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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CMS Gets An Earful From Thousands Of Labs Opposing PAMA Implementation

CMS is currently reviewing more than 4,000 comments submitted by laboratories and their trade groups concerning preliminary Medicare Clinical Lab Fee Schedule (CLFS) rates for 2018. Unless Congress or CMS intervenes, final rates will soon be released and go into effect on January 1, 2018. The lab industry is nearly unanimous in urging CMS to delay implementation of the final rates so that hospital lab pricing data can be included in the calculations. The exception is the Coalition for 21st Century Medicine (C21) which continues to lobby CMS to stay on schedule.

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Big Rate Cuts Finalized For Prostate Biopsies & Flow Cytometry

The Final Medicare Physician Fee Schedule (MPFS) for 2018 includes a 19% cut to the technical component for prostate biopsies (G0416), while the key code for flow cytometry (CPT 88185) is also being cut by 19%. The good news is that the final MPFS includes small increases for CPT 88305 as well as for the key immunohistochemistry codes 88341 and 88342.

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Key AP Rate Changes for 2018

Prostate G0416-TC	-19%
Flow 88185	-19%
Surg. Path 88305-TC	+1.5%
IHC 88341-TC	+3.8%
IHC 88342-TC	+4.4%

Source: CMS

Quest Diagnostics To Buy Cleveland HeartLab

Quest Diagnostics has signed a definitive agreement to acquire Cleveland HeartLab Inc. from its equity investors in an all-cash transaction for $94 million. The transaction is expected to be completed by year's end.

Cleveland HeartLab (CHL) was spun out of Cleveland Clinic in 2009 to commercialize a cardiac-risk assessment test called Myeloperoxidase (MPO). The test was developed by researchers at Cleveland Clinic led by Marc Penn, MD, PhD. Penn is a cardiologist who worked at Cleveland Clinic from 2000-2011, and is currently Chief Medical Officer at CHL.

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Quest Diagnostics To Buy Cleveland HeartLab (*cont'd from page 1*)

Penn's research showed that higher levels of MPO, which is secreted into the blood when arteries get inflamed, are associated with the presence of coronary disease and indicate higher risk of heart attack.

CHL commercializes MPO by performing MPO tests directly at its CLIA laboratory in Cleveland. It also manufactures and sells MPO reagent kits for other laboratories to use in their own testing. Quest Diagnostics had been a CHL client.

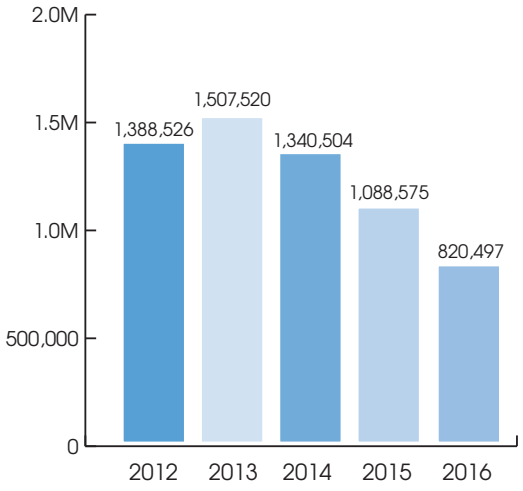
CHL offers MPO testing as part of its Inflammation Assessment Panel, which also includes tests for F2-Isoprostanes, Oxidized LDL, ADMA/SDMA, microalbumin, hsCRP and Lp-PLA2 Activity, at a retail price of $199.

In 2015, the latest available data from CMS, CHL received $5 million in allowed Medicare payments for tests on 33,218 Medicare beneficiaries—an average of $151 per patient. Its five highest-volume CPT codes were 80053 (comprehensive metabolic panel), 85025 (complete Blood Count w/differential), 83698 (Lp-PLA2), 83876 (MPO) and 80061 (standard lipid panel). *Laboratory Economics* estimates that CHL's total current annual revenue is between $30 million and $50 million.

The sale to Quest follows non-coverage decisions for cardiovascular disease risk-assessment panels issued by a number of Medicare carriers and private insurance payers over the past two years. For example, the influential Medicare carrier Palmetto GBA issued a local coverage determination denying coverage of CVD risk assessment panels, except the basic lipid panel, for all non-symptomatic patients effective in late 2015. Palmetto's policy was soon followed by many other payers.

As a result, CVD-risk test volumes, as measured by Medicare Part B allowed claims for five relevant CPT codes, have been cut by nearly half over the past few years (see graph). And most independent labs specializing in CVD testing have been acquired by larger companies, including LipoScience (acquired by LabCorp), Atherotech (Ningbo Medical System) and Boston Heart Diagnostics (Eurofins Scientific).

Volume of Medicare Allowed Services for Cardiovascular-Risk Tests*



*Includes Medicare Part B allowed services for CPT 82664, 83698, 83701, 83704, 83876
Source: *Laboratory Economics* from CMS

Quest says that it will establish a national center of excellence at CHL's laboratory in Cleveland focused on cardiovascular disease testing. Quest also plans to form a partnership with the Cleveland Clinic, which owns a significant stake in CHL. Quest and Cleveland Clinic will form a committee of experts that will evaluate biomarkers discovered by the Clinic. Quest may then use those discoveries to create and commercialize new tests.

Cleveland HeartLab has raised more than $50 million from private investors since 2009. In addition to Cleveland Clinic, other investors in CHL include Healthcare Ventures, Mutual Capital Partners and Excel Venture Management.

Quest Buys California Laboratory Associates

Quest Diagnostics has acquired certain assets of California Laboratory Associates (CLA), a clinical lab network previously operated by the laboratory at Providence Saint Joseph Medical Center (Burbank, CA). Providence Saint Joseph will continue to operate its lab for hospital patients and anatomic pathology services. Financial terms were not disclosed.

Hartford Healthcare Deal Finalized

In addition, Quest completed its previously announced purchase of the outreach laboratory businesses of two hospitals owned by Hartford Healthcare, The William W. Backus Hospital and The Hospital of Central Connecticut, in an all-cash transaction for $30 million.

Recent Acquisitions by Quest Diagnostics

Date	Acquisition Target	Laboratory Type	Purchase Price ($ million)
Pending	Cleveland HeartLab	Esoteric	$94
Pending	Shiel Medical Laboratory	Routine	170
Pending	Cape Cod Healthcare outreach lab	Hospital Outreach	NA
Oct-17	California Laboratory Associates	Hospital Outreach	NA
Sep-17	Hartford Healthcare outreach labs	Hospital Outreach	30
Jul-17	Med Fusion and Clear Point	Esoteric	150
Jun-17	Sierra Nevada Memorial Hospital outreach lab	Hospital Outreach	NA
May-17	PeaceHealth Labs	Hospital Outreach	101

Source: *Laboratory Economics* from Quest Diagnostics

LabCorp Buys Most of Vista Clinical Diagnostics

LabCorp has purchased the retail business of Vista Clinical Diagnostics (Clermont, FL), including some 30+ patient services centers in central and north Florida. All specimens that Vista had received from physician office clients, assisted living facilities and walk-in self-paying customers will now be sent to LabCorp. LabCorp is expected to hire about 40 of Vista's 180 employees.

Vista plans to keep some of its employees and its main lab in central Florida that will now focus solely on serving nursing home clients.

Vista was founded by its President Davian Santana and Nathan Hawkins, who is no longer there, in 2003. Santana told the Orlando Sentinel that he decided to sell because of difficulty winning insurance contracts and the upcoming cuts in Medicare rates.

Aurora Diagnostics Buys CytoPath

Aurora Diagnostics (Palm Beach Gardens, FL) has acquired CytoPath (Alabaster, AL, near Birmingham). CytoPath is a pathologist-owned group that provides surgical pathology and cytopathology services to eight hospitals and five referring physician group clients in Central and Southern Alabama. CytoPath was founded in 1989 and has five pathologists, including its President, Teresa Venz-Williamson, MD.

South Path Merged Into University Health Care in Augusta

South Path Laboratory (Augusta, GA) has been merged into the laboratory at University Health Care System (also in Augusta). South Path's President, Stephen Mullins, MD, has joined University's clinical lab team. South Path is the former anatomic pathology branch of Mullins Pathology and Cytology Laboratory, which was sold to Sonic Healthcare in 2007.

CMS Gets An Earful From Thousands Of Labs (*cont'd from page 1*)
As highlighted in the last issue of *Laboratory Economics*, C21 represents a small group of genetic testing labs that will receive substantial rate hikes for their proprietary tests if the preliminary CLFS rates for 2018 are finalized. Selected comments from C21 and a few of its members are highlighted below.

"C21 believes that the implementation of the private payor rate-based payment amounts on schedule in 2018 is important to the achievement of PAMA's objectives. We are concerned that any such delay would undercut Congress and the agency's objectives of improving transparency and predictability in the setting of rates for clinical diagnostic laboratory tests," wrote Hannah Murphy, Executive Director for C21, in her comments to CMS.

"This is a clear and welcome signal to the industry that CMS is committed to the system envisioned by Congress in the Protecting Access to Medicare Act of 2014, or PAMA," said David Brunel, Chief Ececutive of Biodesix (Boulder, CO), in an October 6 press statement. "Biodesix appreciates that CMS remains committed to modernizing the CLFS rate development process detailed in PAMA since it provides stability to the market while ensuring Medicare beneficiaries access to innovative diagnostics including the VeriStrat test." Biodesix's VeriStrat test is poised to get a 35% price increase to $2,871 in 2018, notes *Laboratory Economics*.

"If PAMA goes through as envisioned, we'll see about a 15% rise in our average selling price and a $6 million to $8 million increase in revenue on the 20% or so volume that is Medicare in our invasive breast business [Oncotype DX test]. So, it's significant and we look forward to being able to reap the benefits of that starting in Q1," Brad Cole, Chief Financial Officer at Genomic Health (Redwood City, CA), told investors on a November 8 conference call.

Other C21 members that will benefit include CareDx Inc. (Brisbane, CA) whose AlloMap test will receive a 14% rate hike to $3,240. Medicare patients currently make up approximately 40% of CareDx's AlloMap revenue.

In addition, Veracyte (South San Francisco, CA) will see its Medicare rate for its Afirma test increase by 12% $3,600. Medicare patients represent approximately 20% of Veracyte's Afirma test volume.

C21 Scores Another Victory With Amendment To 14-Day Rule
In separate news, CMS has finalized a rule that allows independent labs performing Advanced Diagnostic Laboratory Tests (ADLTs) and molecular pathology tests on specimens collected from hospital outpatients in the 0-14 day range to directly bill Medicare. The new rule becomes effective January 1, 2018.

Currently, independent labs performing ADLTs and molecular pathology tests must seek payment from the hospital for tests ordered on patients within 14 days after a specimen has been collected in a hospital outpatient center.

The rule change represents another victory for C21 and its hired lobbying firms (Foley Hoag LLP, McDermott, Will & Emery and Goldbug Strategies). C21 members include molecular and genetic testing lab companies such as CareDx, Myriad Genetics, Foundation Medicine and Genomic Health.

The rule change should lead to increased hospital outpatient test utilization, quicker collection and higher reimbursement for tests offered by C21 members.

Eight Senators Urge CMS To "Delay and Fix" PAMA CLFS Rates

Among the thousands of comments that CMS has received regarding the proposed CLFS rates for 2018 is a letter from eight senators requesting that the agency delay finalizing the rates so that a broader representation of laboratory market can be included in pricing calculations. Pricing data from Quest Diagnostics and LabCorp represent an estimated 70+% of the pricing data submitted to CMS and only 21 hospitals were included when CMS formulated its proposed CLFS rates for 2018, notes *Laboratory Economics*.

The eight senators that signed the letter were Bill Nelson (Dem-FL), Sherrod Brown (Dem-OH), Robert Menendez (Dem-NJ), Cory A. Booker (Dem-NJ), Robert P. Casey Jr. (Dem-PA), Debbie Stabenow (Dem-MI), Michael F. Bennett (Dem-CO) and Sheldon Whitehouse (Dem-RI).

Meanwhile, as reported in the last issue of *Laboratory Economics*, the three biggest members of the American Clinical Laboratory Association (ACLA), Quest Diagnostics, LabCorp and Bio-Reference Labs, are making plans to file a lawsuit in the likely event that CMS moves forward and finalizes its proposed CLFS rates for 2018.

PAMA CLFS Rates Will Drag Medicaid Rates Lower

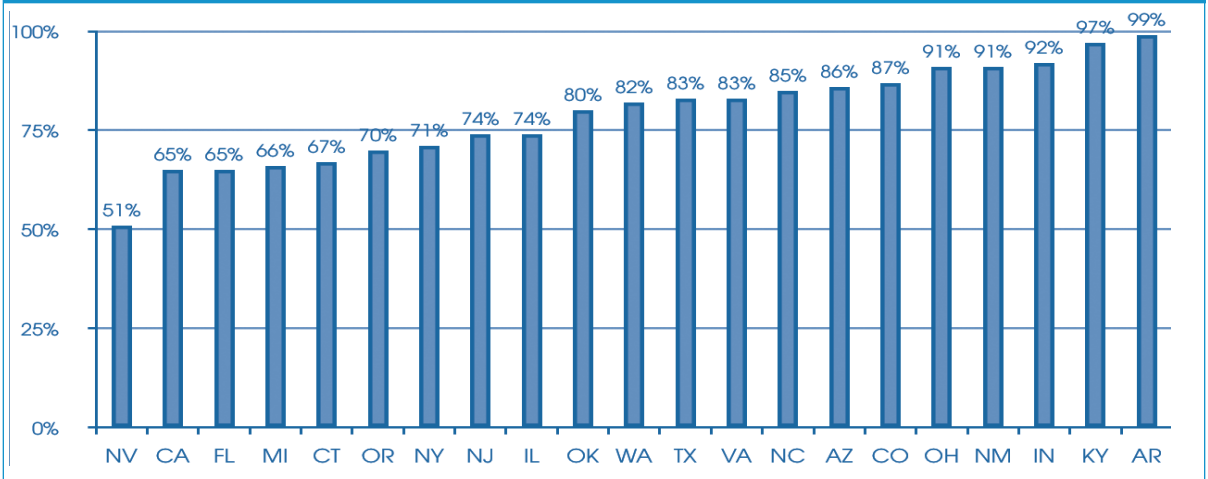
Over the next three years, most states will be forced to lower their Medicaid fee-for-service (FFS) rates for clinical lab tests if the PAMA CLFS rates are finalized for 2018. That's because Medicaid by law is not allowed to pay more than the Medicare National Limitation Amount (NLA) for any particular test.

Medicare rates for most high-volume tests are set to decrease by 10% per year over the next three years under PAMA. So any state with Medicaid rates currently set at an average of about 70% or more of today's Medicare CLFS will be required to lower their rates at some point in the next three years.

A *Laboratory Economics* survey of current Medicaid rates for 21 states showed that only six states have FFS rates for lab tests set at an average of 70% or below. These states (Nevada, California, Florida, Michigan, Connecticut and Oregon) will not be required by law to lower their rates.

However, 15 other states have FFS lab test rates set at more than 70% of current Medicare CLFS rates. State Medicaid plans that will be forced to reduce their lab test rates the most include Arkansas, Kentucky and Indiana.

State Medicaid FFS Lab Test Rates as a Percentage of Medicare CLFS 2017



Source: *Laboratory Economics* from state health departments

PAMA Rate Cuts Will Slam Independent Nursing Home Labs The Hardest

Independent labs serving nursing home and homebound patients will get hit the hardest if the proposed PAMA rate cuts to the Medicare CLFS test codes are finalized. CMS tried to soften the blow of the pending cuts by raising the sample collection fee (G0471) for nursing home and homebound patients by $2, from $3 to $5, effective April 1, 2014. But it won't be enough to offset three straight years of 10% rate reductions for most of their business.

Quest Diagnostics and LabCorp have steered clear of nursing home business because it's extremely labor intensive. Labs serving the patients of nursing homes are required to collect their own specimens (often as early as 5:00 am) and report the test results back on the same day.

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 2015 (the latest year of available data).

Top Independent Labs Serving Nursing Homes by Volume of G0471 Medicare Services for 2015

Laboratory Name	*Location(s)*	*G0471 Volume of Services*	*Number of Medicare Beneficiaries*
U.S. Lab & Radiology Inc.	FL, MA, MI, PA	439,422	53,106
Amerathon LLC	Ohio	399,226	66,074
Kan-Di-Ki LLC (dba Diagnostic Labs & Radiology)	AZ, CA, CO, NV, TX	303,507	49602
Schryver Medical Sales and Marketing	AZ, CA, CO, TX, WA	287,235	52645
Gamma Healthcare	MO, TX	276,468	47,067
American Health Associates Inc.	Florida	253,992	39,956
Aculabs Inc.	New Jersey	228,761	36,974
Chicago Clinical Laboratories	Illinois	145,272	18,867
Boyce and Bynum Pathology Laboratories	Missouri	116,734	20,292
Quest/Shiel Medical Laboratory	New York	105,084	15,756
BestCare Laboratory Services	Texas	100,361	14,031
MDX-MDL Holdings LLC	California	94,739	14,084
LifeScan Laboratory	Illinois	92,314	12,759
Eccolab Group Medical Laboratory	Florida	91,830	11,524
Modern Diagnostic Laboratory	New York	86,723	12,442
Heartland Health Laboratories	Kansas	80,154	9,267
Brookside Clinical Laboratory	Pennsylvania	77,591	10,573
Medical Center Laboratories	Texas	60,285	10,247
BioDiagnostic Labs	New York	54,189	6,810
Sonic/East Side Clinical Laboratory	Rhode Island	45,542	6,145
Citrano Diagnostic Laboratories	Maryland	41,311	6,578
Cerf Diagnostic Laboratory	California	38,590	6,064
Apex Laboratory	New York	38,572	8,120
Access Clinical Laboratory	Texas	37,741	6,261
Carolina Medical Lab Group	North Carolina	36,785	6,314
Total, top 25 nursing home labs		3,532,428	541,558
Total, all nursing home labs		3,784,073	593,451

Note: G0471 is the code specifically used for sample collection from nursing home or homebound patients.
Source: *Laboratory Economics* from CMS

Big Rate Cuts Finalized for Prostate Biopsies (*cont'd from page 1*)

Overall, CMS estimates that the rate changes will decrease Medicare reimbursement to pathologists and AP laboratories by 1% in 2018. However, this will be slightly offset because the conversion factor applied to all services paid through the MPFS is being raised by 0.3% to 35.9996 in 2018.

Prostate Biopsies

The TC for G0416 is being cut by 18.7% to $247.68, while the PC is being raised 0.3% to $186.84. Overall, global reimbursement for G0416 is being lowered by 11.5% to $434.52 in 2018.

Flow Cytometry

Following significant cuts made in 2017, another round of cuts for key flow cytometry codes has been finalized for 2018. CPT 88185 (flow cytometry, TC, add on) is being cut by 18.8% to $30.60. And CPT 88189 (flow cytometry, interpretation, 16 or more markers) is decreasing by 4% to $88.92.

CPT 88305

The global rate for CPT 88305 will increase by 0.8% to $70.20. Reimbursement for the professional interpretation for CPT 88305 is being raised by 0.3% to $39.96. The rate for the technical component is being raised by 1.5% to $30.24.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) is being raised 3% to $111.60; professional interpretation up 0.3% to $37.44; technical component up 4.4% to $74.16.

The global rate for CPT 88341 (IHC, additional slide) is proposed to increase 2.7% to $94.68; professional interpretation up 0.3% to $29.88; technical component up 3.8% to $64.80.

Digital Pathology

The global rate for CPT 88361 (tumor immunohistochemistry using digital imaging) was cut by 5.4% to $148.32; professional read down 18.6% to $49.68; technical component up 2.9% to $98.64.

Final Medicare Rate Changes for Key Pathology Codes for 2018

CPT[1]/Modifier	Short Description	Final 2018[2]	Final 2017[3]	% Chg
88112-Global	Cytopath cell enhance tech	$70.20	$68.91	1.9%
88112-26	Cytopath cell enhance tech	29.52	29.07	1.5%
88112-TC	Cytopath cell enhance tech	40.68	39.84	2.1%
88120-Global	FISH-manual, 3-5 probes	649.79	640.97	1.4%
88120-26	FISH-manual, 3-5 probes	60.84	60.65	0.3%
88120-TC	FISH-manual, 3-5 probes	588.95	580.32	1.5%
88121-Global	FISH-computer assisted, 3-5 probes	541.79	553.76	-2.2%
88121-26	FISH-computer assisted, 3-5 probes	52.20	52.04	0.3%
88121-TC	FISH-computer assisted, 3-5 probes	489.59	501.72	-2.4%
88173-Global	Cytopath eval FNA report	158.04	155.76	1.5%
88173-26	Cytopath eval FNA report	74.88	74.29	0.8%
88173-TC	Cytopath eval FNA report	83.16	81.47	2.1%

CPT[1]/Modifier	Short Description	Final 2018[2]	Final 2017[3]	% Chg
88184-TC only	Flow cytometry/1st marker	68.04	61.73	10.2%
88185-TC only	Flow cytometry/each add'l marker	30.60	37.68	-18.8%
88189-26 only	Flow cytometry, read 16+	88.92	92.59	-4.0%
88305-Global	Tissue exam by pathologist	70.20	69.62	0.8%
88305-26	Tissue exam by pathologist	39.96	39.84	0.3%
88305-TC	Tissue exam by pathologist	30.24	29.79	1.5%
88307-Global	Level V, tissue exam by pathologist	270.00	269.88	0.0%
88307-26	Level V, tissue exam by pathologist	87.84	87.93	-0.1%
88307-TC	Level V, tissue exam by pathologist	182.16	181.96	0.1%
88309-Global	Level VI, tissue exam by pathologist	410.04	413.80	-0.9%
88309-26	Level VI, tissue exam by pathologist	155.88	155.40	0.3%
88309-TC	Level VI, tissue exam by pathologist	254.16	258.40	-1.6%
88312-Global	Special stains, group 1	99.36	99.97	-0.6%
88312-26	Special stains, group 1	28.08	28.35	-1.0%
88312-TC	Special stains, group 1	71.28	71.42	-0.2%
88313-Global	Special stains; group 2	72.00	70.70	1.8%
88313-26	Special stains; group 2	12.60	12.56	0.3%
88313-TC	Special stains; group 2	59.40	58.14	2.2%
88331-Global	Pathology consult during surgery	99.72	98.69	1.0%
88331-26	Pathology consult during surgery	66.60	66.04	0.8%
88331-TC	Pathology consult during surgery	33.12	32.66	1.4%
88341-Global	Immunohistochemistry (Add'l stain)	94.68	92.23	2.7%
88341-26	Immunohistochemistry (Add'l stain)	29.88	29.79	0.3%
88341-TC	Immunohistochemistry (Add'l stain)	64.80	62.45	3.8%
88342-Global	Immunohistochemistry (1st stain)	111.60	108.38	3.0%
88342-26	Immunohistochemistry (1st stain)	37.44	37.32	0.3%
88342-TC	Immunohistochemistry (1st stain)	74.16	71.06	4.4%
88360-Global	Tumor immunohistochem/manual	136.44	142.12	-4.0%
88360-26	Tumor immunohistochem/manual	46.80	57.42	-18.5%
88360-TC	Tumor immunohistochem/manual	89.64	84.70	5.8%
88361-Global	Tumor immunohistochem/computer	148.32	156.83	-5.4%
88361-26	Tumor immunohistochem/computer	49.68	61.01	-18.6%
88361-TC	Tumor immunohistochem/computer	98.64	95.82	2.9%
88377-Global	M/phmtrc analysis ish quant/semi-quant	417.60	410.21	1.8%
88377-PC	M/phmtrc analysis ish quant/semi-quant	66.96	66.75	0.3%
88377-TC	M/phmtrc analysis ish quant/semi-quant	350.64	343.45	2.1%
G0416-Global	Prostate biopsy, any method	434.52	490.96	-11.5%
G0416-26	Prostate biopsy, any method	186.84	186.26	0.3%
G0416-TC	Prostate biopsy, any method	247.68	304.70	-18.7%

[1]CPT Codes and descriptors are copyright 2017 American Medical Association.
[2]Payments based on the final 2018 conversion factor of 35.9996
[3]Payments based on the final 2017 conversion factor of 35.8887
Source: *Laboratory Economics* from CMS

Medicare Expenditures On Anatomic Pathology Rebound In 2016

Medicare Part B carrier allowed charges for the top 20 anatomic pathology procedures increased by 5.9% to $2.015 billion in calendar-year 2016, according to newly released data from CMS. This healthy growth follows a five-year period (2010-2015) during which allowed charges for the top AP codes declined by an average of 4% per year—primarily because of severe rate cuts to CPT 88305-TC in 2013 and CPT 88342 in 2014.

Medicare Part B carrier allowed charges for CPT 88305—by far the most frequently billed anatomic pathology procedure—grew by 5.4% to $1.021 billion in 2016. Volume of allowed services grew by 3.6%, while average price per service was up 1.8%.

Allowed charges for immunohistochemistry stains (CPT 88342 & 88341) grew by 25% to a combined $232.8 million. Volume of allowed services grew by 6%, while average price per service was up 19%.

The weakest areas were flow cytometry (CPT 88185), down 16.2% to $90.5 million, and prostate biopsies (G0416), down 14.6% to $49.9 million

Top 20 Anatomic Pathology Procedures by Medicare Part B Carrier Allowed Charges for 2016 ($ millions)

Code (Description)	*2016*	*2015*	*% Change*
88305 (Level IV, tissue exam by pathologist)	$1,020.8	$968.7	5.4%
88342 (Immunohistochemistry, first stain)	118.0	103.0	14.6
88341 (Immunohistochemistry, each add'l stain)	114.8	83.4	37.6
88312 (Special stains)	102.6	98.9	3.8
88307 (Level V, tissue exam by pathologist)	91.6	86.6	5.7
88185 (Flow cytometry, add on)	90.5	108.0	-16.2
88313 (Special stains)	59.8	64.2	-6.8
G0416 (Surgical pathology for prostate biopsy)	49.9	58.5	-14.6
88120 (FISH-manual for urine specimen)	48.3	47.4	1.8
88112 (Cytopath cell enhance tech)	48.1	44.5	8.2
88377 (M/phmtrc analysis ish manual)	39.0	21.5	81.5
88331 (Pathology consult during surgery)	37.7	38.3	-1.7
88173 (Cytopath eval FNA)	34.5	32.3	6.7
88360 (Quantitative IHC-manual)	28.7	26.6	8.0
88309 (Level VI, tissue exam by pathologist)	24.2	23.5	2.9
88189 (Flow cytometry, read 16+)	23.1	21.8	5.9
88121 (FISH-computer assist for urine specimen)	22.6	24.4	-7.5
88304 (Level III, tissue exam by pathologist)	21.1	20.7	1.8
88374 (M/phmtrc analysis ish computer-assisted)	20.5	13.0	57.2
88361 (Quantitative IHC-computer assisted)	18.7	16.4	14.1
Total, top 20 pathology codes	$2,014.5	$1,901.9	5.9%

Note: Data in table is for Medicare Part B carriers. Claims for institutional services (hospitals, home health agencies, et al.) are processed by Medicare Part A fiscal intermediaries and are not included. Data for services provided to beneficiaries enrolled in risk-based HMOs is also not included.
Source: *Laboratory Economics* from CMS

Audits by Private Payers, Questionable Billing Arrangements on the Rise

Audit activity by both government and private commercial payers has been increasing over the past year and half, with a substantial uptick in recent months, according to healthcare lawyers who focus on clinical labs and pathologists.


Richard Cooper

"Over the past 18 months we've seen an increase in audits, but over the past six months, it's been dramatic," says Richard Cooper, an attorney with McDonald Hopkins (Cleveland, OH). "We're seeing one to two per week."

Not only are audits increasing, but auditors are becoming more aggressive in their tactics, notes Cooper. "They threaten to take away contracts and make not-so-subtle references to criminal action," he says. "Also, the recoupment amounts are increasing substantially—it's not unusual to see 7 or 8 figure recoupment demands."


Hope Foster

Hope Foster, an attorney with Mintz Levin (Washington, DC), agrees that she is seeing the same heightened audit activity, and adds that she has especially seen an increase in audits by private insurers. "Commercial insurers are using investigative techniques that we have classically seen the government use," she says. "As the pressure increases on dollars, plan sponsors are being even more careful in how they spend their dollars, which impacts payers and, in turn, affects their relationships with providers, leading to escalated audit activity."

Many of the audits Cooper is seeing are in the areas of toxicology testing, pharmacogenomics and molecular genetics. "Many are based on medical necessity, such as ordering too broad of a panel or ordering a test too frequently," he explains. "Also, there's a lot of focus on whether providers are collecting copays and deductibles."

Cooper advises clients to make a proper effort to collect copays and deductibles and not to provide broad-based waivers or caps on payment. While laboratories may make exceptions for financial hardship, they need to have a written policy on when such exceptions are granted, he says.

"Piggyback" Arrangements

Both Cooper and Foster say they have also seen an increase in what Cooper calls "piggyback" arrangements in which a laboratory that is out-of-network contracts with an in-network small rural hospital—such as a critical access hospital—to perform routine testing on specimens the lab collects nationwide. The hospital then bills the payer for the testing and passes the payment along to the laboratory, keeping a percentage for itself.

"We are seeing this primarily with toxicology labs," explains Cooper. "It's essentially a payment to use payer contracts."

Cooper says he advises against these types of arrangements because it puts the billing entity at risk. In some cases, these small hospitals bring in laboratory revenues that are two to three times what they make on other services.

"I don't think it's improper for a toxicology lab to perform reference testing services for inpatients and registered outpatients for a hospital, but that's not what I see happening here," he says. "Many arrangements involve outreach specimens from out-of-state sources."

"Each one of these arrangements needs to be analyzed on its own," agrees Foster. "I'm seeing some of these that carve out federal business to avoid risk under federal laws, despite the OIG's criticism of carve-out arrangements, and set up in states where there may not be laws that specifically address this conduct. This is risky as there may be other laws that are implicated, and commercial payers may be critical of such arrangements."

In fact, payers are becoming more aware of these questionable arrangements and are beginning to take legal action against the hospitals. In May of this year, Blue Cross & Blue Shield of Mississippi alleged breach of contract against Sharkey-Issaquena Community Hospital, alleging that it entered into a contract with Sun Clinical Laboratory LLC, Mission Toxicology LLC and its affiliates that allowed them to submit claims to Blue Cross using the hospital's name and billing information even though the services were performed independently of the hospital. The payer said that because the hospital is small and rural, its contract provides for a percentage of charge reimbursement rate.

"Blue Cross contracted at this rate with the hospital as a hospital and not as a laboratory for non-hospital patients, and certainly not to allow third parties to take advantage of the percentage of charge rate," according to the complaint.

Blue Cross said it paid about $9.8 million of the more than $33.8 million in total claims so far. It asked the court to bar the hospital and laboratories from submitting misrepresented claims going forward and asked that it not be required to pay misrepresented claims that are pending.

PathAI Raises $11M To Create AI Tools For Pathology

PathologyAI (Cambridge, MA) has raised $11 million from a group of venture capital firms led by General Catalyst Partners (Cambridge, MA). Other investors included Pillar Companies, Refactor Capital, 8VC, Danhua Capital and KdT Ventures. PathologyAI has now raised a total of $15 million from investors since being formed in 2016. The company plans to use the funds to expand its team of 15 employees and develop artificial intelligence software that can interpret digital pathology images.

Earlier this year, PathAI struck a partnership with Philips that is initially focused on developing decision-support software applications to help pathologists detect and quantify cancerous lesions in breast cancer tissue. The partnership was announced in late March, around the same time that the FDA cleared the Philips IntelliSite Pathology Solution for primary diagnostic use, making it the first digital pathology system to be approved for primary cancer diagnosis in the United States.

PathAI was co-founded by its CEO Andrew Beck, MD, PhD and its Chief Technical Officer Aditya Khosla, PhD. Beck earned his MD from Brown Medical School and completed residency and fellowship training in anatomic pathology and molecular genetic pathology from Stanford University, where he also earned a PhD in Biomedical Informatics. Khosla completed his PhD in machine learning and computer vision at MIT. He completed his MS at Stanford in 2011 and BS at Caltech in 2009.

LAB STOCKS UP 48% YTD

Eighteen lab stocks have risen by an unweighted average of 48% year to date through November 14. In comparison, the S&P 500 Index is up 17%. The top-performing lab stocks so far this year are Exact Sciences, up 337%; Foundation Medicine, up 171%; and CombiMatrix, up 136%. At the two largest public labs, LabCorp is up 17% and Quest Diagnostics is up 1%.

Company (ticker)	Stock Price 11/14/17	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.68	$1.35	98%	$65	NA	2.4	2.8
CareDx (CDNA)	5.84	2.70	116%	167	NA	3.6	10.6
CombiMatrix (CBMX)	6.25	2.65	136%	18	NA	1.2	3.1
Enzo Biochem (ENZ)	9.13	6.94	32%	425	NA	3.9	4.8
Exact Sciences (EXAS)	58.33	13.36	337%	6,980	NA	41.2	12.8
Foundation Medicine (FMI)	48.05	17.70	171%	1,740	NA	14.6	19.3
Genomic Health (GHDX)	28.38	29.39	-3%	987	NA	3.0	5.8
Interpace Diagnostics (IDXG)	1.23	4.40	-72%	27	NA	2.0	0.7
Invitae (NVTA)	7.86	7.94	-1%	395	NA	9.8	5.1
LabCorp (LH)	149.91	128.38	17%	15,260	21.0	1.6	2.6
Myriad Genetics (MYGN)	31.36	16.67	88%	2,170	113.2	2.8	2.8
NeoGenomics (NEO)	8.67	8.57	1%	688	NA	2.8	4.1
Opko Health (OPK)	4.61	9.30	-50%	2,580	NA	2.2	1.2
Psychemedics (PMD)	16.91	24.99	-32%	93	12.5	2.2	5.7
Quest Diagnostics (DGX)	92.42	91.90	1%	12,600	18.6	1.7	2.7
Sonic Healthcare (SHL.AX)	21.37	21.40	0%	9,030	20.9	1.8	2.3
Veracyte (VCYT)	6.07	7.74	-22%	207	NA	2.9	4.3
Vermillion (VRML)	1.43	0.95	51%	86	NA	28.1	17.7
Unweighted Averages			48%	$53,518	37.2	7.1	6.0

Source: Capital IQ

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