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Volume 18, No. 7 July 2023

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UHC Delays Z-Code Start Date

UnitedHealthcare (UHC) has delayed its requirement of "Z-codes" for certain molecular test claims submitted to its commercial health plans to October 1 from its initial scheduled date of August 1. This gives labs a full five months to adapt to the new requirement since it was first announced on May 1, according to a UHC spokesperson.

UHC's new Z-code requirement will initially cover 136 CPT codes as well as 106 proprietary lab analysis (PLA) codes.

But this is only "Wave I." UHC is expected to add the Z-code requirement to certain PCR-based microbiology test claims for commercial plans within the next 12 months.

Full details on pages 4-5.

Proposed Medicare Rate Cuts of 2% for Pathologists

The proposed 2024 Medicare Physician Fee Schedule would result in an average rate cut of 2% for pathology professional rates and 1% for technical services. The reductions are the result of a 3.36% decrease in the proposed conversion factor (CF) for 2024. The conversion factor is the multiplier that Medicare applies to relative value units (RVUs) to calculate reimbursement for all physician services and procedures under Medicare's fee-for-service system.

A cut to the CF is needed to offset a new evaluation and management add-on code, G2211, that will increase payments to primary care physicians and nurse practitioners.

The proposed cut to the CF has already stirred up protest from the College of American Pathologists (CAP) and other specialty groups are sure to object as well.

More details on page 10.

Labcorp to Acquire Legacy's Outreach Lab

Labcorp has agreed to acquire select assets of the outreach laboratory business of Legacy Health (Portland, OR) and to manage its inpatient hospital labs under a long-term agreement. Legacy management has pointed to severe financial problems as a reason for the sale. The health system is currently losing about $10 million a month, which has forced it to dip into its own reserves. *Continued on page 2.*

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LABCORP TO ACQUIRE LEGACY'S OUTREACH LAB (*cont'd from page 1*)

Legacy owns and operates six hospitals in Oregon and southwest Washington as well as 85 physician office clinics and urgent care centers. Its biggest hospitals include Legacy Emanuel Medical Center (Portland; 498 beds) and Legacy Good Samaritan Medical Center (Portland; 213 beds).

Legacy reported an operating loss of $115 million for the nine months ended December 31, 2022, versus operating income of $12 million in the same period a year earlier; revenue was up 4% to $1.952 billion. Anna Loomis, Chief Financial Officer at Legacy, attributed the loss to higher personnel costs, longer patient stays, inflation and low reimbursement rates by Medicare and Medicaid. About 70% of Legacy's 500,000 patients are on Medicare, which typically pays hospitals less than private insurance.

Sale of Legacy Laboratory Services

The sale to Labcorp should give Legacy some breathing room.

Legacy will maintain ownership and licensure of its hospital labs as well as retain ownership of its core lab in Northeast Portland. Legacy's outreach lab business is focused on the Portland and Vancouver regions. *Laboratory Economics* estimates it has roughly $50 million in annual revenue.

No layoffs are anticipated as a result of the deal. Labcorp is expected to lease Legacy's core lab facility and hire about 700 Legacy lab employees.

In addition to clinical lab testing, Labcorp is expected to provide technical component services for anatomic pathology. Professional interpretations for Legacy's anatomic pathology services will continue to be provided by Cascade Pathology (Portland), which is owned by Sonic Healthcare.

Labcorp will also manage Legacy's inpatient hospital labs through a long-term agreement to provide staffing, management and supply chain services.

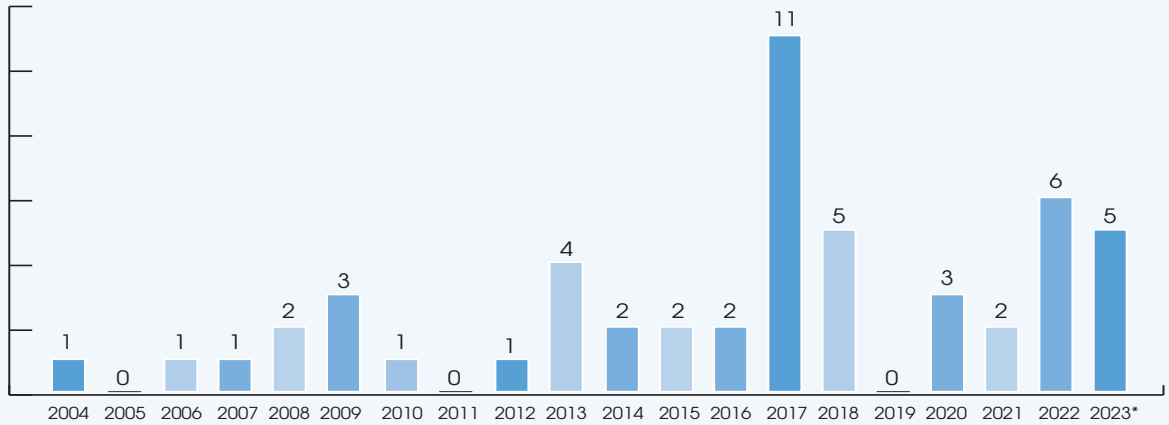
Colaborate (Tampa, FL) advised Legacy on the transaction, which is expected to close later this year.

Labcorp's deal with Legacy follows a similar agreement with nearby Providence Oregon, which was announced in May (see *Laboratory Economics*, June 2023, page 7).

Hospital Outreach Lab Sales Could Break Record

Meanwhile, both Quest Diagnostics and Labcorp have indicated that they have a full plate of potential hospital outreach lab acquisitions in the pipeline. One industry insider tells *Laboratory Economics* that there are as many as 12 hospital lab deals currently under negotiation. The greatest number of transactions (11 deals) took place in 2017—just prior to three straight years of 10% rate cuts to the Medicare CLFS due to PAMA. So far this year there have been five hospital outreach lab sales.

Number of Hospital Outreach Lab Sales Per Year



*Year to date through July 17, 2023. Source: *Laboratory Economics*

Labcorp Completes Spin-Off of Fortrea CRO Business

Labcorp completed the spin-off of its contract research organization (CRO) business to shareholders on June 30. The spin-off has resulted in two independent publicly traded companies, Labcorp (lab testing) and Fortrea Holdings (CRO). Fortrea is focused on providing Phase I-IV clinical trial management services to pharmaceutical and biotech companies.

Fortrea has 19,000 employees and is headquartered in Durham, North Carolina. Fortrea recorded net income of $178 million on revenue of $3.1 billion for the 12 months ended March 31, 2023.

Fortrea began trading on the Nasdaq under symbol FTRE in late June. It has a market value of approximately $3.1 billion based on current trading at $35 per share and 88.6 million shares outstanding. Including outstanding net debt of $1.5 billion gives Fortrea an enterprise value of $4.6 billion--a multiple of 26x net income and 1.5x annual revenue.

Fortrea at a Glance ($ millions)

Chairman & CEO	Tom Pike
Annual revenue	$3,081
Adjusted EBITDA	$387
Net income	$179
# Employees	19,000

Source: Fortrea Holdings

Labcorp initially entered the CRO business through the acquisition of Covance for an enterprise value of $5.6 billion in 2015. Labcorp then acquired several smaller CROs, including Chiltern for $1.2 billion in 2017.

Tom Pike is Chairman and CEO of Fortrea. Adam Schechter continues as Chairman and CEO of Labcorp, which has kept its core lab testing business and retained two related pieces from its CRO business (clinical trials testing and early-stage development).

Enzo Cuts Sales Price for Clinical Lab Assets

Enzo Biochem (Farmingdale, NY) has lowered the purchase price that Labcorp will pay for its clinical lab division (aka Enzo Clinical Labs) by $32.75 million—from an initial $146 million to $113.25 million. The new price is equal to 3x Enzo Clinical Labs' current annual revenue run rate of $38 million.

The lowered price follows Enzo's latest financial report which showed that revenue at its clinical lab division fell to $16.1 million in the three months ended April 30, 2023, down 39% from $26.2 million in the same period a year earlier. Enzo attributed the decline to: 1) a sharp drop in Covid-19 testing; 2) a reduction in core testing volume caused by downtime following a ransomware attack in early April; and 3) adjustments due to changes in payer policy and collection experience.

Meanwhile, Enzo Biochem plans to lay off 247 employees at its laboratory and office locations in Long Island, New York, according to filings with the New York State Department of Labor.

Labcorp is expected to consolidate most of Enzo's test volume into its regional lab in Raritan, New Jersey—about 90 miles west of Enzo's main lab in Long Island.

After Enzo completes the sale of its clinical lab division, the company will be left with its life sciences division, which develops, manufactures and sells reagents and test kits to clinical labs, researchers and pharmaceutical companies.

UNITEDHEALTHCARE PUSHES BACK Z-CODE REQUIREMENT (*cont'd from page 1*)

A UHC spokesperson tells Laboratory Economics that there are over 75,000 molecular diagnostic tests—with an average of 10 new tests added per day—and only 500 CPT codes to track all of these tests. This makes it difficult for ordering providers, labs and payers to properly identify the tests being performed to ensure accurate and appropriate payment, according to UHC.

Background on Z-Codes

Z-codes are five-character alpha-numeric codes assigned to molecular diagnostics tests by Palmetto GBA's MolDX program. Z-codes are used in conjunction with CPT codes on lab test claims. Z-codes are housed in a test registry catalog called the DEX Diagnostics Exchange that is managed by the MolDX program.

Palmetto GBA, which is owned by BlueCross BlueShield of South Carolina, is the Medicare Administrative Contractor (MAC) for Alabama, Georgia, North and South Carolina, Tennessee, Virginia and West Virginia.

Palmetto GBA's MolDX program is designed to help health plans better manage the utilization and reimbursement of molecular diagnostic tests. Its Z-code system includes a technical assessment that evaluates the clinical validity and utility of each molecular diagnostic test on a pass/fail basis.

The MolDX Program was developed in 2011 and has issued a total of more than 20,000 Z-codes to date, according to Gabriel Bien-Willner, MD, PhD, Program Medical Director for MolDX and Chief Medical Officer at Palmetto GBA.

Initially, MolDX focused on genetic tests, but more recently it has expanded into PCR-based infectious disease panel testing. The MolDX program currently has 15 FTEs, including five medical directors, and is currently receiving between 100 and 300 Z-code technical assessment applications per week. Bien-Willner says that Z-code turnaround time averages about two months.

Widespread Use of Z-Codes for Medicare Lab Claims

In addition to Palmetto GBA, there are three other MACs that use MolDX and Z-codes for their Medicare Part B test claims.

The three MACs that currently do not participate in MolDx are National Government Services (IL, MA, NY, etc.), Novitas (MD, NJ, PA, TX, etc.) and First Coast (Florida).

Clarisa Blattner

In addition, Clarisa Blattner, Senior Director of MDx Support Services at XiFin (San Diego, CA), notes that UnitedHealthcare has already been requiring Z-codes for its Medicare Advantage claims for more than one year. UHC currently covers 7.1 million Medicare Advantage members nationwide. Other private insurers that are using MolDX/Z-codes for their Medicare Advantage claims include BCBS of North Carolina, Medical Mutual of Ohio and Fallon Health (Worcester, MA). "I think that other private insurers will follow suit over time," adds Blattner.

UnitedHealthcare First to Require Z-Codes for Commercial Plans

Optum, which is owned by UnitedHealth Group, has an exclusive license with Palmetto GBA as a reseller of the DEX registry and its Z-codes. Optum markets the DEX product to other health insurers.

UHC is the first to require Z-codes for a broad list of genetic tests on facility and professional claims for commercial members effective October 1. UHC currently covers a total of 27 million commercial health plan members.

UHC received approximately 600,000 claims from in-network providers for molecular diagnostic tests performed for its commercial members in 2022. Over one-third of those claims used CPT codes that do not allow identification of the specific test being performed, according to a UHC spokesperson.

UHC says that providing the Z-code on a claim, along with the appropriate CPT code, will clearly identify the test being performed and eliminate some of the administrative burden that labs may encounter when billing for these services. Molecular diagnostics test claims for the specified 136 CPT codes and 106 proprietary lab analysis (PLA) codes that do not have both a CPT and Z-code will be denied payment starting October 1, according to UHC.

The scope of lab tests requiring Z-Codes by UHC commercial plans includes:

- ❑ All adult molecular diagnostic tests that are relevant to the Medicare age population (age 65+)
- ❑ Prenatal cell-free DNA Screening (PCFS) (formerly Noninvasive Prenatal Screening (NIPS))
- ❑ Prenatal Carrier Screening tests
- ❑ Specific services billed under 81479:
    - Prenatal cell-free DNA Screening (formerly Noninvasive Prenatal Screening (NIPS)
    - Prenatal Carrier Screening (genetic disease carrier status for procreative management)
    - Pharmacogenomics testing (PGx) including single-gene and multi-gene panels

Z-Code Requirement Likely for PCR-Based Infectious Disease Testing

UHC has clearly indicated plans to expand its Z-code requirement for other types of molecular tests. The question is "Which tests and when?"


Ann Lambrix

Ann Lambrix, Vice President, RCM Solutions at Lighthouse Lab Services (Charlotte, NC), thinks UHC commercial plans will follow a path similar to its Medicare Advantage Z-code rollout.

UHC Medicare Advantage plans started with Z-code requirements for genetic test claims and were then expanded last summer to include certain PCR-based microbiology test panels. These include test panels for urinary tract infections, respiratory viruses and sexually transmitted diseases.

PCR-based tests are some of the fast-growing tests, exceeding the growth of even genetic tests (see *Laboratory Economics*, April 2023, pp. 1, 4). Lambrix anticipates that UHC could begin requiring Z-codes for these tests later this year or early next year.

Lambrix notes that a lack of clinical utility evidence, which is defined as the impact on patient management and interpretation of results, is the most common reason why tests do not pass the MolDX technical assessment. Right now, she says that infectious disease syndromic panels are having the greatest difficulty, because labs are early in the process of establishing clinical utility for these tests. Payers, including MolDX, are demanding a reason why the less expensive gold standard (culture-based tests) will not support the same results or reach the same outcome for patient care, according to Lambrix.

Lambrix notes that other private payers have also begun instituting coverage policies designed to rein in the growth of PCR-based microbiology testing. For example, some plans are placing limits on the number of pathogens they will reimburse or requiring providers to use culture-based tests, according to Lambrix. (See page 6 for more on PCR-based microbiology testing.)

CAP Has "Serious Concerns" with UnitedHealthcare's Z-Code Rollout

The College of American Pathologists (CAP) has sent a letter to Optum requesting a meeting to discuss its partnership with Palmetto GBA and UnitedHealthcare's new Z-code requirement. CAP and Optum are in the process of scheduling the meeting, says Jonathan Myles, MD, Chair of CAP's Council on Government and Professional Affairs.

Myles notes that HIPAA designated AMA CPT as the official code set for use in claims, and CAP made the argument back when the Z-codes first started that it violated HIPAA to require the use of an alternative code set. Only CMS (HCPCS level II codes) or the AMA (CPT codes) may develop code sets for laboratory services under HIPAA. If a provider desires to file an electronic health care claim, a health plan must accept such a transaction that is filed in HIPAA standard format. Furthermore, only HIPAA-approved code sets may be required by a plan in connection with electronic health care claims, adds Myles.

Myles maintains that the existing CPT Editorial Panel has the infrastructure and capacity to process code requests on a quarterly basis, provide transparency and offer a public forum at regular intervals several times a year. This process would be the appropriate method for insurers to address any issues with information on specific tests without adding further requirements and reporting complexity.

CAP has requested that Optum and UHC remove Z-code requirements.

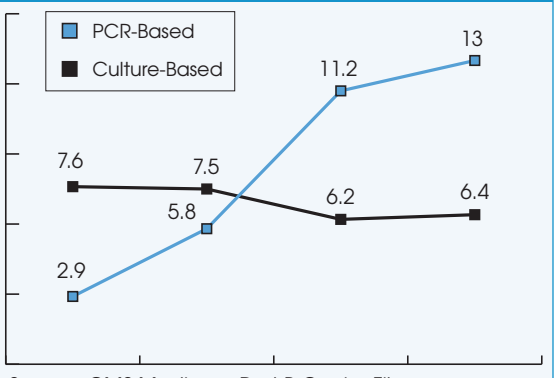
The Case for PCR-Based Microbiology Tests

The Covid-19 pandemic increased physician appreciation of the speed and accuracy of PCR-based testing. This in turn has helped accelerate the transition from culture-based methods for microbiology testing to PCR-based methods, according to Jorge Fonseca, Director of Product Management at Thermo Fisher Scientific.

For example, the volume of Medicare Part B carrier allowed claims for PCR-based microbiology tests (CPT 87798, 87481, 87801, 87640, etc.) increased by an average of 65% per year between 2018 and 2021. Over the same time frame, culture-based tests (CPT 87086 & 87088) fell by 6% per year.

Beyond just increased accuracy and turnaround times, PCR-based testing offers the ability to run panels that can simultaneously analyze multiple pathogens from a single sample, saving critical resources and time. For some infections, like sexually transmitted diseases and urinary tract infections, overlapping symptoms can make determining the exact illness difficult. But PCR-based testing can pinpoint specific pathogens and help determine the right antibiotic treatment, notes Fonseca.

Culture-Based vs. PCR-Based Medicare Test Volume (millions)



Source: CMS Medicare Part B Carrier Files

Meanwhile, payers are demanding that labs provide clinical evidence that justifies PCR-based testing, which can cost as much as several hundred dollars per patient vs. $8-15 for culture-based testing.

Fonseca says that there are plenty of published clinical studies backing the use of PCR for respiratory, gastrointestinal and sexually transmitted infections. In addition, he says that new clinical studies backing PCR for urinary tract infections and women's health panels (bacterial vaginosis and vaginitis) are now being published every few months.

Versant Buys PRW Laboratories

Versant Diagnostics (Oakbrook, IL) acquired PRW Laboratories (Charlottesville, VA), which specializes in dermatopathology, in early May. PRW Labs has seven dermatopathologists (4 full-time/3 part-time) and was founded in 2011 by James Patterson, MD; David Rowe, MD; and Mark Wick, MD.

Haverford Healthcare Advisors (Radnor, PA) provided advisory services to PRW Labs in this transaction.

Versant is a startup pathology company founded by Ven Aduana, MD, Jim Billington and Brian Carr in 2021 (see *LE*, November 2021). Versant, which currently manages about 38 pathologists at five practices, has $100 million in financing (both equity and debt) from Iron Path Capital (Nashville, TN). Versant is acquiring pathology practices and then seeking to add volume through the use of digital pathology.

DermTech Announces Restructuring Layoffs

DermTech (San Diego, CA) is suspending all of its pipeline development programs and focusing its resources on increasing its DermTech Melanoma Test (DMT) billable volume and expanding payer coverage.

The company's DMT test uses four skin patch stickers to non-invasively collect cells from a suspicious skin spot. The samples are then analyzed for the presence of genomic markers associated with melanoma at DermTech's laboratory in southern California. The DMT is reimbursed by Medicare through a Proprietary Laboratory Analysis code (0089U) at $760.

As a result of its restructuring actions, DermTech will lay off about 40 employees, representing about 15% of its workforce. The job cuts will mainly impact sales, marketing and administrative employees.

DermTech expects annualized savings of $25 million to $35 million after completing the restructuring. It expects to take a one-time restructuring charge of about $2 million in the second quarter.

DermTech reported a net loss of $31.3 million in the three months ended March 31, 2023, versus a net loss of $30.1 million in the same period a year earlier; revenue was down 6% to $3.5 million.

DermTech had cash and short-term securities of $108.4 million as of March 31, 2023. The company believes it will have sufficient cash resources to fund its planned operations into the first quarter of 2025.

Quest Diagnostics Introduces At-Home Genetic Test

Quest Diagnostics has launched its first direct-to-consumer genetic test, Genetic Insights, which is available through its consumer site questhealth.com. The test costs $199 plus a $12 physician service fee. PWNHealth, a telemedicine vendor owned by EverlyWell (Austin, TX), is providing oversight of orders. The test is available to consumers in all states except Alaska, Arizona, Hawaii and New York.

Individuals that order online receive an at-home saliva-collection kit and ship back their sample to a Quest laboratory. Quest then analyzes 36 genes to determine the patient's potential risk of having nearly two dozen inheritable conditions, including heart and blood disorders, breast and colon cancer, and the carrier status for sickle-cell anemia, cystic fibrosis and Tay-Sachs disease.

Test results are available online within three to five weeks. A one-on-one phone or video session with a PWNHealth board-certified genetic counselor to discuss results is offered at no extra charge.

OIG Recommends CMS Claw Back Up to $888 Million for CPT 81408

Inadequate oversight by the Centers for Medicare & Medicaid Services (CMS) of payments for the genetic test code CPT 81408 may have risked up to $888 million in improper payments, according to a recent audit by the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG).

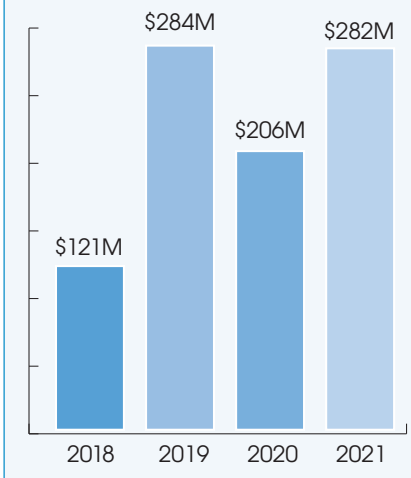
The OIG report analyzed Medicare Part B claims for more than 450,000 genetic tests billed under CPT 81408 that had dates of service from 2018 through 2021. The Medicare rate for CPT 81408 is $2,000.

CPT 81408 (Molecular pathology procedure, Level 9) may be billed when testing for multiple genes associated with rare diseases. The majority of the examples of diseases associated with the 24 genes listed for CPT 81408 in AMA's CPT description are rare childhood diseases—such as Duchenne and Becker muscular dystrophy, Joubert syndrome, and Marfan syndrome.

Therefore, the OIG report said that the genes associated with these diseases would not generally be tested for in the Medicare population and the use of CPT 81408 should be infrequent.

However, Medicare Part B payments for CPT 81408 totaled $282 million in 2021. This placed CPT 81408 as the eighth highest paid Medicare Part B test in 2021—just after seventh place CPT 85025 (Complete blood cell count). (See *Laboratory Economics*, January 2023, page 3.)

Medicare Part B Payments for CPT 81408



Source: CMS

The OIG's analysis of claims data identified ICD-10 Code: I10 (hypertension/ high blood pressure), as the principal diagnosis code that was included on the most claims billed under CPT code 81408. The use of CPT 81408 is not reasonable and necessary in connection with hypertension, according to OIG.

The OIG report noted that five of the seven Medicare Administrative Contractors (MACs) that process Part B claims have Local Coverage Article guidance that prohibits or limits the use of CPT 81408. However, two MACs (Novitas and First Coast) have no edits for CPT 81408, allowing for auto-payment of the code. Nearly all (97%, or $866 million) of the Medicare Part B payments for CPT 81408 between 2018 and 2021 went to labs located in regions covered by Novitas (MD, NJ, PA, TX, etc.) or First Coast (Florida).

During its audit, OIG found that their oversight activities failed to ensure that all Medicare enrollees had established relationships with ordering providers. They also failed to ensure that Medicare payments for a specific CPT code were related to diseases associated with genes that would generally be tested and billed under that code. Finally, the oversight activities failed to ensure adequate monitoring of the number of tests billed under the code.

Because there were no longer any Part B payments being made for CPT 81408 by the end of the OIG audit period (December 31, 2021), OIG considers the issues identified by its report to be corrected.

However, OIG has recommended that CMS direct the appropriate MACs to review claims billed under CPT 81408 for the audit period and recover up to $888 million for claims that were at risk of improper payment.

US Genomix Led in Medicare Payments for CPT 81408

Bio Choice Laboratory (Houston, TX), which did business as US Genomix, received a total of $125.8 million in Medicare Part B payments for CPT 81408 between 2018 and 2021, according to data from CMS. US Genomix went out of business last year.

Performance Laboratories (Oklahoma City, OK) collected the second highest amount of Medicare Part B payments for CPT 81408—a total of $79.8 million between 2018 and 2021. Khalid Satary, 51, was the owner of Performance Labs, which is now out of business. In September 2019, the U.S. Department of Justice charged Satary with soliciting medically unnecessary genetic tests from Medicare beneficiaries through telemarketing and health fairs (see *Laboratory Economics*, October 2019, page 11). After failing to appear at his December 12, 2022 court date, Satary was declared a fugitive of justice. DOJ believes that Satary is currently living in Dubai, United Arab Emirates.

Top 25 Labs by Medicare Part B Payments for CPT 81408 (2018 – 2021)

Laboratory Name	*Location (City, State)*	*Grand Total Medicare Payments (2018 - 2021)*
Bio Choice Laboratory (dba US Genomix)	Houston, TX	$125,782,789
Performance Laboratories	Oklahoma City, OK	79,819,928
Sonoran Desert Pathology Associates	Monterey Park, CA	33,988,321
Elite Medical Laboratory Solutions	Tomball, TX	30,474,337
First Choice Laboratory	Fort Lauderdale, FL	30,190,364
Clinical Lab Solutions	Fort Myers, FL	28,069,403
LabSolutions	Atlanta, GA	22,144,170
AmeriHealth Laboratory	Dallas, TX	21,260,986
Med Health Services Management	Monroeville, PA	20,776,000
Redwood Lab Services	Houston, TX	20,358,211
Personalized Genetics	Pittsburgh, PA	19,615,680
Suretox Laboratory	Elmwood Park, NJ	18,262,282
Trinity Clinical Laboratories	Lewisville, TX	17,914,400
Express Diagnostics	Somerset, NJ	16,859,920
Phi Life Sciences	Rockville, MD	15,186,080
Advanced Diagnostics Laboratory	Cherry Hill, NJ	14,796,477
Biogen Labs	Stafford, TX	14,454,000
Metric Lab Services	Ridgeland, MS	12,945,800
Artemis DNA	Houston, TX	11,576,883
LPS Toxicology Laboratories	New Orleans, LA	11,332,720
Cergena Laboratories	New Orleans, LA	10,406,000
Specialty Drug Testing	Monroe, LA	9,784,320
Cquentia Arkansas Lab	Fayetteville, AR	9,605,815
Scientific Marketing Instrumentation and Laboratory	Conroe, TX	9,235,520
Best Care Laboratory	Haledon, NJ	9,114,000
Total for top 25 labs		**613,954,405**
Total for all 176 labs		**$888,169,038**

Source: *Laboratory Economics* from CMS

PROPOSED MEDICARE RATE CUTS OF 2% FOR PATHOLOGISTS (*cont'd from page 1*)

The College of American Pathologists and other physician advocacy organizations are lobbying CMS and Congress to mitigate proposed cuts to the conversion factor. Comments on the proposed rule are due to CMS by September 11. The Final MPFS for 2024 is expected to be released in November.

Surgical Pathology-CPT 88305

The national Medicare rate (unadjusted for geographic location) for the PC of CPT 88305 is proposed to be cut by 3.4% to $35.37, while the TC will decrease by 0.6% to $35.04. Overall, the proposed global rate for CPT 88305 will decline by 2% to $70.41.

Prostate Biopsies

The global rate for G0416 (Surgical pathology for prostate biopsy) is proposed to decrease by 1.8% to $356.62; professional interpretation down 3.7% to $168.32; technical component down 0.1% to $188.30.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) is proposed to rise by 3.1% to $104.14; professional interpretation down 3.4% to $33.08; technical component up 6.4% to $71.06.

The global rate for CPT 88341 (IHC, additional stain) is proposed to increase by 2.7% to $89.40; professional interpretation down 4.5% to $26.53; technical component up 6% to $62.88.

Special Stains

The global rate for CPT 88312 (Special stains, group 1) is proposed to be cut by 2.5% to $110.69; professional interpretation lower by 3.3% to $25.22; technical component down 2.2% to $85.47.

The global rate for CPT 88313 (Special stains; group 2) is proposed to be cut by 1.4% to $81.54; professional interpretation down 3.4% to $11.46; technical component down 1% to $70.08.

Proposed Medicare Rate Changes for Key Pathology Codes for 2024

CPT/HCPCS	Short Description	Proposed 2024[1]	Actual 2023[2]	Proposed Rate % Change
88305-Global	Tissue exam by pathologist	$70.41	$71.84	-2.0%
88305-26	Tissue exam by pathologist	35.37	36.60	-3.4%
88305-TC	Tissue exam by pathologist	35.04	35.24	-0.6%
88307-Global	Level V, tissue exam by pathologist	283.27	292.79	-3.3%
88307-26	Level V, tissue exam by pathologist	77.61	80.99	-4.2%
88307-TC	Level V, tissue exam by pathologist	205.65	211.80	-2.9%
88312-Global	Special stains, group 1	110.69	113.52	-2.5%
88312-26	Special stains, group 1	25.22	26.09	-3.3%
88312-TC	Special stains, group 1	85.47	87.43	-2.2%
88313-Global	Special stains; group 2	81.54	82.69	-1.4%
88313-26	Special stains; group 2	11.46	11.86	-3.4%
88313-TC	Special stains; group 2	70.08	70.82	-1.0%
88341-Global	Immunohistochemistry (Add'l stain)	89.40	87.09	2.7%
88341-26	Immunohistochemistry (Add'l stain)	26.53	27.79	-4.5%
88341-TC	Immunohistochemistry (Add'l stain)	62.88	59.30	6.0%
88342-Global	Immunohistochemistry (1st stain)	104.14	100.98	3.1%
88342-26	Immunohistochemistry (1st stain)	33.08	34.23	-3.4%
88342-TC	Immunohistochemistry (1st stain)	71.06	66.76	6.4%
G0416-Global	Prostate biopsy, any method	356.62	363.27	-1.8%
G0416-26	Prostate biopsy, any method	168.32	174.86	-3.7%
G0416-TC	Prostate biopsy, any method	188.30	188.41	-0.1%

Note: Rates presented in table are national rates (unadjusted for geographic location)
[1]Payments based on proposed 2024 conversion factor of 32.7476; [2]Payments based on the 2023 conversion factor of 33.8872
Source: *Laboratory Economics* from CMS

Lab Lobby Spending Near Record

Twelve of the lab industry's largest trade organizations and companies spent a near-record total of $11.5 million on lobbying efforts in 2022, according to data from the nonprofit OpenSecrets.org (Washington, DC), which tracks lobbying and political contributions. Over the past five years, lobby spending by the 12 lab organizations has risen by an average of 11% per year.

Individually, the **American Clinical Laboratory Assn.** (ACLA) had the biggest lobbying budget last year at a record $3.9 million. ACLA's lobby firms include Alston Bird, Covington & Burling and Rampy Northrup LLC. Lobbying efforts were directed at implementation of the Protecting Access to Medicare Act (PAMA) and the Medicare CLFS, and potential FDA regulation of laboratory-developed tests (LDTs).

Exact Sciences spent a record $1.7 million. It focused its lobbying efforts on legislation that would provide Medicare coverage of multi-cancer early detection screening tests (HR 1946/S 1873) and provide coverage and payment for blood-based colorectal cancer screening tests (S 2149). Exact also supports provisions of VALID Act (HR 4128/S 2209) which would grant the FDA authority to review and pre-market approve LDTs.

Quest Diagnostics ($1.1 million) and **LabCorp** ($1 million) also spent large amounts. Lobbying efforts were mostly directed at the Centers for Disease Control & Prevention (CDC), the Dept. of Health & Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), the Food & Drug Administration (FDA) and the Executive Office of the President.

Several genomic testing lab companies also spent heavily on lobbying last year.

Myriad Genetics spent a record $970,000. It focused on the VALID Act and issues related to Medicare and Medicaid coverage of pharmacogenomic tests for mental health treatment decisions.

Guardant Health also spent a record $880,000. Its focus was on increased funding for the U.S. Preventive Services Task Force and potential FDA regulation of LDTs.

Lab Industry Lobby Spending

Organization	*2022*	*2021*	*2020*	*2019*	*2018*
American Clinical Laboratory Assn.	$3,858,092	$3,164,921	$1,766,906	$1,251,843	$1,168,193
Exact Sciences	1,680,000	1,290,000	426,000	270,000	340,000
Quest Diagnostics	1,080,000	1,840,000	880,000	890,000	1,850,000
Labcorp	1,040,000	1,630,000	1,750,000	1,650,000	1,390,000
Myriad Genetics	970,000	770,000	716,000	910,000	640,000
Guardant Health	880,000	800,000	667,500	260,000	240,000
Coalition for 21st Century Medicine	520,000	552,500	498,500	520,000	620,000
College of American Pathologists	464,889	477,040	784,063	1,190,890	1,300,049
Foundation Medicine	380,000	590,000	610,000	320,000	320,000
Association for Molecular Pathology	269,000	248,000	230,000	250,000	240,000
Opko/BioReference Labs	200,000	200,000	210,000	175,000	165,000
American Society for Clinical Pathology	132,000	125,500	138,500	168,625	208,675
Total, 12 organizations	**$11,473,981**	**$11,687,961**	**$8,677,469**	**$7,856,358**	**$8,481,917**

Source: www.opensecrets.org

Lab Stocks Up 13% Year-to-Date In 2023

Twenty-four lab stocks have risen by an unweighted average of 13% year to date through July 14. In comparison, the S&P 500 Index is up 18% year to date. The top-performing lab stocks thus far in 2023 are Interpace Biosciences, up 107%; Exact Sciences, up 96%; and NeoGenomics, up 87%. Labcorp is up 5% (after adjusting for spinoff of Fortrea) and Quest Diagnostics is down 10%.

Company (ticker)	Stock Price 7/14/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
Interpace Biosciences (IDXG)	$2.15	$1.04	107%	$65	$34	1.9
Exact Sciences (EXAS)	96.87	49.51	96%	19,360	2,200	8.8
NeoGenomics (NEO)	17.26	9.24	87%	2,390	530	4.5
DermTech Inc. (DMTK)	3.16	1.77	79%	49	14	3.4
Opko Health (OPK)	2.09	1.25	67%	1,800	913	2.0
Myriad Genetics (MYGN)	22.50	14.51	55%	1,890	695	2.7
Guardant Health (GH)	38.32	27.20	41%	4,920	482	10.2
Fulgent Genetics (FLGT)	38.76	29.78	30%	320	365	0.9
Natera (NTRA)	49.56	40.17	23%	5,300	868	6.1
Veracyte (VCYT)	28.81	23.73	21%	1,920	311	6.2
Sonic Healthcare (SHL.AX)*	35.71	29.97	19%	19,110	8,670	2.2
Exagen (XGN)	2.70	2.40	13%	29	46	0.6
Labcorp (LH)	212.77	202.30	5%	24,840	14,755	1.7
Psychemedics (PMD)	4.91	4.90	0%	27	25	1.1
Enzo Biochem (ENZ)	1.33	1.43	-7%	85	71	1.2
Quest Diagnostics (DGX)	140.44	156.44	-10%	20,290	9,603	2.1
CareDx (CDNA)	9.77	11.41	-14%	277	320	0.9
GeneDx (formerly Sema4)[1]	6.72	8.71	-23%	45	224	0.2
ProPhase Labs (PRPH)	7.11	9.63	-26%	118	94	1.2
Aspira Women's Hlth (AWH)[2]	3.51	4.95	-29%	25	9	3.0
Castle Biosciences (CSTL)	15.95	23.54	-32%	207	152	1.4
Invitae (NVTA)	1.21	1.86	-35%	1,560	510	3.1
Biodesix (BDSX)	1.11	2.30	-52%	101	41	2.5
Biocept (BIOC)[3]	1.19	15.90	-93%	6.6	7	1.0
Totals & Averages			**13%**	**$104,735**	**$40,938**	**2.6**

1) GeneDx had a 1-for-33 reverse stock split on May 4. 2) Aspira had a 1-for-15 reverse stock split on May 11.
3) Biocept had a 1-for-30 reverse stock split on May 16.
*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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