Jondavid Klipp, Editor, jklipp@laboratoryeconomics.com VOLUME 18, NO. 1 JANUARY 2023

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Revised Conversion Factor Softens Blow To Pathologists

The $1.7 trillion Consolidated Appropriations Act (CAA) signed into law on December 29 provided a 2.5% positive adjustment to Medicare's physician conversion factor for 2023. The initial physician CF had been scheduled for a 4.47% cut, whereas the updated physician CF is a 2.08% cut. As a result, the global Medicare reimbursement rate for CPT 88305 will remain flat in 2023 versus a previously scheduled 2% cut. In addition, the CAA contained another one-year freeze for the Medicare Clinical Laboratory Fee Schedule (CLFS). *Details on pages 10-11.*

FTC Proposes Banning Noncompetes

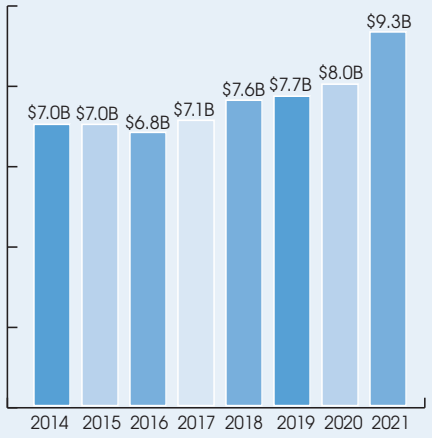
On January 5, the Federal Trade Commission announced a Notice of Proposed Rulemaking that would ban U.S. businesses from imposing noncompete clauses on workers. If approved, the rule would make it so employers cannot prohibit workers, including doctors, from resigning and immediately joining competing companies. It would also require employers to rescind existing noncompetes and actively inform workers that they are no longer in effect. *Details on page 4.*

OIG Report Shows 16% Jump in CLFS Spending

The Medicare Part B program spent $9.3 billion on clinical lab tests last year, according to the latest OIG review of Clinical Lab Fee Schedule (CLFS) payments. Total payments for CLFS tests, including payments to independent labs, physician offices and hospitals, increased by 17% from $8 billion in 2018, driven primarily by increased spending on genetic tests. Over the seven-year period from 2014 through 2021, overall Medicare Part B CLFS spending increased at an annual rate of 4%.

Continued on page 2.

Overall Medicare Part B Spending on CLFS Tests



Source: OIG analysis of Medicare Part B Spending on Lab Tests, December 2022

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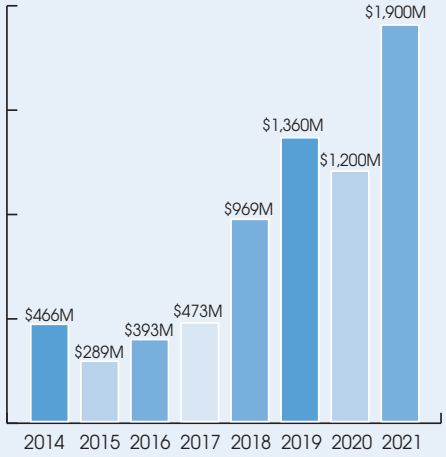
Happy New Year!

OIG Report Shows 16% Jump in CLFS Spending (*cont'd from page 1*)

Medicare Part B spending on genetic tests increased to $1.9 billion in 2021, up 56% from $1.2 billion in 2020. Genetic tests, as a group, comprise four categories of tests: molecular pathology tests, multianalyte algorithmic assays, genomic sequencing procedures, and proprietary lab analysis tests. Total spending on these genetic tests accounted for 20% of Medicare Part B spending for all CLFS tests in 2021. The average payment per genetic test was $666 in 2021. Over the seven-year period from 2014 through 2021, Medicare Part B spending on genetic tests increased at an annual rate of 22%.

Medicare Part B Spending on Genetic Tests



Source: OIG analysis of Medicare Part B Spending on Lab Tests, December 2022

Medicare Part B Spending on Chemistry Tests

In 2021, Medicare Part B spent $2.1 billion on 164.5 million chemistry tests, compared with $1.9 billion spent on 152.9 million tests in 2020. Chemistry tests—which averaged about $13 per test in 2021—include the most common types of tests (e.g., Comprehensive metabolic panel, lipid panel, TSH, etc.).

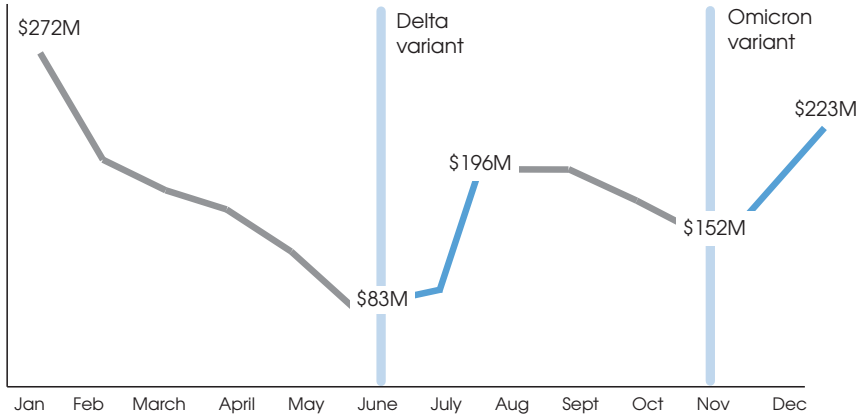
Despite the increase in chemistry test volume in 2021, it still remains below the pre-pandemic level of 174.1 million tests in 2019. This indicates that fewer Medicare enrollees are seeking the routine or preventive care appointments where these tests are ordered. "Low volume for chemistry tests raises questions about the pandemic's long-term impact on Medicare enrollee health," according to the OIG report.

The Top 25 CLFS Tests

The OIG report highlighted the top 25 tests in 2021, which represented 59% of Medicare payments for all lab tests paid under the CLFS. Of the total $5.485 billion that Medicare spent on the top 25 tests in 2021, carrier payments to independent labs and POLs totaled $4.279 billion, or 78%, and payments to hospital labs totaled $1.206 billion, or 22%.

Medicare spending grew the fastest for CPT 87426 (Covid-19 antigen detection by immunoassay technique), up 191% to $101.5 million in 2021.

Volume of Medicare Part B Chemistry Tests



Source: OIG analysis of Medicare Part B Spending on Lab Tests, December 2022

Spending also increased rapidly for CPT 81407 (Molecular pathology procedure, Level 8), up 135% to $81.6 million; CPT 87635 (Covid-19, Amplified probe technique), up 48% to $104.8 million; and CPT 81408 (Molecular pathology procedure, Level 9), up 37% to $282.2 million.

Top 25 Lab Tests Based on Medicare CLFS Payments in 2021 ($ millions)

Code	Description	Medicare CLFS Payments to Independent Labs & Physicians	Medicare CLFS Payments to Hospital Labs	Total Medicare CLFS Spending for 2021	2020-2021 % Change
U0003	Covid-19, nucleic acid, high-thoughput	$652.4	$283.5	$935.9	-8%
80053	Comprehensive metabolic panel	$287.7	$137.6	$425.3	6%
80061	Lipid panel	$237.4	$117.8	$355.2	6%
84443	Thyroid stimulating hormone (TSH)	$236.5	$97.9	$334.4	6%
U0005	Covid-19, $25 add-on payment for 2-day results	$228.9	$76.5	$305.4	NA
85025	Complete blood cell count	$208.1	$92.1	$300.2	4%
81408	Molecular pathology procedure, Level 9	$282.2	$0.0	$282.2	37%
82306	Vitamin D-3 level	$190.3	$76.9	$267.2	12%
81528	DNA-based colorectal cancer screening	$252.6	$0.0	$252.6	21%
U0004	Covid-19, any technique, high-throughput	$164.5	$56.3	$220.8	-9%
87798	Infectious agent detect by DNA or RNA	$209.6	$4.1	$213.7	16%
G0483	Drug test, definitive, 22+ classes	$201.9	$1.1	$203.0	-9%
83036	Hemoglobin A1C level	$135.6	$46.7	$182.3	7%
80307	Testing for presence of drug	$146.5	$9.9	$156.4	-3%
G0482	Drug test, definitive, 15-21 classes	$128.2	$2.0	$130.2	2%
87635	Covid-19, Amplified probe technique	$45.2	$59.6	$104.8	48%
87426	Covid-19, ELISA detection	$70.7	$30.8	$101.5	191%
83970	Parathyroid hormone	$67.6	$33.8	$101.4	9%
81162	BRCA 1&2 gene analysis	$93.1	$0.9	$94.0	8%
81519	Breast cancer gene expression	$92.6	$0.1	$92.7	21%
80048	Basic metabolic panel	$48.6	$41.7	$90.3	1%
82607	Vitamin B-12	$61.9	$26.0	$87.9	12%
G0480	Drug test, definitive, 1-7 classes	$77.6	$9.0	$86.6	-1%
81407	Molecular pathology procedure, Level 8	$81.6	$0.0	$81.6	135%
G0481	Drug test, definitive, 8-14 classes	$77.1	$2.0	$79.1	-2%
	Total for top 25 tests	$4,278.5	$1,206.2	$5,484.7	13%

Source: OIG analysis of Medicare Part B Spending on Lab Tests, December 2022

FTC Proposes Banning Noncompetes (*cont'd from page 1*)
The FTC said that noncompetes are a "widespread and often exploitative practice that suppresses wages, hampers innovation, and blocks entrepreneurs from starting new businesses."

If approved, the rule could significantly increase the competition for and wages of lab employees, especially pathologists and sales reps. It might also spur the development of new clinical lab and pathology companies.

The four-member FTC Commission voted 3-1 to publish the Notice of Proposed Rulemaking, which is the first step in the FTC's rulemaking process. FTC Chair Lina M. Khan, who voted in favor of the proposed rule, said that "By preventing workers from starting their own businesses and limiting the pool of talent available for startups to hire, noncompetes also limit entrepreneurship and new business formation. This in turn reduces product quality while raising prices."

The proposed rule would exempt noncompete clauses made between the seller and buyer of a business where the seller, or partner, held at least a 25% ownership of the business being sold.

The public has 60 days to submit comments on the proposed rule. The FTC will review the comments and may make changes, in a final rule, based on the comments and further analysis. A final FTC rule would supersede any state laws pertaining to noncompete contracts.

Iowa Pathology Associates Sues Dermpaths Over Noncompete Contracts

Iowa Pathology Associates (IPA-Des Moines) and its six shareholder-pathologists have filed a lawsuit against four of IPA's other shareholder-pathologists in Polk County District Court. The lawsuit, filed on December 16, alleges that the four pathologists have violated their employment agreements by secretly forming a competing laboratory while still employed by IPA.

The four IPA pathologists being sued—Drs. Jared Abbott, Renee Ellerbroek, Caitlin Halverson and Tiffani Milless—each specialize in dermatopathology. Each has a two-year employment contract with IPA that expires January 31, 2023. Among other things, these contracts require the pathologists to devote their full time and best efforts to IPA and not engage in the practice of medicine except on the behalf of IPA.

However, IPA alleges that the four pathologists began conspiring to form a competing dermatopathology lab, Goldfinch Laboratory, sometime in 2021. IPA says that the defendants filed for Articles of Incorporation for Goldfinch in January 2022, obtained an NPI number in September 2022, and have obtained an office for Goldfinch in Urbandale, Iowa (less than 12 miles from IPA's office).

In addition, the lawsuit alleges that the four pathologists "have rampantly sought to solicit employees and clients to leave IPA in favor of Goldfinch." At least one client—Iowa Dermatology Consultants—has announced plans to leave IPA for Goldfinch. "Iowa Derm has referred approximately 1,279 cases to IPA over the last seven months alone, resulting in hundreds of thousands of dollars of business," according to the lawsuit.

The four pathologists have since provided written notice to IPA and their plans to resign and transition to Goldfinch effective January 31, 2023.

IPA is seeking a restraining order to temporarily stop the four pathologists from taking any further steps to set up the Goldfinch lab; from soliciting IPA customers; from using IPA's confidential information; and seeking IPA staff to join Goldfinch. IPA is also seeking monetary damages plus attorneys' fees.

The four pathologists have not yet filed a response to the lawsuit.

Spotlight Interview with Clinical Reference Laboratory CEO Robert Thompson


Robert Thompson

Clinical Reference Laboratory (Lenexa, KS) is one of the largest privately held clinical testing labs in the United States. *Laboratory Economics* recently spoke with Chief Executive Robert Thompson.

Tell us a little about Clinical Reference Laboratory. What areas and clientele do you serve?
We are not a traditional clinical lab. We don't serve physician offices or hospitals. We don't take private insurance or Medicare; we are strictly business-to-business laboratory. We have three lines of business: 1) testing for life insurance applicants; 2) drugs of abuse testing; and 3) health and wellness testing.

Traditionally, in the past, health and wellness testing was done at a health fair. We were the lab that tested a lot of those specimens. Our mix has changed to more at-home testing. Wellness providers are sending collection kits to the home and people collect their own specimens. We do a lot with microsamples, particularly dried blood spots and capillary blood from the arm or shoulder (not fingerstick). This hurts much less than a fingerstick and collects more blood, which opens up much broader testing menus.

At-home testing has really grown since the pandemic began. People appreciate the convenience of not going to a patient service center for a venipuncture collection. We have more than 50 tests (and growing) that can be run on capillary blood.

How many employees does CRL have?
About 650. We have a primary lab in Lenexa and a backup lab in Olathe, Kansas. We don't have any pathologists on staff—we don't do pathology work. We had set up a genetic testing lab, but we decommissioned it until we began using those platforms for Covid testing, using a saliva-based assay in conjunction with Co-Diagnostics out of Utah. We ended up servicing the state of Kansas—schools, employers, the state. And it kept growing—we ended up testing the Los Angeles unified school district and large employers, colleges and universities—2020 and 2021 were extremely busy years. We repurposed some of the Tecans we already had and were able to turn around results within 48 hours from collection.

Are you seeing a pickup in demand for Covid PCR testing over the winter?
No, currently we are running about 2,000 per week. We test for employers, and most of the employers have shrunk the size of the screening programs, and some have been eliminated. At our peak in early 2021, we had been averaging about 12,000 Covid PCR tests per day.

What new tests do you plan to add to the menu in the next 12 months?
We're constantly adding tests in the microsampling world. Clients come to us and ask for certain tests. Right now, there's a lot of interest in female hormone testing – AMH [anti-Mullerian hormone], SMH, female testosterone. We are starting to get requests for expanded cardiac panels.

CRL acquired Confirm Biosciences in 2020. Have you made any other acquisitions?
No, that's the only one. Confirm's primary business is rapid drug testing cups. We felt our product portfolio needed to include that. It has worked out well.

Have you had difficulty hiring lab employees?
Oh yes. Fortunately, we have been able to maintain a core group of long-tenured employees.

We have some people who have been here 10 or 15 years. Our need for new employees stems from growth, especially in drugs-of-abuse testing. We have had some issues finding people to run the accession line, also confirmation scientists. We get students from local colleges with science backgrounds and train them. We also raised our wages, which has helped, and we brought in computer technology to make accessioning easier. We are highly automated.

Are you projecting growth for next year? If yes, what is driving growth?
Yes, we expect low double-digit growth. The drugs-of-abuse business is tied to job hiring, and hiring has slowed somewhat in the second half of 2022.

What are your volumes?
Every day we run more than 25,000 specimens, so more than 6 million tests a year.

What do you see as your biggest challenges and opportunities?
In terms of opportunities, smoothing and digitizing the flow of information that goes along with drug testing in the employer space. We are a digital laboratory. When Covid came around, we created a site where you registered the specimen, and it walks you through how to collect the specimen and ship it to the laboratory. We are digital both inside the lab and outside the lab. We own a company called FormFox, which is a digital chain of custody—it's used in occupational health clinics across the country. A digital workflow allows us to provide outstanding customer service. We are taking that into the at-home market. Our biggest challenge is labor and as we grow, finding good people.

Exact Sciences "Gift Card" Lawsuit Now In Discovery Phase

A whistleblower lawsuit alleging that Exact Sciences' patient gift card program violated the Federal Anti-Kickback Statute (AKS) and False Claims Act survived a motion to dismiss late last year.

The lawsuit was originally filed by 73-year-old retired pathologist Niles Rosen, MD, in June 2019. Rosen filed an amended complaint (case: 8:19-cv-1526) in April 2021 in the U.S. District Court for the Middle District of Florida (Tampa).

In mid-December, Rosen and his legal team and lawyers from Exact Sciences met with a mediator to try and negotiate an agreement, but no deal was reached. And so, the lawsuit is moving through the discovery phase.

Case History
The seeds of the lawsuit were planted in November 2017 when a gastroenterologist prescribed Exact's Cologuard test for Rosen. Cologuard, which is used to screen for colon cancer, requires a patient bowel movement for testing. Exact shipped Rosen a plastic bucket for sample collection, but he decided not to complete the test process. About three months later, Exact sent Rosen a letter with a $75 Visa reward card offered to him if he would ship a sample back, according to the lawsuit.

According to the complaint, the letter stated that "Because your health is important, Exact Sciences Laboratories will send you a $75 Visa reward card for completing your Cologuard test! In order to qualify for this special offer, your sample must be received at Exact Sciences Laboratories by Thursday, March 22, 2018."

Rosen says the reward card induced him to ship his sample back to Exact. He then got the reward card and used it to buy items unrelated to health care, according to the lawsuit.

After receiving Rosen's specimen, Exact was able to perform the test and bill Medicare. Exact was paid $499 by Medicare for Rosen's test. The lawsuit says that Medicare paid Exact for a total of 334,424 Cologuard tests and paid more than $160 million in 2018 while "offering unlawful cash equivalent inducements directly to Medicare beneficiaries."

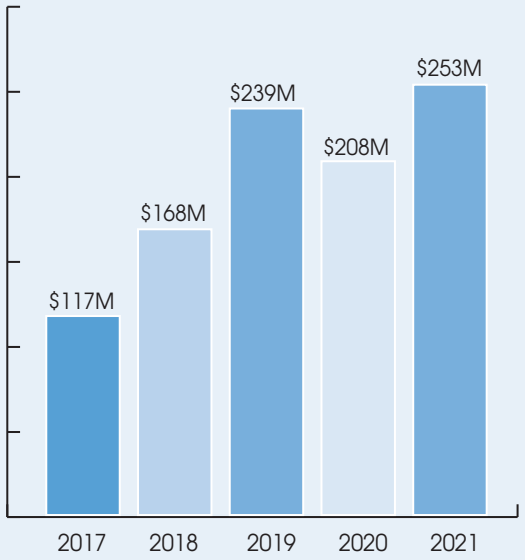
"It was a straight-up kickback," contends attorney Marlan Wilbanks from Wilbanks & Gouinlock (Atlanta), which is representing Rosen. "You can't offer cash or cash equivalents to anyone to induce them to use a government service."

Rosen seeks on behalf of the U.S. government and himself an award of civil penalties, treble damages and costs.

Exact's Response

Exact contends that encouraging a patient to have a preventive care service that was already ordered by a doctor isn't an inducement under the AKS. Furthermore, Exact says that it intends to vigorously defend itself against Rosen's claims and seek, among other things, the company's attorneys' fees and costs incurred in defending this action. In addition, Exact says it jettisoned its gift card program several years ago.

Medicare Spending on Cologuard



Medicare payments to Exact Sciences for Cologuard testing (CPT 81528) grew from $117 million in 2017 to $253 million in 2021 for an annual growth rate of 21%. The Medicare CLFS reimbursement rate for Cologuard is $508.87.

Source: OIG Analysis of Medicare Part B Lab Test Spending, 2017-2021

DOJ Declines to Intervene

Exact received a civil investigative demand by the Department of Justice in February 2020. Exact provided documents related to its gift card program to the government. In March 2021, the DOJ filed a notice of its election to decline intervention in Rosen's lawsuit. This election does not prevent Rosen from continuing his whistleblower suit and the DOJ could chose to intervene at a later date.

Whistleblower Rosen's Unique Background

Rosen practiced pathology for 20 years and then he became Medical Director of the CMS National Correct Coding Initiative (NCCI) program in 1998. In late 2005, he also assumed the role of Program Director of the NCCI. Rosen worked at both of these positions until he retired in March 2019. The purpose of the CMS NCCI program is to promote correct coding and reduce inappropriate payments.

Matrix Sells Lab To Karrington

Matrix Medical Network (Scottsdale, AZ) has sold its Matrix Clinical Laboratory to Karrington Clinical Laboratory (Fulton, MD). Matrix had originally acquired the CLIA-certified and CAP-accredited lab (formerly named Biocerna) in late 2020. Matrix now plans to focus on its home health business. Karrington is a new company led by Henry Bell, MD.

Spotlight Interview with Proscia's Nathan Buchbinder

Proscia Inc. (Philadelphia, PA) markets a digital pathology software platform (Concentriq) that helps upload, organize into patient cases, annotate, and store whole slide images. Concentriq is currently being used by more than 6,000 scientists and pathologists at 300+ clinical and research organizations around the world. Proscia has also developed AI-based applications, including a program for quality control of digitized images (currently for the research market only). Here's a summary of our recent interview with Nathan Buchbinder, Co-Founder & Chief Product Officer at Proscia.

Nathan Buchbinder

Describe when and who founded Proscia.
Proscia was founded in 2014 by myself and two other computer scientists from Johns Hopkins University and University of Pittsburgh. These include our Chief Executive David West and our Chief Technology Officer Coleman Stavish. We currently have 100 employees.

How much capital has Proscia raised?
We raised $37 million in June 2022 bringing our total funding to $72 million. More than 10 private equity firms have invested in Proscia, including the following that have board seats: Emerald Development Managers, Flybridge Capital Partners, Razor's Edge Ventures and Scale Venture Partners.

Why were drug development research firms so quick to adopt digital pathology?
Because their return on investment (ROI) on digitizing slides was self-evident and nearly immediate. Ten of the top 20 pharmaceutical companies, including Amgen, Bayer and Bristol Myers Squibb, are using Proscia to help manage their digitized slide images. These companies operate research sites and collaborate with third-party contract research organizations all around the world. Concentriq gives them a single hub where digitized slide images can be accessed and shared.

What's the current status of digital pathology for clinical diagnostics?
Adoption started much slower in the clinical market. Some of our early adopters, including Thomas Jefferson University Hospitals and Johns Hopkins' Department of Pathology, initially used digital pathology primarily for research and education.

However, over the past two years, we've seen a huge surge in demand from the clinical market, including integrated delivery networks, reference labs and even smaller pathology practices (~5 pathologists). These labs are using digital pathology for peer reviews, conferencing, consults, and tumor boards, as well as primary diagnosis of cancer cases.

Most of our customers are in life sciences and research, but that's quickly changing.

What's your advice for pathology labs planning to transition to digital pathology?
Number one, get everyone involved at the start, not just executives and pathologists, but lab managers and histotechs. Number two, don't underestimate the value of having an archive of digitized slides, not only in terms of internal research and education, but also its value to third-party life sciences and pharmaceutical companies.

What's your outlook for digital pathology adoption in the United States?
It will be widespread with nearly 100% adoption within five years. Drivers include the new Category III CPT codes for digital pathology and the potential for Medicare reimbursement. In addition, the application of AI, which requires digitized slides, will increase pathologist accuracy and efficiency.

The shift from microscope to monitor will be transformational. Winners and losers will be determined based on how fast and how well they implement technology. It could help the biggest commercial labs gain share in anatomic pathology or result in a different outcome that we can't imagine today.

What's Old Is New Again: Key Compliance Issues for Clinical Laboratories


Karen Lovitch

Laboratory Economics recently spoke with Karen Lovitch, Chair of health law and health care enforcement defense practices at Mintz Levin (Washington, D.C.) about top compliance challenges for clinical laboratories.

What have been the top compliance issues for clinical laboratories this past year?
What's old is new again. Dealing with discounts and waivers for out-of-network patients or patients whose care is not covered by a third-party payer remains a concern. Labs truly want the best for their patients – they want them to have access to testing, regardless of whether the patient's insurer pays for it. Labs often will adjust patient bills on an individual basis, and many have financial assistance programs. Labs are struggling with what is the most patient-friendly and compliance-friendly way to approach patient billing.

Depending on the source of payment, offering a discount to induce the patient to receive testing from the laboratory technically can implicate EKRA [the Eliminating Kickbacks in Recovery Act of 2018], the federal anti-kickback statute [AKS], or certain state laws, but implementing a reasonable, written financial assistance policy can lower the risk.

Collection of specimens also continues to be a challenge for labs that are not large enough to have a network of phlebotomists or patient service centers. Earlier this year there was an advisory opinion from the Health and Human Services Office of Inspector General (HHS OIG, 22-09, April 25, 2022) on paying draw fees to hospitals. A lab requested an opinion on whether it could pay contracted hospitals on a per-patient-encounter basis to collect, process and handle specimens that are then sent to the lab for testing. The lab would bill third-party payers, including federal health care programs, for testing. The OIG concluded that the proposed arrangement could implicate the AKS because it involved compensation paid by a laboratory to a party that could make or influence referrals to the laboratory for testing. The OIG is suspicious of any arrangement where a lab pays an actual or potential, direct or indirect referral source for specimen collection. Labs should proceed with caution when considering any arrangement involving payment for specimen collection fees.

I also should mention the telefraud arrangements that have received a lot of attention over the past few years. The Department of Justice has publicized many criminal enforcement actions involving laboratories that allegedly obtained fraudulent orders for laboratory testing through telemedicine visits, referred those orders to other unsuspecting laboratories for test performance, and then billed Medicare and other third-party payers for the testing. Reference laboratories therefore should consider whether they should check the background of referring laboratories and consider whether to include reference lab arrangements as part of their compliance work plan.

Are you still seeing a lot of fraud related to Covid testing?
Covid-19 testing fraud reports naturally have died down quite a bit recently, but an important court case related to Covid-19 testing fraud was resolved in 2022 when Mark Schena, President of Arrayit Corporation, was convicted of health care fraud.

However, private third-party payers continue to audit Covid-19 testing claims and are denying large swaths of testing based on lack of medical necessity. Generally, these claims relate to employer testing and school testing. In addition, some states, such as New York, required testing of nursing home employees and expected the commercial insurance companies to cover it, but some have refused to cover the testing, which left labs stuck in the middle. Labs need to know

what the payer policies are now and need to abide by them. If Covid-19 testing isn't covered, labs should consider seeking payment up front.

What can new labs created during the pandemic do to minimize compliance risk?
Their situation is similar to many new labs or other businesses that focus first on business issues and do not always ramp up as quickly as they should with respect to compliance. Any lab interested in compliance program basics should start with the OIG's website, https://oig.hhs.gov/documents/compliance-guidance/806/cpglab.pdf.

What steps should all labs take right now to ensure they remain in compliance?
Every lab should have a person who has responsibility for legal and compliance matters even if the lab does not have a formal compliance program yet. Best compliance practices include appointing a compliance officer who oversees a compliance committee that meets regularly, implementing compliance policies and a training program, auditing and monitoring, allowing for anonymous reporting of compliance issues, not retaliating against those who report, following up on credible reports, and taking action against those who are non-compliant. Labs also should monitor guidance and other publications published by the Centers for Medicare and Medicaid Services, the Office of Inspector General for the Department of Health and Human Services, and other relevant state and federal agencies.

Revised Conversion Factor Softens Blow To Pathologists (*cont'd from page 1*)

Below we highlight the final Medicare rates for several key pathology codes for 2023. Medicare rates are critical not only because Medicare is the largest payer for pathology services, but also because most commercial insurance plans as well as Medicaid programs baseline their rates to the Medicare Physician Fee Schedule.

CPT 88305

The global rate for CPT 88305 (Level IV, tissue exam) has declined by 0.2% to $71.84; professional interpretation down 2.1% to $36.60; technical component up 1.8% to $35.24.

Prostate Biopsies

Global reimbursement for G0416 (prostate biopsy, any method) has increased by 1.3% to $363.27, including a 1.5% cut to the professional component and a 4.1% increase to the technical service.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) has been cut by 1.4% to $100.98; professional interpretation down 1.1% to $34.23; technical component down 1.6% to $66.76.

Global reimbursement for CPT 88341 (IHC, each additional stain) decreased by 2.8% to $87.09. Professional rates have been lowered by 0.9% to $27.79; technical component down 3.7% to $59.30.

Flow Cytometry

Technical rates for flow cytometry (CPT 88184 & 88185) have been raised by 9%. Professional rates (CPT 88187-88189) have been lowered by 1-2%.

The Clinical Laboratory Fee Schedule

The Consolidated Appropriations Act also provided for a one-year reprieve from Medicare cuts of up to 15% for some 800 clinical lab tests that would have otherwise gone into effect in 2023. This marks the third straight year that Medicare CLFS rates have been frozen. Furthermore, the CAA included another one-year delay in the next PAMA data reporting period. The next reporting period will be January 1, 2024 through March 31, 2024, and will be based on the original data collection period of January 1, 2019 through June 30, 2019.

Final Medicare Rate Changes for Key Pathology Codes for 2023

CPT/HCPCS	Short Description	Final 2023[1]	Actual 2022[2]	% Rate Change
88184-TC only	Flow cytometry/1st marker	$75.23	$69.21	8.7%
88185-TC only	Flow cytometry/each add'l marker	24.06	22.15	8.6%
88187-26 only	Flow cytometry, read 2-8	35.24	35.99	-2.1%
88188-26 only	Flow cytometry/read 9-15	61.67	62.98	-2.1%
88189-26 only	Flow cytometry, read 16 & greater	83.36	84.44	-1.3%
88304-Global	Level III, tissue exam by pathologist	43.04	42.22	1.9%
88304-26	Level III, tissue exam by pathologist	11.18	11.42	-2.1%
88304-TC	Level III, tissue exam by pathologist	31.85	30.80	3.4%
88305-Global	Level IV, Tissue exam by pathologist	71.84	71.98	-0.2%
88305-26	Level IV, Tissue exam by pathologist	36.60	37.37	-2.1%
88305-TC	Level IV, Tissue exam by pathologist	35.24	34.61	1.8%
88307-Global	Level V, tissue exam by pathologist	292.79	290.69	0.7%
88307-26	Level V, tissue exam by pathologist	80.99	82.36	-1.7%
88307-TC	Level V, tissue exam by pathologist	211.80	208.33	1.7%
88309-Global	Level VI, tissue exam by pathologist	441.55	441.58	0.0%
88309-26	Level VI, tissue exam by pathologist	142.33	144.65	-1.6%
88309-TC	Level VI, tissue exam by pathologist	299.22	296.92	0.8%
88311-Global	Decalcify tissue	20.67	21.11	-2.1%
88311-26	Decalcify tissue	12.20	12.46	-2.1%
88311-TC	Decalcify tissue	8.47	8.65	-2.1%
88312-Global	Special stains, group 1	113.52	114.55	-0.9%
88312-26	Special stains, group 1	26.09	26.30	-0.8%
88312-TC	Special stains, group 1	87.43	88.25	-0.9%
88313-Global	Special stains; group 2	82.68	82.36	0.4%
88313-26	Special stains; group 2	11.86	12.11	-2.1%
88313-TC	Special stains; group 2	70.82	70.25	0.8%
88331-Global	Pathology consult during surgery	102.68	103.47	-0.8%
88331-26	Pathology consult during surgery	61.00	61.95	-1.5%
88331-TC	Pathology consult during surgery	41.68	41.53	0.4%
88341-Global	Immunohistochemistry (Add'l stain)	87.09	89.63	-2.8%
88341-26	Immunohistochemistry (Add'l stain)	27.79	28.03	-0.9%
88341-TC	Immunohistochemistry (Add'l stain)	59.30	61.60	-3.7%
88342-Global	Immunohistochemistry (1st stain)	100.98	102.43	-1.4%
88342-26	Immunohistochemistry (1st stain)	34.23	34.61	-1.1%
88342-TC	Immunohistochemistry (1st stain)	66.76	67.83	-1.6%
G0416-Global	Prostate biopsy, any method	363.27	358.52	1.3%
G0416-26	Prostate biopsy, any method	174.86	177.53	-1.5%
G0416-TC	Prostate biopsy, any method	188.41	180.99	4.1%

[1]Payments based on the 2023 conversion factor of 33.8872

[2]Payments based on the 2022 conversion factor of 34.6062

Source: *Laboratory Economics* from College of American Pathologists and CMS

Lab Stocks Fell 57% In 2022

Twenty-four lab stocks fell by an unweighted average of 57% in 2022. Overall, only one lab stock rose and 23 fell. The top-performing lab stock in 2022 was ProPhase Labs, up 34%. Quest Diagnostics was down by 10% (total return with dividends was -8%) and Labcorp was down by 25% (total return was -24%). In comparison, the S&P 500 Index fell by 19% last year (total return was -18%).

Company (ticker)	Stock Price 12/30/22	Stock Price 12/31/21	2022 Price Change	Diluted EPS (Trailing 12 months)	Price-to-Earnings Ratio
ProPhase Labs (PRPH)	$9.63	$7.17	34%	1.53	6.3
Quest Diagnostics (DGX)	156.44	173.01	-10%	10.19	15.4
Labcorp (LH)	235.48	314.21	-25%	18.82	12.5
Psychemedics (PMD)	4.90	7.02	-30%	(0.36)	NA
Sonic Healthcare (SHL.AX)*	29.97	46.63	-36%	3.03	9.9
Exact Sciences (EXAS)	49.51	77.83	-36%	(4.09)	NA
Veracyte (VCYT)	23.73	41.20	-42%	(0.61)	NA
Castle Biosciences (CSTL)	23.54	42.87	-45%	(2.05)	NA
Myriad Genetics (MYGN)	14.51	27.60	-47%	(0.97)	NA
Enzo Biochem (ENZ)	1.43	3.21	-55%	(0.55)	NA
Biodesix (BDSX)	2.30	5.29	-57%	(1.69)	NA
Natera (NTRA)	40.17	93.39	-57%	(5.68)	NA
Fulgent Genetics (FLGT)	29.78	100.59	-70%	8.73	3.4
Guardant Health (GH)	27.20	100.02	-73%	(5.94)	NA
NeoGenomics (NEO)	9.24	34.12	-73%	(1.33)	NA
Opko Health (OPK)	1.25	4.81	-74%	(0.46)	NA
CareDx (CDNA)	11.41	45.48	-75%	(1.40)	NA
Exagen (XGN)	2.40	11.63	-79%	(2.35)	NA
Aspira Women's Hlth (AWH)	0.33	1.77	-81%	(0.27)	NA
Biocept (BIOC)	0.53	3.62	-85%	(0.98)	NA
Interpace Biosciences (IDXG)	1.04	$7.47	-86%	(5.72)	NA
Invitae (NVTA)	1.86	15.27	-88%	(13.88)	NA
DermTech Inc. (DMTK)	1.77	15.80	-89%	(3.83)	NA
GeneDx (formerly Sema4)	0.26	4.46	-94%	(0.93)	NA
Unweighted Averages			-57%		9.5

*Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from SeekingAlpha.com

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