

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

United Adds Teeth To Preferred Lab Network

When UnitedHealthcare (UHC) first announced its Preferred Laboratory Network (PLN) back in May (see *LE*, May 2019) there were no financial incentives in place to drive members to choose a PLN lab versus a regular in-network lab. But that’s changing. UHC recently began offering the PLN with zero-dollar out-of-pocket charges for lab tests for the majority of its fully-insured members in select states. UHC also is making this same PLN benefit available to its self-insured employer groups beginning in 2020. *Continued on page 4.*

Pathology Rates Will See Little Change Next Year, But Significant Cuts Scheduled For 2021

The Final Medicare Physician Fee Schedule (MPFS) for 2020 reduces the professional interpretation rate for CPT 88305 by 1% to \$39.34, and increases the technical component by 5% to \$32.12. Overall, CMS estimates that 2020 Medicare rates for professional anatomic pathology services will be unchanged, while independent pathology lab technical rates will increase by 1%.

However, the Final MPFS also finalized a new plan to provide higher reimbursements to primary care providers at the expense of specialists like pathologists in 2021. *Full details on page 5.*

Trident Pays \$8.5M To Settle Kickback Allegations; Emerges From Bankruptcy Reorganization

TridentUSA Health Services (Sparks, MD) has agreed to pay \$8.5 million to settle two False Claims Act cases filed by former employees, Ravi Srivastava and Peter Goldman, on behalf of the United States. Whistleblower Srivastava had been Trident’s Chief Information Officer and Goldman had been a regional sales manager. They alleged that from June 2006 through September 2019, Trident’s MobilexUSA subsidiary provided mobile x-rays to nursing home clients at below cost for their Part A Medicare patients in order to obtain referrals for more lucrative Part B Medicare patients. *Continued on page 2.*

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Trident Settles Kickback Allegations; Emerges From Bankruptcy (*cont'd from p. 1*)

Srivastava will receive \$2 million as his share of the government's \$8.5 million recovery, and Goldman will get \$106,250. In addition, Trident is required to pay \$1 million to the whistleblowers' attorneys. The settlement, announced on September 25, helped clear the way for Trident to complete its bankruptcy reorganization.

Trident and its subsidiaries provide mobile x-ray, clinical lab testing and ultrasound tests to some 12,000 nursing homes in 36 states. The company has annual revenue of approximately \$475 million and about 5,300 employees. Its largest clinical lab subsidiaries include U.S. Lab & Radiology (Brockton, MA), Diagnostic Laboratories (Burbank, CA) and Schryver Medical Sales and Marketing (Denver, CO).

Trident filed for Chapter 11 bankruptcy reorganization on February 10 (see *LE*, March 2019) as a result of its heavy debt burden of \$785 million that became unsustainable due to declining occupancy rates at nursing homes, Medicare CLFS rate cuts and a botched billing system conversion.

On September 20, Trident emerged from bankruptcy reorganization. The reorganization eliminated \$600 million of debt and handed over 100% equity ownership to the hedgefund Silver Point Capital (Greenwich, CT), which provided \$185 million of exit financing. Silver Point's David Reganato, Partner and Head of Restructuring, has been given a board seat. David Velez, formerly Trident's Chief Operating Officer, has been named Chief Executive Officer at the reorganized Trident.

Trident reported a net loss (excluding bankruptcy reorganization expenses) of \$20.8 million on revenue of \$261 million for the period February 10 through August 31, 2019. Post reorganization, Trident will benefit from reduced interest expense as well as a number of operational changes, including measures to increase collection rates, scaling back certain services and reducing labor costs. The company is also expanding its radiology services provided to the growing home health market.

Consolidation Among Nursing Home Labs

The combination of falling nursing home occupancy rates combined with the PAMA rate cuts to the Medicare CLFS has led to significant consolidation among independent labs serving this market.

- **BioReference Labs** (Elmsford, NJ) stopped providing phlebotomy services to nursing homes at the end of September.
- **Center's Health Care** (New York City), which operates 49 nursing homes primarily in New York, acquired **Modern Diagnostic Laboratory** (New York City) in late March.
- **Gamma Healthcare** (Poplar Bluff) acquired the nursing home lab business of **Boyce and Bynum Pathology Laboratories** (Columbia, MO) in late 2018.
- **American Clinical Laboratories** (Stone Mountain, GA) sold its physician office client business to **LabCorp** in December 2018, while its nursing home business was taken over by **Clinical Laboratory Services** (Winder, GA).
- **Bestcare Laboratory Services** (Webster, TX) was closed in late-2018 after a federal judge ordered the company to pay \$30.5 million for overcharging Medicare for mileage to transport patient specimens collected from nursing homes. In addition, HHS OIG placed a 15-year ban on Bestcare and its owner, Karim Maghareh, PhD, from participation in all federal health care programs.
- **Reliable Mobile Labs** (Tempe, AZ and Medford, OR) abruptly closed in early 2018.

Top 25 Independent Nursing Home Labs

There are approximately 75 independent lab companies across the United States that are focused on the nursing home market. The table below lists the top 25 companies as measured by their volume of Part B services for G0471 in 2017 (the latest year of available data). G0471 is the billing code used exclusively for blood draws taken from nursing home and home health patients.

On a consolidated basis, TridentUSA Health Services is the largest nursing home lab with combined volume of 956,153 for G0471 at five lab subsidiaries in 2017. Its total Part B payments for all testing services was \$50 million in 2017.

American Health Associates (Miramar, FL) is next with volume of 851,305 for G0471 and total Part B payments of \$38 million in 2017.

Gamma Healthcare (Poplar Bluff, MO) is third largest with G0471 volume of 291,566 and total Part B payments of almost \$18 million in 2017. In addition, Gamma acquired the nursing home lab business of Boyce and Bynum Pathology Laboratories (Columbia, MO) in late 2018.

Top Independent Labs Serving Nursing Homes by Volume of G0471 Medicare Part B Services for 2017

Laboratory Name	Primary Location	G0471 Volume of Services	Total Part B Payments*
American Health Associates	FL, OH	851,305	\$38,327,301
Trident/U.S. Laboratories	FL, MA, MI, PA, RI	450,105	16,974,817
Gamma Healthcare	MO, TX	291,566	17,665,816
Trident/Diagnostic Laboratories	AZ, CA, CO, NV, TX	245,530	18,176,743
Aculabs Inc.	NY, NJ	187,124	7,939,451
Chicago Clinical Laboratories	Illinois	150,049	7,059,912
Trident/Schryver Medical Sales	CA, CO, TX, WA	144,173	9,227,771
Modern Diagnostic Laboratory (sold to Centers Health)	New York	134,610	7,122,200
Lifescan Laboratory	Illinois	108,562	4,665,847
Boyce & Bynum Pathology Labs (nursing home lab business sold to Gamma)	Missouri	101,888	9,989,451
Trident/MDX-MDL Holdings	California	92,970	4,106,234
BestCare Laboratory Services (out of business)	Texas	90,374	3,968,758
Eccolab Group	Florida	83,693	5,166,965
BioDiagnostic Labs	New York	54,054	2,189,100
Apex Laboratory	Florida, New York	52,704	11,842,703
Heartland Health Labs	Kansas	50,752	3,250,950
Brookside Clinical Laboratory	Pennsylvania	48,706	2,579,088
CD Laboratories	Maryland	46,685	3,178,451
Clinical Laboratory Services	Georgia	40,051	6,248,367
Collaborative Laboratory Services	Connecticut	34,848	2,822,270
Carolina Medical Lab Group	North Carolina	33,080	2,646,509
Reliable Mobile Labs (out of business)	AZ, OR, TN	31,599	6,289,312
Health Network Labs	Pennsylvania	29,307	12,271,172
Sonic/East Side Clinical Laboratory	Rhode Island	24,016	6,114,555
Trident/Metrostat Clinical Laboratory	Texas	23,375	1,386,254

*Total Part B carrier payments for G0471 and all lab tests

Source: *Laboratory Economics* from CMS

United Adds Teeth To Preferred Lab Network (*cont'd from page 1*)

A UHC spokesperson says that its large-group fully-insured members in Illinois, Indiana, Iowa, Kansas, Michigan, Missouri, Nebraska, Oklahoma and Texas now have zero out-of-pocket payment responsibility (no co-pay and no co-insurance), if they use one of the five PLN labs effective October 1, 2019. UHC plans to expand this same benefit to other states and commercial market segments, including its self-funded ASO (administrative services only) employer groups, in 2020.

UHC's Preferred Lab Network currently includes BioReference Labs (including GeneDx), Invitae, LabCorp (and all subsidiary labs), Mayo Clinic Laboratory and Quest Diagnostics (including AmeriPath). UHC plans to update the PLN (adding or subtracting labs) annually.

UHC has 8.3 million fully-insured commercial members throughout the United States and offers administrative and network management services to another 19 million members in self-funded employer groups. Its self-funded employer groups will need to opt in to the PLN benefit design change, and UHC has not indicated how many of these groups will adopt the change.

In addition, UHC covers 9.7 million members in Medicare Advantage and supplement plans plus another 6.4 million in Medicaid plans. These members are mostly served through exclusive capitated lab arrangements and are not likely to be affected by the PLN benefit change.

On an October 22 conference call, Quest CEO Steve Rusckowski said, "We're hopeful that this change coupled with the changes taking place in 2020 will continue to allow us to grow our presence and our share with United, but also with other payers because we do believe it's a trend overall in the marketplace."

Quest CFO Mark Guinan noted that the new PLN benefit design offers a clear incentive to patients. "Hey, if you use one of the preferred labs you pay zero out-of-pocket. That's a very simple message instead of trying to compare how expensive each option might be."

BeaconLBS Program Discontinued in Florida

UHC pulled the plug on the BeaconLBS pilot in Florida effective August 31. BeaconLBS, which is owned by LabCorp, had run a lab benefit management (LBM) program in Florida for approximately 430,000 UHC commercial members since 2015.

Even though the LBM program in Florida has ended, BeaconLBS will continue to administer UHC's national Genetic and Molecular Lab Testing Notification/Prior Authorization program, which has been rolling out across the country for certain UHC commercial plans since Nov. 1, 2017. The 430,000 UHC commercial members in Florida were transitioned to the national prior authorization program in September.

On an October 24 conference call, LabCorp CEO Dave King noted, "From my perspective BeaconLBS was a huge success in Florida. Certainly there was some market push-back about utilization management. But there were significant savings realized. There was a much higher level of network adherence from physicians, so it certainly works."

Tighter Controls on Out-of-Network Lab Referrals

Following a short delay, UHC is launching a new out-of-network lab test referral request process for its commercial plans starting Nov. 8, 2019 (see *LE*, March 2019). The new protocol requires physicians to get written consent from a patient before using an out-of-network lab. The patient consent form indicates that the patient has agreed to use an out-of-network lab despite the potential increased out-of-pocket costs. The physician must also get approval from UHC before using an out-of-network lab.

Pathology Rates Will See Little Change Next Year (*cont'd from page 1*)

CMS released the Final MPFS Rule for 2020 on November 1. Below we highlight the final Medicare rates for several key pathology codes for 2020. Medicare rates are critical not only because Medicare is the largest payer for pathology services, but also because nearly all commercial insurance plans and Medicaid baseline their rates on the MPFS.

Special Stains

The global rate for CPT 88312 (Special stains, group 1) will increase by 5% to \$107.19; professional interpretation up 0.1% to \$27.79; technical component up 7% to \$79.40. The global rate for CPT 88313 (Special stains, group 2) will increase by 4.5% to \$77.23; professional interpretation up 0.2% to \$12.63; technical component up 5% to \$64.60.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) will decrease by 1% to \$107.19; professional interpretation down 0.8% to \$36.81; technical component down 1.4% to \$70.37. The global rate for CPT 88341 (IHC, additional slide) will decline by 0.2% to \$94.19; professional interpretation down 1.1% to \$29.59; technical component up 0.1% to \$64.60.

Prostate Biopsies

Global reimbursement for G0416 (prostate biopsy, any method) decreased by 10% to \$347.90, including a 19% cut to the technical component and a 0.1% reduction to the professional service. The good news is that 2020 is the last year of the phase-in cuts to G0416 from its misvalued code revaluation in 2015/2016.

Flow Cytometry

CPT 88185 (flow cytometry, TC, add on) was lowered by 10% to \$22.38. This completes the phased-in cuts for CPT 88185 under Medicare's Misvalued Code Initiative.

Pap Testing Interpretations

A CMS review of the physician work relative value units (RVUs) used to calculate the professional component of cytopathology screening services resulted in a 38% reduction in the RVUs for several codes (88141, G0141, G0124 and P3001). For example, the phased-in cut for 88141 (cytopathology, cervical or vaginal, requiring interpretation by physician) for 2020 is 19% to \$26.35, which will be followed by another similar reduction in 2021.

Pathology Cuts Finalized for 2021

Concern over potential shortages of primary care physicians has led CMS to finalize significant rate hikes for the evaluation and management (E&M) codes used to reimburse these physicians for office/outpatient visits. Under budget-neutrality requirements, these rate hikes are being offset by rate reductions to specialists who rarely bill for E/M services, including pathologists. As a result, pathologist professional rates are projected to decrease by 8% in 2021, while the technical fees paid to independent pathology labs will decline by 4%.

Exactly how CMS will implement these cuts to pathology professional and technical payments is not yet clear. Will the cuts be applied equally across the board to all professional pathology codes (-8%) and all technical component codes (-4%), or will there be variations depending on the code? "We're very eager to find out how CMS will do it... There are some ways of implementing this that we would prefer over others," said Stephen Black-Schaffer, MD, on a College of American Pathologists conference call on November 8. Based on current information, Black-Schaffer said that a hospital-based pathologist at a general hospital should expect an 8% reduction in Medicare payments in 2021. More details are expected when CMS publishes its next proposed MPFS in late summer 2020.

Final Medicare Rate Changes for Key Pathology Codes for 2020

CPT/HCPCS	Short Description	Final 2020¹	Final 2019²	Rate % Change
88120-Global	FISH-manual, 3-5 probes	\$589.34	\$608.70	-3.2%
88120-26	FISH-manual, 3-5 probes	60.27	60.19	0.1%
88120-TC	FISH-manual, 3-5 probes	529.07	548.52	-3.5%
88121-Global	FISH-computer assisted, 3-5 probes	450.40	488.33	-7.8%
88121-26	FISH-computer assisted, 3-5 probes	50.89	51.18	-0.6%
88121-TC	FISH-computer assisted, 3-5 probes	399.51	437.15	-8.6%
88184-TC only	Flow cytometry/1st marker	68.21	67.75	0.7%
88185-TC only	Flow cytometry/each add'l marker	22.38	24.87	-10.0%
88187-26 only	Flow cytometry, read 2-8	39.34	38.92	1.1%
88188-26 only	Flow cytometry/read 9-15	66.04	65.95	0.1%
88189-26 only	Flow cytometry, read 16 & greater	88.78	88.30	0.5%
88305-Global	Tissue exam by pathologist	71.46	70.28	1.7%
88305-26	Tissue exam by pathologist	39.34	39.64	-0.8%
88305-TC	Tissue exam by pathologist	32.12	30.63	4.9%
88307-Global	Level V, tissue exam by pathologist	281.50	273.54	2.9%
88307-26	Level V, tissue exam by pathologist	86.62	86.85	-0.3%
88307-TC	Level V, tissue exam by pathologist	194.88	186.68	4.4%
88309-Global	Level VI, tissue exam by pathologist	427.66	415.53	2.9%
88309-26	Level VI, tissue exam by pathologist	152.66	153.53	-0.6%
88309-TC	Level VI, tissue exam by pathologist	275.00	262.00	5.0%
88312-Global	Special stains, group 1	107.19	101.99	5.1%
88312-26	Special stains, group 1	27.79	27.75	0.1%
88312-TC	Special stains, group 1	79.40	74.24	7.0%
88313-Global	Special stains; group 2	77.23	73.88	4.5%
88313-26	Special stains; group 2	12.63	12.61	0.2%
88313-TC	Special stains; group 2	64.60	61.27	5.4%
88331-Global	Pathology consult during surgery	100.33	99.11	1.2%
88331-26	Pathology consult during surgery	65.32	65.59	-0.4%
88331-TC	Pathology consult during surgery	35.01	33.52	4.4%
88341-Global	Immunohistochemistry (Add'l stain)	94.19	94.42	-0.2%
88341-26	Immunohistochemistry (Add'l stain)	29.59	29.91	-1.1%
88341-TC	Immunohistochemistry (Add'l stain)	64.60	64.51	0.1%
88342-Global	Immunohistochemistry (1st stain)	107.19	108.48	-1.2%
88342-26	Immunohistochemistry (1st stain)	36.81	37.12	-0.8%
88342-TC	Immunohistochemistry (1st stain)	70.37	71.36	-1.4%
G0416-Global	Prostate biopsy, any method	347.90	386.34	-9.9%
G0416-26	Prostate biopsy, any method	185.50	185.60	-0.1%
G0416-TC	Prostate biopsy, any method	162.40	200.74	-19.1%
88141	Cytopath, cerv/vag, with interpretation	26.35	32.44	-18.8%
88175	Liquid-based Pap test with auto screen & manual redo	26.61	29.44	-9.6%
87624	DNA-based HPV test, high-risk types	35.09	38.99	-10.0%

¹Payments based on the 2020 conversion factor of 36.09; ²Payments based on the 2019 conversion factor of 36.04

Source: *Laboratory Economics* from CMS

Key Legal Issues in Laboratory Mergers & Acquisitions

Consolidation in the clinical lab and anatomic pathology markets has been a steady and ongoing process for the past 20+ years. For an inside look at some common legal issues encountered during a laboratory transaction, *Laboratory Economics* spoke with two healthcare attorneys from McDonald Hopkins (Cleveland): Rick Cooper, Co-Chair, National Healthcare Practice Group, and Christal Contini, Co-Chair, Mergers and Acquisitions. Cooper and Contini, together with the other members of their firm's laboratory industry team have advised clients on multiple laboratory transactions, including 20 over the past three years. Cooper and Contini have represented clinical, anatomic, molecular, toxicology and independent and hospital-owned laboratories in deals ranging in size from \$10 million to \$250 million.



Rick Cooper



Christal Contini

Non-Compete Agreements

There's been a trend toward buyers seeking more comprehensive non-compete agreements for longer durations. For example, non-compete contracts have typically been set to 5-year terms, but we have seen an increase in buyers negotiating for 7-10 year terms.

From the seller's perspective, you want to limit the scope as much as possible either to a specific geography and/or a specific type of testing that specifically relates to the business being sold (e.g., clinical, anatomic pathology, genomic testing).

In addition, health systems selling their outreach labs need to be mindful of non-compete contract language that might limit their ability to make future acquisitions of physician practices that operate their own labs.

Contingent Payments and Earnouts

Sellers will want to minimize the portion of the purchase price they receive that's contingent on the performance of their lab while under the new owner's control. As a seller, you'll want full payment at the close of the deal.

However, contingent payments, or earnouts, based on future performance are useful in situations where a lab is expected to dramatically increase its revenue in the future because of, for example, the recent addition of a new insurance contract or launch of a new testing service.

As a seller, you'll want the terms that trigger a contingent payment to be as clear and specific as possible. And you'll want a process for resolving any potential disputes over the calculation of a contingent payment to be included in your deal contract.

Finally, you'll want to avoid "all or nothing" contingent payments that are based on hitting a single volume, revenue or EBITDA goal. A tiered approach that pays, for example, 80% of the max payment if 80% of the volume or revenue target is met, can mitigate buyer-seller disputes.

Compliance Issues that Scare Potential Buyers

The best approach is to have your lab's operations audited by an outside compliance expert prior to putting your lab up for sale. That way you can find, fix and disclose any issues to potential buyers. The worst thing that can happen is to have a buyer discover a material issue during their due diligence process and wonder "Is this the tip of the iceberg?"

Questionable Financial Arrangements with Referring Physicians

Questionable financial arrangements could include, but are not limited to, placement of equipment and personnel at referral source locations, or medical director agreements or lease arrange-

ments which do not meet applicable safe harbor requirements, including well-documented fair market value. Fixing these issues can result in the loss of certain client relationships and may lower revenue, but it must be done.

The Complexity of Hospital Lab Outreach Transactions

At most hospitals, laboratory outreach, outpatient and inpatient testing are tightly integrated with each segment using the same employees, instruments, lab space, LIS, et al. Untangling the pieces to identify test volume, payer contract pricing, net collected revenue and other financial information specific to the lab outreach business is often a difficult and time-consuming process.

Another layer of complexity is added when the transaction also involves hospital outpatient and/or inpatient testing. In these instances, the hospital will require long-term service contracts spelling out required service and quality metrics from the buyer.

From the buyer's perspective, they spend a lot of time (90-180 days) preparing new electronic interfaces with the physician office clients they'll be adding. They want to be sure that the minute the deal is completed, they can "flip a switch" and be connected to their newly acquired clients.

Showing a United Front

The owners at the selling lab need to designate one or two representatives that will handle communication with any potential buyer. Any infighting or internal issues amongst the owners over the terms of a deal should be resolved behind closed doors.

Keep the Trains Running on Time

The process of selling a laboratory rarely moves as quickly as initially anticipated and can take anywhere from six months to two years to complete. Often, when a laboratory is moving toward a sale, its employees get insecure about the future of their employment and seek work at a competing lab. This can lead to a loss of clients or contracts that can affect the final sales price or derail a deal all together. "Stay bonuses" can be used to retain and motivate senior management and key employees during a sale process. A typical stay bonus might involve paying key employees a percentage of their salary as a bonus in return for staying with the laboratory through the close of the transaction. The amount of this bonus varies by the position and the importance of the employee in maintaining key relationships.

The EKRA Law Banning Commission-Based Lab Sales Reps Remains In Effect

On October 24, 2018, The Eliminating Kickbacks in Recovery Act of 2018 (EKRA) became law (see *LE*, December 2018). EKRA was part of broader legislation (The SUPPORT Act) intended to address the national opioid crisis.

The EKRA 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 insurance plans as well as Medicare and Medicaid). EKRA applies to all laboratories (toxicology, molecular, routine clinical, anatomic pathology, et al.), not merely labs that perform testing for recovery homes and clinical treatment facilities. Violation of EKRA is punishable by a fine of up to \$200,000 and/ or imprisonment of up to 10 years for each occurrence.

The American Clinical Laboratory Association and its largest member labs have lobbied to have EKRA narrowed so that it applies only to laboratories associated with substance abuse services. However, to date, no changes have been made to the EKRA law.

McDonald Hopkins' attorney Rick Cooper says that although there are no changes to EKRA expected in the near term, there may eventually be some narrowing of the law made in the long horizon.

Spotlight Interview With CellNetix's CEO Kathleen Fondren

CellNetix Pathology & Laboratories, currently based in Seattle, will move to a new 46,000-square-foot operational hub in the Greater Seattle suburb of Tukwila next spring. *Laboratory Economics* recently spoke with CEO Kathleen Fondren about CellNetix's expansion plans.



Kathleen Fondren

Why did you decide to expand?

We are continuing to grow, and about 18 months ago we started looking at strategic options. After our merger with Puget Sound Institute of Pathology (PSIP) in 2017, we realized we needed to expand our space. Also, our molecular division has grown and we needed adequate space that keeps up with the equipment and facility demands. From a logistics perspective, it also makes sense. Seattle is growing and with that comes a lot of traffic challenges and congestion. We wanted to relocate to an area where we would still have access to our key customers but also have better access to the airport and the I-5 corridor and make access easier for our couriers. Economically, it also made sense for us. We decided on a space in Tukwila, which is about nine miles away. We are taking over the entire top floor of an existing space and building for the future. Additionally, we will have enough space for 12 to 16 grossing stations.

How many clients do you have?

Overall, about 1,250, including 28 hospitals. The bulk of our volume comes from the hospitals along with several large, multi-specialty practices.

What kind of growth have you seen since you merged with PSIP?

The merger resulted in 28% growth. Since then, we have seen another 6% organic growth annually. We have opportunities in the pipeline, and expect to see double-digit growth in 2020. We currently process about 230,000 surgical cases a year, with another 150,000 Pap smears. After the merger with PSIP, we integrated about 70,000 surgical cases into our laboratory. After integration, we began the process of optimizing our operations. We felt it would be beneficial to have the most efficient operation possible before designing and moving into our new space. We also brought on board a new chief operating officer in early 2019, Tim Rich, the former CEO of Phenopath (acquired by Quest Diagnostics in 2018). We have improved efficiencies and service since he's been with us.

What areas will you be able to grow as part of this expansion?

We will be able to design the space to be more efficient for our molecular laboratory. Another area that is key is that we will be able to expand our staff area to make their experience while they are at work as pleasant as it can be. We have about 350 employees, although not all are at the core laboratory. We have about 65 pathologists. We will continue to maintain a satellite operation in Seattle where many of our pathologists are located serving our downtown Seattle hospitals and customers.

Do you use digital pathology?

Yes, we do. We're looking to be able to leverage digital pathology at some of our more remote sites and the ability to have primary sign-out. Currently, we're using Leica's Aperio system mostly for preliminary diagnosis for IHC stains, and the pathologist still waits for the slides to give their final diagnosis. We're hoping we can start to use it for primary sign out of cases as well, so the diagnosis will be made from the digital image.

What do you see as your biggest challenges as you transition to the new facility?

My biggest consideration is that we retain our staff—that's number one. We're looking at ways to be creative with staff scheduling, to help them commute when traffic is lighter. Our next challenge is making sure we execute the move seamlessly so we can continue to operate without interruption.

Nearly Half of MDx Test Claims Still Being Denied

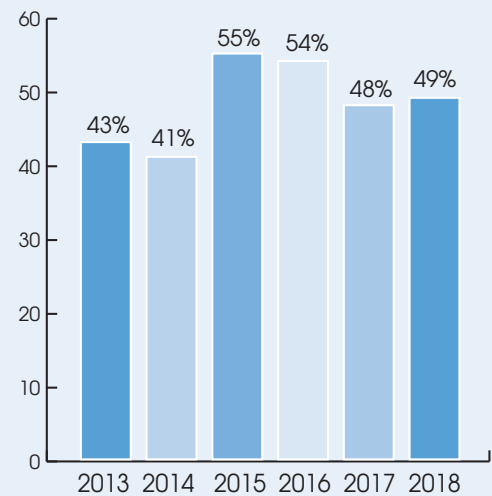
Forty-nine percent of molecular diagnostic (MDx) test claims were denied by Medicare Part B contractors in 2018, according to an exclusive analysis of the latest available Part B data by *Laboratory Economics*. The denial rate for MDx test claims has ranged from 41% to 55% since 2013, and it greatly exceeds the average 5% to 10% denial rate for routine lab tests.

The introduction of more specific CPT codes in 2013 has allowed both Medicare Administrative Contractors (MACs) and commercial insurance plans to deny claims for tests that they say have been improperly bundled, lack medical necessity or do not have adequate evidence of clinical utility. As with all types of claims, missing or incorrect patient demographic data (name, address, DOB, et al.) is also a common reason for denials.

High-volume MDx tests with high Part B denial rates include CPT 81599 (unlisted multianalyte assays with algorithmic analyses) at 93% denied claims, CPT 81227 (CYP2D9 genotyping), 84%, CPT 81479 (unlisted molecular pathology procedure), 81%, and CPT 81291 (MTHFR gene analysis), 77%.

Despite the high denial rates, Medicare Part B spending on MDx tests more than doubled to \$1.1 billion in 2018 from \$493 million in 2016 for an annual compound growth rate of 49%.

Medicare Part B Claims Denial Rates on MDx Tests



Source: Medicare Part B aggregate denied claims vs. submitted claims for CPT codes 81162, 81200-81599, and 88363, 88381 and G0452 for 2013-2018

Top 15 MDx Tests by Medicare Part B Allowed Charges

Code (brief description)	Part B Allowed Charges, 2018	Part B Allowed Charges, 2016	2-Year CAGR
81528 (Cologuard colorectal cancer screening)	\$170,684,377	\$62,981,228	65%
81479 (Unlisted molecular pathology procedure)	135,670,753	108,452,107	12%
81408 (Molecular pathology procedure, Level 9)	123,156,681	590,550	1,344%
81519 (Oncotype Dx breast cancer gene expression profiling)	78,474,014	61,127,540	13%
81162 (BRCA 1&2 gene analysis)	50,896,967	41,441,298	11%
81490 (Vectra DA rheumatoid arthritis test)	35,117,313	29,154,815	10%
81317 (PMS2 gene analysis)	32,237,646	4,352,908	172%
81493 (Corus CAD coronary artery disease gene analysis)	30,576,000	23,579,850	14%
81201 (APC gene analysis)	30,393,020	1,035,801	442%
81298 (MSH6 gene analysis)	26,848,339	945,393	433%
81545 (Afirma thyroid cancer test)	22,852,625	14,326,889	26%
81406 (Molecular pathology procedure, Level 7)	22,300,111	1,598,959	273%
81455 (Targeted genomic sequence analysis panel)	21,722,945	687,216	462%
81539 (4Kscore prostate cancer probability test)	19,429,114	NA	NA
81595 (AlloMap heart transplant gene expression profiling)	18,662,400	13,351,793	18%
Total, Top 15 MDx Tests	819,022,304	363,626,348	50%
Total, All MDx Tests	\$1,090,658,737	\$492,809,370	49%

Source: CMS Medicare Part B national data for CPT codes 81162, 81200-81599, and 88363, 88381 and G0452 for 2016 and 2018

More Executive Changes At LabCorp's Diagnostic Division

After only a few days in the position, LabCorp Diagnostics' CEO John Ratliff has resigned to take a top executive position at an unnamed company. Ratliff, age 59, had become head of LabCorp's diagnostic testing business effective November 1. He had formerly been CEO of Covance, LabCorp's drug development business.

Former LabCorp President and CEO Dave King, 62, had been serving as interim head of LabCorp's diagnostic testing business since January 1, 2019. King retired from his day-to-day executive positions at LabCorp on November 1, but is staying on as Chairman through at least the end of next year.

LabCorp says that its diagnostics division will now be led by two individuals. Brian Caveney, MD, 46, has been named Executive Vice President and President of Diagnostics. Caveney was formerly Chief Medical Officer at LabCorp. In addition, Mark Schroeder, 58, has become Executive Vice President and President of Laboratory Operations and Global Supply Chain. Schroeder was formerly LabCorp's Chief Supply Chain Officer.

Exact Sciences Completes Genomic Health Acquisition

Exact Sciences (Madison, WI) finalized its purchase of Genomic Health (Redwood City, CA) on November 8. The deal was initially valued at \$2.8 billion when first announced on July 29. However, a subsequent 30% drop in Exact's shares lowered the deal value to \$2.5 billion. Each share of Genomic Health was exchanged for \$27.50 in cash (worth \$1.1 billion) plus 0.45 shares of Exact Health (worth \$1.4 billion). The net deal worth was approximately \$2.2 billion after adjusting for \$275 million of cash held by Genomic Health at the time of the close. Thus the deal valued Genomic Health at 4.9 times its projected revenue of \$452 million for 2019.

Kim Popovits, 60, Chairman and CEO of Genomic Health, resigned from her positions after the transaction closed. She received a severance package of cash and vested stock and options worth \$13.4 million.

Meanwhile, Genomic Health's Chief Operating Officer Brad Cole has been hired by Exact as General Manager of the company's newly acquired Oncotype DX franchise.

Enzo Hires Investment Bank Lazard

Enzo Biochem (New York City) has hired the investment bank Lazard to assist in "strategic relationships and new venture creation." This news comes as Harbert Management Corp. (HMC-Birmingham, AL) has purchased a 12% equity stake in Enzo and nominated two new independent directors to its board. HMC wants Enzo to sell its drug development business and non-core patents, and focus on bringing its laboratory division, Enzo Clinical Labs, back to profitability (see *LE*, October 2019).

Separately, Enzo reported net income of \$2.5 million for its fiscal year ended July 31, 2019, compared to a net loss of \$10.3 million for the previous fiscal year. Total revenue was \$81.2 million, down 20% from \$101 million a year ago. The company's laboratory division recorded revenue of \$51.1 million, down 28% from \$71.1 million, as a result of reduced reimbursement rates and changes to medical and procedural requirements for genetic testing by payers.

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Lab Stocks Up 25% Year To Date

Twenty lab stocks have risen by an unweighted average of 25% year to date through November 12. In comparison, the S&P 500 Index is up 23% so far this year. The top-performing lab stock thus far in 2019 is Natera, which has soared 179%, followed by Guardant Health, up 96%, and Veracyte, up 89%. Shares of LabCorp are up 31%, while Quest Diagnostics is up 22%.

Company (ticker)	Stock Price 11/12/19	Stock Price 12/31/18	2019 Price Change	Enterprise Value (\$ millions)	Enterp Value/ EBITDA	Enterp Value/ Annual Revenue
LabCorp (LH)	\$166.12	\$126.36	31%	\$23,230	12.3	2.0
Quest Diagnostics (DGX)	101.92	83.27	22%	17,980	11.8	2.4
Sonic Healthcare (SHL.AX)	29.15	22.11	32%	16,260	16.6	2.7
Exact Sciences (EXAS)	79.91	63.10	27%	10,130	NA	14.0
Guardant Health (GH)	73.56	37.59	96%	6,380	NA	34.6
Natera (NTRA)	39.01	13.96	179%	2,940	NA	10.3
NeoGenomics (NEO)	23.20	12.61	84%	2,370	50.4	6.3
Genomic Health (GHDX)*	63.44	64.41	-2%	2,160	31.9	4.9
Myriad Genetics (MYGN)	24.20	29.07	-17%	1,960	26.5	2.4
Invitae (NVTA)	17.24	11.06	56%	1,510	NA	7.7
Opko Health (OPK)	1.43	3.01	-52%	1,200	NA	1.3
Veracyte (VCYT)	23.73	12.58	89%	965	NA	8.3
CareDx (CDNA)	20.27	25.14	-19%	853	NA	7.4
Castle Biosciences (CSTL)	26.09	16.00	63%	209	21.3	4.6
Exagen (XGN)	19.49	14.00	39%	133	NA	3.5
Enzo Biochem (ENZ)	2.86	2.78	3%	78	NA	1.0
Psychemedics (PMD)	9.04	15.87	-43%	48	6.4	1.2
Interpace Diagnostics (IDXG)	0.78	0.80	-3%	27	NA	1.1
Cancer Genetics Inc. (CGIX)	3.11	7.20	-57%	10	NA	0.4
Biocept (BIOC)	0.66	0.86	-24%	5	NA	1.4
Unweighted Averages			25%	\$88,448	22.1	5.9

*Genomic Health was acquired by Exact Sciences on November 8, 2019.

Source: *Laboratory Economics* and Capital IQ

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