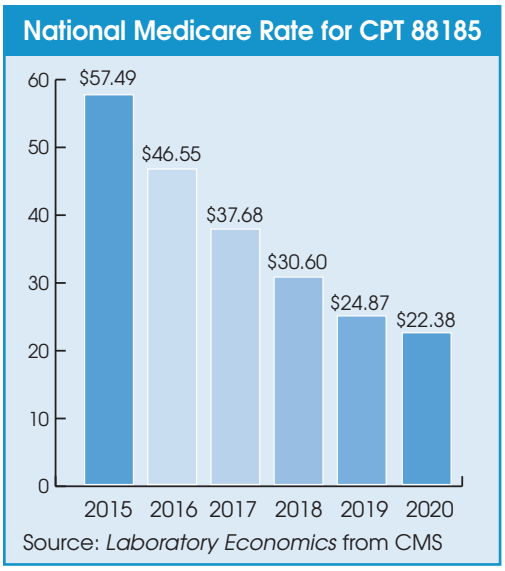
[1]Payments based on the 2019 conversion factor of 36.0391; [2]Payments based on the 2018 conversion factor of 35.9996
Source: Laboratory Economics from CMS

NeoGenomics To Buy Genoptix For $140 Million

NeoGenomics (Fort Myers, FL) has agreed to acquire Genoptix Inc. (Carlsbad, CA) for $125 million in cash and 1 million NeoGenomics shares, currently worth about $15 million. The deal is expected to close by early December.

Genoptix operates a 27,000-square-foot laboratory just north of San Diego that provides hematopathology and solid tumor testing services to oncology practices. Genoptix currently has a total of 370 employees, including 14 hematopathologists, and processed a total of 170,000 patient test reports in 2017.

The buyout comes almost two years after Genoptix was acquired from Novartis by a pair of private investment firms, Ampersand Capital Partners and 1315 Capital, and a management group for an undisclosed sum in January 2017. Novartis had originally purchased Genoptix in early 2011 for an enterprise value of $330 million. At the time of the Novartis acquisition, Genoptix had 500 employees and annual revenue of $195 million.



Laboratory Economics estimates that Genoptix's current annual revenue is roughly $100-125 million. NeoGenomics expects to add $85 million of annual revenue from the addition of Genoptix, after accounting for the switch over to NeoGenomics' lower-priced in-network insurance contracts.

Genoptix's revenue has been under pressure for the past few years, in large part due to Medicare rate cuts to key flow cytometry services used to diagnose and monitor leukemia and lymphoma. For example, the national Medicare rate for CPT 88185 (flow cytometry/TC add-on) has been reduced by the maximum allowed 19% per year cut since being reviewed by CMS under its "potentially misvalued code" initiative in 2015. Medicare reimbursement for CPT 88185 is scheduled for another 19% cut in 2019, and then a final 10% reduction in 2020 before it stabilizes at approximately $22.38.

NeoGenomics plans to continue Genoptix's laboratory operations in Carlsbad with their scope to be determined over time. Certain administrative functions may be consolidated at NeoGenomics' large Aliso Viejo laboratory facility located about 40 minutes south of Carlsbad. NeoGenomics anticipates that it can achieve $25 million per year of cost savings and reach a 25% EBITDA margin from Genoptix by the end of three years.

NeoGenomics & Genoptix at a Glance

	NeoGenomics	*Genoptix*	*Combined*
Employees:	1,100	370	1,470
Pathologists:	31	14	35
Main labs:	Ft. Myers, FL; Aliso Viejo, CA; Houston, TX	Carlsbad, CA	—
Annual Revenue:	$265M	$85M	$350M
Annual patient cases:	430,000	~170,000	~600,000

Source: *Laboratory Economics'* estimates and NeoGenomics

Quest Diagnostics Buys 2 Small Hospital Lab Outreach Businesses

Quest Diagnostics announced two separate deals to acquire small hospital outreach labs in October.

On an October 23 conference call with analysts and investors, Quest Chairman and CEO Steve Rusckowski noted, "Increasingly, smaller independent labs and hospital outreach labs are struggling financially, due to lower Medicare reimbursement, not only directly due to PAMA, but also under contracts with pricing indexed to Medicare. Some have begun to exit the business, citing PAMA as a factor. We're continuing to plan and manage our business as if PAMA is here to stay."

Quest has acquired Hurley Medical Center's clinical lab outreach operation in Flint, Michigan, for an undisclosed amount. Hurley indicated reimbursement pressure as a factor in deciding to exit its lab outreach business. Hurley is shutting down at least three outreach PSC sites and now referring its lab outreach patients to Quest PSCs instead. "We are fortunate that Quest is in our community and able to continue to provide access and availability for patients seeking cost-efficient outreach lab services," said Hurley President and CEO Melany Gavulic in a statement released by the hospital.

In addition, Quest has entered into a definitive agreement to acquire the clinical lab outreach operations of Marin General Hospital (Greenbrae, CA). The deal is expected to be completed by year's end. "We feel they will be better able to maintain the standards our community wants and deserves at a reasonable cost. We will collaborate to ensure a smooth transition," said Lee Domanico, Chief Executive Officer at Marin General Hospital.

Quest has now acquired a total of 10 hospital lab outreach businesses since PAMA was signed into law in April 2014.

Hospital Outreach Labs Acquired by Quest Diagnostics Since PAMA

Date	*Laboratory Outreach*	*Location*	*Purchase Price ($ mill)*
Oct-18	Marin General Hospital outreach lab	Northern California	NA
Oct-18	Hurley Medical Center outreach lab	Central Michigan	NA
Jun-18	Cape Cod Healthcare outreach lab	Cape Cod, MA	$35
Oct-17	California Laboratory Associates	Los Angeles area	NA
Sep-17	Hartford Healthcare outreach labs	Connecticut	$30
Jun-17	Sierra Nevada Memorial Hospital outreach lab	Northern California	NA
May-17	PeaceHealth Labs	Washington/Oregon	$101
Feb-16	Clinical Laboratory Partners	Connecticut	$135
Aug-15	MemorialCare Health System outreach lab	Los Angeles area	$35
Apr-14	Steward Health outreach lab	Massachusetts	$34

Source: *Laboratory Economics* from Quest Diagnostics

LabCorp Signs Expanded Agreement With Baptist Health

LabCorp has announced a comprehensive laboratory agreement with Baptist Health (Louisville, KY), the largest not-for-profit health system in Kentucky. The new agreement expands upon LabCorp's existing five-year relationship as the primary reference laboratory for Baptist Health's nine hospitals (combined 2,700 licensed beds) and for Baptist Health Medical Group's physician network (3,000 employed and affiliated physicians). Under the expanded agreement, LabCorp will help Baptist Health establish a core lab at Baptist Health Louisville, to streamline system-wide laboratory testing processes. Baptist Health will own and control the new core lab. LabCorp will provide managerial support to Baptist Health's lab services, assist in process standardization across Baptist Health, and provide certain purchasing services for lab equipment and supplies.

Enzo Discusses Payment Pressures Facing Labs

Enzo Biochem Inc. (Farmingdale, NY) reported revenue of $16.8 million from its clinical laboratory testing business for the three months ended July 31, 2018, down 18% from $20.4 million for the same period a year earlier. Enzo's clinical testing gross margins were 33% in the latest quarter compared to 41% a year ago. Enzo said that approximately half of the revenue decline related to an account loss with the remainder due to lower reimbursement rates and shifts in test mix away from certain higher-priced genetic tests.

Enzo operates a full-service clinical lab in Long Island, New York, a network of 32 patient service centers throughout greater New York and New Jersey, and a small rapid response lab in New York City. Approximately 16% of Enzo's clinical lab revenue is from Medicare, while UnitedHealthcare and Oxford Health Plan represent approximately 39%.

On October 16, Enzo held a conference call with analysts that highlighted some of the challenges that it and other clinical lab companies now face. On the topic of reimbursement pressure, Enzo's President and CFO Barry Weiner noted: "Most recently, insurers are notifying their network laboratories that they intend to renegotiate contractual payment rates following CMS payment rate reductions instituted by PAMA. While laboratories are all too familiar with these types of changes, which have taken place gradually over the past year, the pace and wide range of change occurring currently among payers is unprecedented."

Enzo's plan for dealing with current reimbursement pressure includes scaling up through new in-network insurance contracts and geographic expansion into Connecticut and the New England states.

Bako Diagnostics Wins Court Ruling In Non-Compete Lawsuit

The Delaware Court of Chancery has enjoined two former pathologist executives from Bako Diagnostics (Alpharetta, GA) from starting a competing dermatopathology lab company. "The court intends to issue a formal written order regarding the hearing in the coming weeks and we look forward to putting this matter behind us," according to a statement from Bako Diagnostics.

The dispute centered on Bradley Bakotic, DPM, DO, a dermatopathologist and former Chairman and CEO at Bako Diagnostics, who left the company with co-founder Joseph Hackel, MD, in September 2017. Late last year, the pair filed a preemptive lawsuit, seeking to invalidate their agreements not to compete against Bako Diagnostics for two years after departing.

In response, Bako Diagnostics filed counterclaims on February 12, 2018 to protect its business and uphold the non-compete agreements made by Dr. Bakotic and Dr. Hackel when they sold their interests in Bako in 2016 for over $30 million and $14 million, respectively (see *Laboratory Economics*, August 2018).

Consonance Capital Acquires StrataDx

In related news, Consonance Capital Partners (New York City) has acquired StrataDx (Lexington, MA) for an undisclosed amount. StrataDx is a dermatopathology and oral pathology laboratory that employs five dermpaths, three oral pathologists and three surgical pathologists.

Consonance Capital is also the owner of Bako Diagnostics, which it acquired in January 2016 in a deal that valued the company at $242.5 million.

Consonance Capital plans to maintain the StrataDx laboratory with current CEO Lisa Cohen, MD, in charge of operations.

Spotlight Interview with Altius Diagnostics Chief Scientific Officer Tania Sasaki


Tania Sasaki, PhD

Altius Diagnostics Laboratory (Bellevue, WA), a small toxicology lab founded three years ago in the Seattle area, has navigated the challenging laboratory landscape and experienced significant growth over the past 18 months. The lab now plans to expand into other areas of clinical laboratory testing. *Laboratory Economics* recently spoke to Tania Sasaki, PhD, Chief Scientific Officer.

How big is Altius and what was the impetus in starting the lab?
There are five owners and we have about twelve employees. Our goal was to start a niche, boutique lab to provide another option to some of the bigger labs.

Who are your clients and what areas do you serve?
Our clients are primarily pain management clinics and addiction/rehab centers. We're nationwide with the exception of New York, because of laboratory licensing requirements.

Do you do employment drug screening or are you focused primarily on prescription drug monitoring?
All of our testing is medication monitoring in the clinical space. We test for around 60 different drugs and metabolites, both prescription and illicit.

Are you growing, and if so, by how much?
The first year to year and a half was challenging as a start-up lab, but over the past 18 months I would say we've seen growth of 30% to 50%. Now that we're more established, I expect that growth rate to level out.

What do physicians do with the test results they receive from you if it appears that a patient is abusing prescription drugs?
The goal of testing is about patient care; it's not meant to be punitive. If there's an unexpected positive test result, the practitioner will counsel the patient, and may release the patient from a pain management program because patients typically sign a contract with the provider. But providers don't kick the patient out and leave him/her "hanging." The provider will refer the patient to an addiction specialist, a psychologist or someone who can help them address the drug problem.

What are your thoughts on the fairly new bundled G-codes for toxicology testing?
To some extent the spirit of the changes make sense. However with all the focus on the opiate epidemic and designer drugs (novel psychoactive substances – NPS), it is difficult for a laboratory to offer tests for the "latest and greatest" NPS. It's expensive and time consuming to constantly develop and validate new tests. Therefore, it's really challenging for a lab to go through R&D and offer tests that are relevant given the current reimbursement structure. We have made the business decision not to develop tests for novel psychoactive substances because the substances change so rapidly. If necessary, we will reference those tests out to another lab. We have developed tests for things like Kratom, an herbal leaf whose active ingredient does not change.

Have you been affected by the 10% PAMA CLFS cuts in 2018 (with another 10% cut in 2019)?
Toxicology labs got a little bit lucky because the cuts were not as bad as we had expected. Initially, [Medicare] was going to decrease the G codes approximately 10% each year for the next three years, but they revised that in December. CMS inadvertently omitted the G codes from its final determinations, so they corrected it and cross-walked the G codes to CPT code 82542, so the cut was not quite 3% for 2018, and will remain the same in 2019 and 2020.

Do you have any plans to expand into other areas of clinical lab testing?
We are planning to add general chemistry testing to our offerings. Our goal is to fill a niche where providers aren't getting the services they need, especially small providers. We have also discussed adding hormone testing and possibly genetics, too. The goal is to expand our test menu to include tests outside toxicology by the end of 2019.

What are the greatest advancements being made currently in toxicology testing?
Toxicology testing is a relatively mature field. Novel psychoactive substances have been a challenge because they change so rapidly. There have been some new techniques that allow you to retrospectively go back and analyze data from a sample to gain additional information without having to re-prepare and re-test it. So, if a new fentanyl analog is identified, we have the ability to go back and re-examine data that have already been collected and obtain information about a potentially positive result.

How do you see toxicology testing changing over the next five years?
Because it is a mature field, I don't think there's going to be a game changer. I think the challenge is how we can perform testing easier, cheaper and faster, as well as keep up with the ever-changing designer drugs. I do think we will see more affordable, more accurate point-of-care testing that could be easily performed in non-reference labs, such as physician's office labs.

Lab Worker Wages Growing By 2-3% Per Year

Average annual wages for medical lab workers in the United States rose by an average of approximately 2-3% per year between 2013 and 2017, according to data from the American Society for Clinical Pathology's latest Wage Survey of Medical Laboratories, published online Oct. 1 in the *American Journal of Clinical Pathology (AJCP)*.

The latest ASCP Wage Survey collected a total of 14,682 lab worker responses in April 2017. Demographic data collected showed that 81% of respondents were female and 19% were male. The average age of lab personnel who responded was 43.

Average Annual Wages by Title and Level

Job Title	2013	2015	2017	4-Year CAGR
MLS/MT/CLS (lab director level)	$92,946	$96,990	$102,019	2.4%
Pathologist Assistant (staff level)	96,346	91,797	96,788	0.1%
MLS/MT/CLS (manager level)	77,113	83,263	88,321	3.5%
Cytotechnologist (staff level)	64,416	65,943	72,377	3.0%
MT/MLS/CLS (staff level)	56,430	57,383	61,112	2.0%
Histotechnologist (staff level)	55,390	60,913	56,370	0.4%
Histotechnician (staff level)	49,837	57,439	54,238	2.1%
MLT/CLT (staff level)	42,619	39,733	45,715	1.8%
Phlebotomist (staff level)	32,448	31,142	32,985	0.4%

Source: ASCP's Wage Survey of Medical Laboratories for 2013, 2015 and 2017

Medical technologist/medical laboratory scientist/clinical laboratory scientist (MT/MLS/CLS) at the laboratory director level had the highest average annual wages at $102,019, with an average annual increase of 2.4% from 2013-2017.

Staff-level phlebotomist had the lowest average annual wage ($32,985), and was also among the slowest in terms of wage growth (0.4% per year).

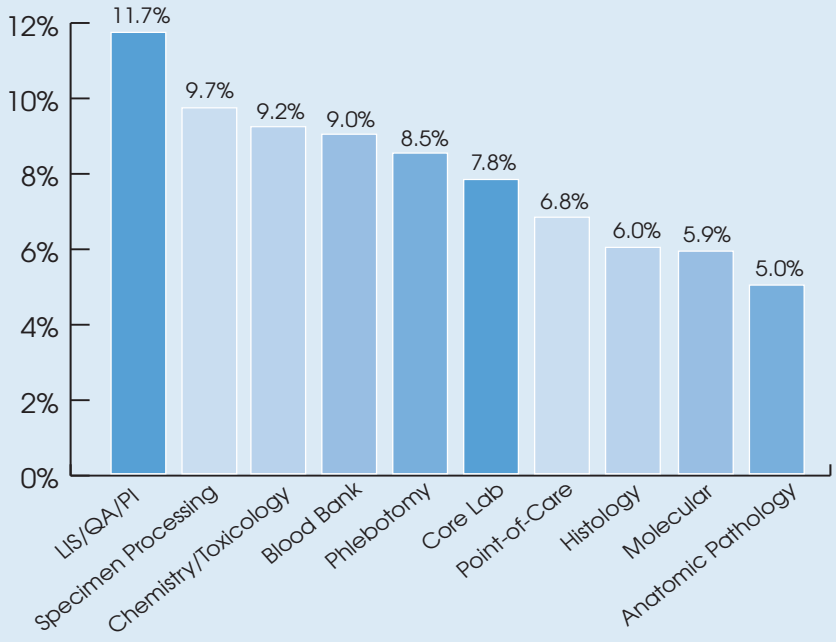
The most common comment submitted by survey respondents (cited by 39%) addressed being underpaid/underappreciated (especially compared with nursing and other allied health professions).

LIS/QA/PI Workers Are Hardest To Find

A separate ASCP survey published earlier this year showed that laboratory information system/quality assurance/performance improvement (LIS/QA/PI) departments were having the greatest difficulty in finding and hiring workers.

The vacancy rate for LIS/QA/PI staff positions is 11.7%, the highest vacancy rate out of all departmental staff surveyed. Survey respondents from the LIS/QA/PI department indicated that they anticipate a 28.3% overall retirement rate in the next 5 years, the highest overall retirement rates among all departments. Furthermore, survey respondents said it takes 6 months to a year on average to hire a supervisor in LIS/QA/PI.

Staff Vacancy Rates by Laboratory Department



Source: ASCP Vacancy Survey for 2016-2017

The ASCP Vacancy Survey was conducted in late 2016/early 2017 and collected responses from 1,340 lab managers representing 51,586 employees. A summary of the survey results was published in American Journal of Clinical Pathology (Volume 149, Issue 5, 29 March 2018, Pages 387–400).

Correction: Key BRCA Testing Code CPT 81162 Will Remain In 2019

The previous issue of *Laboratory Economics* incorrectly stated that the key BRCA gene analysis code CPT 81162 was being deleted and replaced by two new significantly lower-priced component codes next year.

In fact, the 2019 CPT still includes 81162 with only a minor revision to its description indicating that it is to be used to report full BRCA1/BRCA2 sequencing and deletion/duplication testing when performed on the same date of service.

Medicare reimbursement for CPT 81162 will only be reduced by 10% to $2,028 in 2019.

Consequently, Myriad Genetics and Ambry Genetics, the two independent labs performing the highest volume of CPT 81162, will not see as severe a decline in Medicare payments from this testing as *Laboratory Economics* had predicted.

Lab Stocks Up 58% Year To Date

Prices for 18 publicly-traded lab stocks are up 58% on an unweighted average basis through November 8. In comparison, the S&P 500 Index is up 3% 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 $99 million and annual revenue of $104.7 million for an EV/revenue ratio of 0.95. The most expensive lab company is Guardant Health, which recently came public. Guardant currently has an enterprise value of $2.9 billion and annual revenue of $67.2 million for an EV/revenue ratio of 42.9.

Company (ticker)	Stock Price 11/08/18	Stock Price 12/29/17	2018 Price Change	Enterprise Value ($ millions)	Enterp Value/ Annual Revenue
Enzo Biochem (ENZ)	$3.31	$8.15	-59%	$99	0.9
Cancer Genetics Inc. (CGIX)	0.70	1.85	-62%	32	1.1
Interpace Diagnostics (IDXG)	1.45	1.02	42%	30	1.6
Opko Health (OPK)	3.86	4.90	-21%	2,050	2.0
LabCorp (LH)	170.99	159.51	7%	23,440	2.1
Quest Diagnostics (DGX)	97.55	98.49	-1%	16,830	2.2
Sonic Healthcare (SHL.AX)	22.31	21.40	4%	12,500	2.3
Psychemedics (PMD)	18.03	20.56	-12%	94	2.3
Myriad Genetics (MYGN)	32.82	34.35	-4%	2,900	3.8
Veracyte (VCYT)	14.01	6.53	115%	353	4.4
NeoGenomics (NEO)	18.00	8.57	110%	1,280	4.7
Natera (NTRA)	21.31	8.99	137%	1,330	5.7
Invitae (NVTA)	14.46	9.08	59%	876	8.1
Genomic Health (GHDX)	90.18	29.39	207%	3,244	8.6
CareDx (CDNA)	28.38	7.34	287%	856	15.1
Exact Sciences (EXAS)	75.48	52.54	44%	7,170	20.3
Foundation Medicine (FMI)*	137.00	68.20	101%	5,350	26.5
Guardant Health (GH)	36.86	19.00	94%	2,885	42.9
Unweighted Averages			58%	$81,319	8.6

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

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