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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

ACLA Lawsuit Seeks PAMA "Do Over"

The American Clinical Laboratory Association (ACLA) has filed a lawsuit against Acting Secretary of the U.S. Department of Health and Human Services Eric Hargan challenging the process by which CMS calculated new reimbursement rates for lab tests paid through Medicare's Clinical Lab Fee Schedule (CLFS). The lawsuit argues that CMS wrongly excluded the vast majority of labs, including nearly all hospital labs, from reporting their private-payer data. The case was filed on December 11 and is being reviewed by Judge Emmet G. Sullivan in the U.S. District Court for the District of Columbia. If successful, the lawsuit will require HHS to return to the drawing board and publish a new rule that will include pricing data from all segments of the lab industry. "We think we have a strong case, but litigation against the government is always challenging," ACLA President Julie Khani tells *Laboratory Economics*. *Continued on page 2.*

How Will The PAMA Cuts Affect Your Lab in 2018?

Medicare's final CLFS for 2018, based on private-payer data, will result in cumulative cuts averaging roughly 35% for most high-volume test codes over the next few years. The cuts will be phased in, with a maximum 10% annual reduction for the first three years of implementation (2018-2020), and, for the following three years (2021-2023), the reduction cannot be more than 15% per year. Barring immediate legislative action or a court injunction (see story above), the new CLFS rates will become effective January 1, 2018. The new payment rates will hurt most labs, but there will be some segments that benefit. For *Laboratory Economics*' analysis of how various lab segments will be impacted, see pages 3-7.

ATP Loophole Will Help Offset PAMA Cuts

CMS has finalized private-payer-based CLFS rates for 2018 that will result in cumulative phased-in cuts averaging roughly 35% for most high-volume test codes over the next few years. CMS estimates that the Medicare program will save $670 million, or nearly 10% off its total annual Part B lab spending, in 2018 alone.

However, a change in the way that Medicare pays for panels containing certain automated chemistry tests could drastically reduce actual savings realized in 2018. CMS is discarding its longstanding way of paying for automated test panels (ATPs) because it was unable to collect private-payer pricing data for these unique panels. The ATP system was designed to remove the incentive for labs to maximize reimbursement by devising custom chemistry panels and billing for the component tests individually.

Under the new system, custom chemistry panels that are currently paid by Medicare in the range of $7.15 to $16.64 per panel may now get paid as high as $76.59. *Continued on page 10.*

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ACLA Lawsuit Seeks PAMA "Do Over" (*cont'd from page 1*)

The lawsuit is not seeking a preliminary injunction that would prevent CMS from implementing the drastically reduced rates contained in the final 2018 CLFS. "We would expect the new rates to go into effect on January 1," notes Khani.

Regardless of what happens in the lawsuit, a legislative solution remains necessary that will require HHS to go back to the drawing board and publish a new rule that requires all segments of the lab industry, including hospital outreach labs, to report their private-payer pricing data, according to Khani.

The lawsuit was filed to give the lab industry more visibility and leverage as it lobbies Congress for a legislative solution.

Ideally, new legislation would:

1) Delay implementation of the 2018 CLFS rates.
2) Require CMS to do a new survey of private-payer payment rates that includes a representative sample of the lab market, including hospital outreach labs.
3) Allow labs to report representative samples of their private-payer rates to lessen the burden of reporting information.
4) Set lower limits (currently 10% to 15% per year) on the maximum percentage rate cut that can be made to a test code each year

"CMS clearly disregarded and violated the [PAMA] statute's specific, unambiguous directives requiring commercial rate information to be reported and collected from a broad, diverse group of market participants," said Mark D. Polston, partner at King & Spalding (Washington, DC), the law firm which is representing ACLA in the suit. Prior to joining King & Spalding in 2012, Polston spent seven years at HHS, where he was Chief Litigation counsel for CMS.

Pricing data submitted by Quest Diagnostics and LabCorp represented an estimated 60% to 70% of the information used by CMS to calculate the new CLFS rates. Independent labs and physician office labs accounted for most of the remainder. Only 21 hospitals reported pricing information, representing less than 1% of the data.

The lawsuit claims that by relying predominantly on pricing data from Quest and LabCorp, HHS purposefully "cherry-picked" the data to lower Medicare CLFS payment rates. "A hidden tab labeled 'Hidden Data' in the Secretary's 2018 payment rates file confirms that the two largest independent laboratories generally have lower private payor rates than other reporting entities and that including their data resulted in lower calculated Clinical Laboratory Fee Schedule payment rates," according to the lawsuit. *Laboratory Economics* notes that after the lawsuit was released, CMS deleted the "Hidden Data" from the public files on its website.

HHS has not yet responded to the lawsuit. However, the government is likely to argue that its rates can't be challenged and reference a section of the PAMA law that states, "There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the establishment of payment amounts under this section."

Khani says the lawsuit received broad support from ACLA's board member companies, which include Aculabs Inc., ARUP Laboratories, Bio-Reference Labs, Joint Venture Hospital Labs, LabCorp, Mayo Medical Labs, Miraca Life Sciences, NeoGenomics, Quest Diagnostics and Sonic Healthcare USA.

The ACLA board also includes Myriad Genetics and Genomic Health. These companies are also members of Coalition for 21st Century Medicine, which strongly supports the PAMA market-based rates going in effective on January 1.

How Will The PAMA Cuts Affect Your Lab in 2018? *(cont'd from page 1)*

The National Labs

Quest Diagnostics currently receives approximately $900 million per year from Medicare CLFS payments, which represents 12% of its overall annual revenue of $7.7 billion. Quest anticipates that the CLFS rate reductions will lower its Medicare revenue by roughly 4%, or $37 million, in 2018.

Quest says that changes in the way that Medicare pays for automated test panels (ATPs) will help offset the full impact of the CLFS rate cuts in 2018 (see separate article on page 1). However, the company expects its Medicare CLFS rates to decline by 10% in 2019 and by another 10% in 2020. Ultimately, Quest will lose about $200 million per year of revenue from the CLFS rate reductions.

Quest anticipates that it will make up for the loss in revenue through increased acquisitions. The company is also gearing up to introduce new Advanced Diagnostic Laboratory Tests (ADLTs), which receive preferential Medicare pricing. Quest's Athena Diagnostics, which specializes in testing for neurological diseases, including Alzheimer's, is expected to be a source of ADLT development. And the recently acquired Cleveland HeartLab will focus on new ADLTs for cardiovascular disease.

LabCorp gets about $800 million per year from Medicare CLFS payments, accounting for approximately 8% of its overall annual revenue of $10 billion. The company anticipates that its Medicare CLFS revenue will decline by between 6% and 8% in 2018, and by a similar amount in 2019.

LabCorp is in the process of negotiating a new contract with United Healthcare. Its current contract expires at the end of next year. On an October 27 teleconference, LabCorp CEO Dave King, noted, "I certainly think as we go into these conversations, we are making it known to the commercial payers that any price reduction—remember, PAMA is an ongoing process with reporting required once every three years—that they seek would roll through to government pricing in the future. I think that is a constraint of, at least on our willingness to think about, significant price reductions in terms of commercial contract renegotiation."

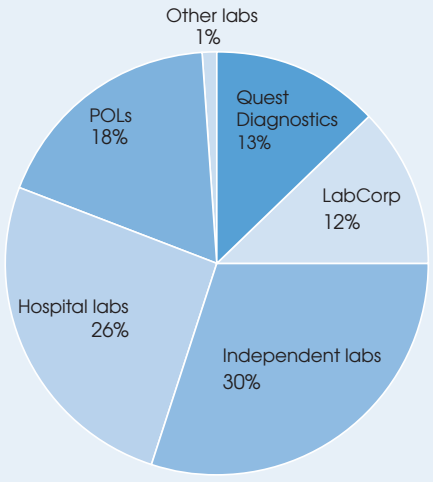
Where Medicare's $6.8 Billion for Lab Tests went in 2016

Medicare payments for lab tests under the Clinical Laboratory Fee Schedule totaled $6.8 billion in 2016, accounting for about 2% of all Part B payments in 2016. Medicare paid for a total of 436 million tests at an average of $15.60 per test. An average of 3.4 tests was billed per patient claim.

In 2016, Quest Diagnostics accounted for about 13% of Medicare CLFS payments for lab tests and LabCorp accounted for 12%.

Independent labs represented 30% of Medicare payments for lab tests. Hospital labs accounted for 26% of these payments, and physician office labs accounted for 18% of payments. Other labs, including nursing homes and dialysis facilities, accounted for the remaining 1%.

Market Share for Part B CLFS Payments, 2016



Source: *Laboratory Economics* from CMS

Physician Office Labs

Physician office labs (POLs) will fare well next year for many of the tests they perform most frequently. Private payer rates for most waived tests performed at POLs often averages 100% to 150% of the Medicare CLFS. As a result, a handful of test codes where POLs dominated the pricing information submitted to CMS will get significant Medicare price hikes in 2018.

For example, approximately 95% of the volume of testing for CPT 87084 (culture of specimen by kit) is performed at POLs at urology, family practice and internal medicine practices. The Medicare rate for CPT 87084 is increasing by 129% to $27.07 in 2018.

Another example is CPT 83037 (glycosylated hemoglobin A1c by FDA-cleared home device), where 98% of the volume of testing is performed at POLs at family practice, internal medicine and endocrinology practices. The Medicare rate for CPT 83037 is increasing by 69% to $22.50 in 2018.

The increased Medicare reimbursement probably won't lead to major changes to the operation of most POLs. That's because office-based clinical lab testing represents an average of only about 2-3% of the overall revenue generated at the typical family practice, internal medicine or Ob/Gyn group.

However, the price hikes being given to common POL tests do demonstrate the huge influence that more comprehensive pricing data can have when CMS made its private-payer pricing calculations, notes *Laboratory Economics*.

Medicare Rate Changes for Common Physician Office Lab Tests

Code	Description	2017 Rate	2018 Rate	% Change
87084	Culture of specimen by kit	$11.82	$27.07	129.0%
82805	Blood gases w/o2 saturation	38.92	78.77	102.4%
83037	Glycosylated hemoglobin (A1c)	13.32	22.50	68.9%
80047	Metabolic panel ionized CA	11.60	13.73	18.4%
82948	Reagent strip/blood glucose	4.35	5.04	15.9%
87430	Strep A ag ia	16.44	16.81	2.3%
82962	Glucose blood test	3.21	3.28	2.2%
87804	Influenza assay w/optic	16.44	16.55	0.7%
87880	Strep A assay w/optic	16.44	16.53	0.6%
81002	Urinalysis nonauto w/o scope	3.50	3.48	-0.6%
81025	Urine pregnancy test	8.67	8.61	-0.7%
82270	Occult blood feces	4.46	4.38	-1.8%
82272	Occult blood feces 1-3 tests	4.46	4.23	-5.2%
82947	Glucose blood quantitative	5.39	4.85	-10.0%
85025	Complete blood count	10.66	9.59	-10.0%
G0328	Fecal blood screen immunoassay	21.82	19.64	-10.0%

Source: *Laboratory Economics* from CMS

Hospital Outreach Labs

Medicare Part B CLFS payments to hospital labs totaled $1.77 billion in 2016, according to CMS. That represents an average of roughly $350,000 of lab outreach testing revenue from Medicare for each of the nation's 5,000 community hospitals. An across-the-board 10% reduction in Medicare CLFS payments, means that the average community hospital will lose about $35,000 of annual revenue as a result of the PAMA cuts in 2018, and a total of roughly $100,000 once all the cuts are phased in over the next few years.

Importantly, most hospital outreach labs are insulated from the risk of having the cuts ripple through to their private-payer rates because these rates are negotiated as part of their hospital's overall outpatient contracts and are not tied to the CLFS. Furthermore, Medicare rates for outpatient lab tests are not affected because they were bundled into an outpatient prospective payment system in 2014.

As a result, the PAMA pricing cuts are not likely to gain much attention from the CEO or CFO at most smaller hospital systems, notes Barry Portugal, President of Health Care Development Services Inc. (Nokomis, FL), a consulting firm focused on strategic planning for hospital labs and pathology groups.

However, Portugal notes that the PAMA rate cuts will obviously have a bigger impact on large hospital outreach labs that can have Medicare CLFS revenue in the range of $2 million to $10 million per year.

Portugal believes that the worst off will be those hospital outreach lab programs that function as independent labs. Hospital-owned independent labs can receive as much as 30% to 50% of their revenue from the Medicare CLFS and may have commercial contracts tied to the CLFS as well.

Over the past three years, in anticipation of the CLFS cuts, several of the largest hospital-owned independent labs have already been sold to Quest or LabCorp, including PAML, PeaceHealth Labs and Clinical Lab Partners.

Separately, in a declaration attached to ACLA's lawsuit against CMS, John Kolozsvary, Chief Executive of Joint Venture Hospital Laboratories (JVHL), warned that the reimbursement rates phased in under PAMA will ultimately be lower than the cost of providing lab services for some JVHL members, particularly those affiliated with critical access hospitals. As a result, some of JVHL's members will be forced to discontinue operating their outreach labs. JVHL negotiates private insurance contracts on behalf of 123 participating hospital labs across Michigan, northern Ohio, and northern Indiana, as well as for 40 pathology groups.

Medicare CLFS Revenue at Select JVHL Members ($ millions)

Hospital Name & Location	*CLFS Revenue 2016*
St. John Providence Hospital & Medical Center (Detroit, MI)	$8.1
Beaumont Laboratory (Royal Oak, MI)	7.6
Sparrow Regional Laboratories (Lansing, MI)	5.7
Beaumont Hospital (Dearborn, MI)	5.2
University of Michigan Hospital – MLabs (Ann Arbor, MI)	4.0
Covenant HealthCare System (Saginaw, MI)	2.7
OSF St. Francis Hospital (Escanaba, MI)	2.6

Source: ACLA Lawsuit, Khani Declaration, Exhibit 35

Anatomic Pathology Laboratories

Anatomic pathology procedures paid through the Medicare Physician Fee Schedule will not be affected by the PAMA rate cuts to the CLFS. However, many AP labs do perform Pap and HPV screening tests, which are paid through the CLFS and subject to rate reductions.

PathGroup (Brentwood, TN), ProPath (Dallas, TX), Aurora Diagnostics (West Palm Beach, FL), Pathology Reference Laboratory (San Antonio, TX) and APP-Unipath (Denver, CO) are among the larger independent pathology labs with significant cervical cancer screening volumes. Overall, there are more than 500 labs that do Pap and HPV testing in the United States.

Medicare reimbursement for the key code CPT 88175 (cytopath c/v auto fluid redo) is currently set at $36.34, but will decline by 10% to $32.71 in 2018, and will ultimately fall by 27% to $26.61. Similarly, the Medicare rate for CPT 87624 (HPV high-risk types) will be lowered by 10% to $43.33 in 2018, and will ultimately drop by 35% to $31.26.

Medicare represents a small percentage of payment for cervical cancer screening, so the big question is "What will private insurance payers do?"

The cervical cancer screening market is already shrinking due to lengthening intervals between screenings. If private payers start ratcheting down rates, then lower-volume labs may find this business unviable, and testing will consolidate at the larger labs.

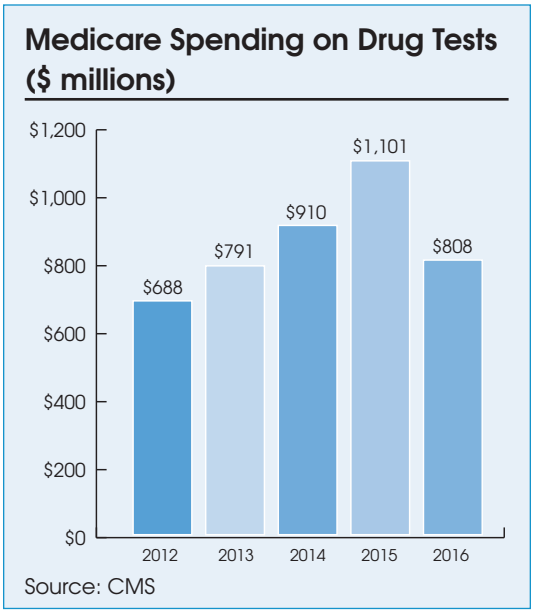
Independent Labs Serving Nursing Home Patients

The last issue of *Laboratory Economics* highlighted the fact that independent labs serving nursing homes will get hit the hardest by the Medicare CLFS rate cuts (*LE*, December 2017, p. 6). ACLA's lawsuit contains a declaration from Peter Gudaitis, President of Aculabs (East Brunswick, NJ), that details the devastating impact the cuts will have on his lab.

Aculabs performs more than 10 million lab tests per year for approximately 750,000 patients at 320 nursing homes and assisted living facilities in New Jersey, Pennsylvania, Maryland and Delaware. Its phlebotomists travel to these sites every morning to draw blood and bring the samples back to Aculabs' testing facilities in either Cherry Hill (near Philadelphia) or East Brunswick (near New York City).

Approximately 95% of Aculabs' revenue is tied to the Medicare CLFS, either directly billed to Medicare or paid by nursing home clients at a negotiated rate typically expressed as a percentage of the Medicare CLFS. Gudaitis estimates that Aculabs' revenue will be reduced by approximately 30% over the next three years as a result of the new PAMA-devised rates.

"If CMS's failure to require data reporting from all applicable laboratories is not corrected, it will only be a matter of one or two years before the company started by my father and built by my family for the last 45 years will be forced out of business," wrote Gudaitis.



Toxicology Labs

After peaking in 2015 at $1.1 billion, Medicare spending on drug tests decreased by 26% to $808 million in 2016. The decrease in payments coincided with CMS's use of new bundled payment codes for drug tests. Prior to 2016, CMS paid separately for each drug class for which a patient was tested. Starting in 2016, in order to discourage overutilization, CMS paid a set amount for multiple tests, regardless of which drugs were being tested. The new payment system resulted in rate reductions that ranged from 30% to 75% depending on the tests ordered.

The 2018 CLFS rates will result in additional substantial rate cuts. For example, G0483 (drug tests, definitive, per day, 22 or more drug classes) will be reduced by 10% in 2018 and will ultimately drop by a total of 24%. In addition, G0480 (drug tests, definitive, per day, 1-7 classes) will be cut by 10% in 2018 and will ultimately drop by a total of 59%. Remember, these changes are following the significant cuts made in 2016.

Reimbursement pressure is forcing toxicology labs to either diversify into new markets, mostly molecular diagnostics, or go out of business.

Private Insurance Payers

The release of final Medicare CLFS for 2018 sheds some light on the different rates that private insurance companies pay different types of labs. Together, Quest Diagnostics and LabCorp accounted for roughly 60% to 65% of the pricing data submitted to CMS, while independent labs accounted for 25% to 30%, and physician office labs accounted for 8%.

The new CLFS rates for 2018 will directly influence lab rates set by Medicaid and the Federal Employees Health Benefits Program. The big question now is "Will Aetna, United, Cigna, BCBS plans, etc. make proportional changes to their lab fee schedules based on the new PAMA CLFS rates as contracts come up for renewal over the next 12-24 months?"

Laboratory Economics believes the national labs have secured long-term contracts that lock in rates for 3-7 years to delay the reset of these contracts at potentially much lower rates. But smaller labs with annual contracts seem to be at risk.

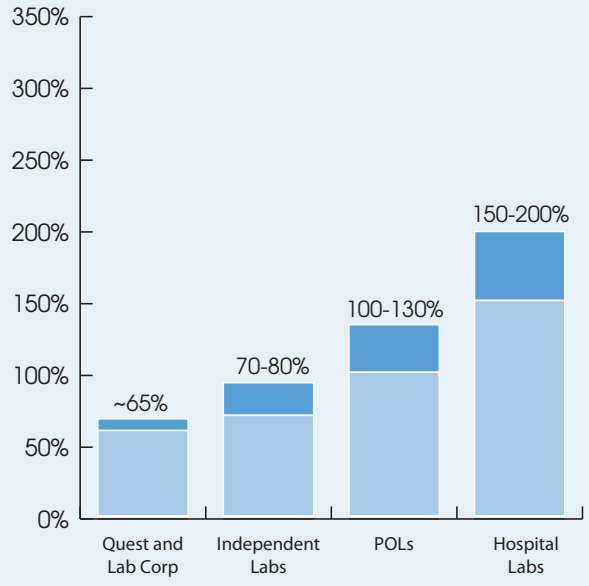
"It is difficult to predict what private payers will do, but certainly the larger insurers (United, Aetna, Cigna, et al.) were already aware of the discrepancy in pricing between the large labs, smaller labs and hospital labs. Undoubtedly, they are also looking at industry reaction to determine the impact of the Medicare cuts," notes Lale White, President of XIFIN Inc. (San Diego, CA).

White says that while national lab pricing has, in the past, prompted private payers to cut reimbursement levels to the rest of the market, hospitals have always maintained substantial negotiating leverage for their entire book of business.

More recently, White points out that narrow networks and coverage (things like pre-authorizations and limited or non-coverage) have been much bigger issues than reimbursement.

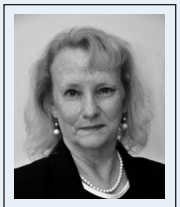
Going forward, she says that private payers will need to be thoughtful in how they balance fee schedules and consider access and out-of-network costs. "It would be impossible to suggest that they will not be influenced at all by the new Medicare CLFS rates, but it will not be their sole consideration."

Estimated Average Private Payer Rates as Percentage of Medicare, 2017



Source: Estimated by *Laboratory Economics*

Spotlight Interview with Centra Health's Director of Laboratories


Lakricia Duncan

Centra Health is a regional nonprofit healthcare system based in Lynchburg, Virginia. Created in 1987 through the merger of Lynchburg General and Virginia Baptist, the health system now serves more than 380,000 people throughout central and southern Virginia. *Laboratory Economics* recently spoke with Lakricia Duncan, Managing Director of Laboratories for the health system.

How many laboratories does Centra Health have?
We have four hospital laboratories, and we have a freestanding emergency department, which has its own lab. We also have 12 labs in our multi-physician groups. We have 240 lab employees altogether. Our core lab is at Lynchburg, and we use LabCorp as our reference laboratory.

How much are you growing in terms of volume and revenues?
This year we did about 2.5 million tests, including approximately 60% from inpatient testing, 10% outpatient and 30% outreach. Over the past two years, our volume growth has been 14% and we're projecting growth of about 8% next year.

What is driving your growth?
Centra has grown by adding on new facilities. We also expect other internal growth, which will bring in more business. We've seen a lot of growth from the POLs, and we've added business from other referral sources that were using another lab. We also are starting to work with the Opioid Coalition of Central Virginia, and we will be doing their lab testing starting in January. We're also doing free clinic work for Access Network, which serves patients without insurance or who are on Medicaid.

Where are you seeing the greatest growth?
In terms of testing areas, we're seeing growth in pain management, respiratory panels and PCR testing.

Do you have any new initiatives underway?
We're working with Cerner to standardize our electronic medical records, which should help us build interfaces more quickly. We're also standardizing the equipment in all our labs to help us save money, as well as renegotiating contracts and decreasing point-of-care testing where it makes sense. We've been using Lean Six Sigma to make our processes more efficient. Also, we have a medical laboratory technician program in conjunction with Central Virginia Community College, and we're starting a phlebotomy school with them this spring. Being able to recruit staff has a huge impact on our bottom line. We saved $2 million the first year by recruiting and hiring our students in place of using temporary staff.

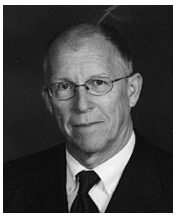
How will your lab adapt to the new PAMA Medicare payment system for lab tests?
Medicare is about 70% of our total patient population. We're projecting cuts of $1.2 million the first year and $3.6 million over three years. We have to be more cost effective, and we have to work with our vendors carefully. We are reviewing our test menu, looking at tests that make sense to keep and those that don't. We spend almost a $1 million on POC testing each year, so we are looking to reduce that. We think we can save a couple hundred thousand dollars.

What are your greatest challenges?
Other than PAMA, our biggest challenge is converting to the new EMR. We're also preparing for a new hematology system and a new chemistry line.

What are your biggest opportunities?
There are many opportunities to expand into new parts of Virginia. Right now, we only have one sales person, so we really need to build our sales team.

ATP Loophole May Offset PAMA Cuts (*cont'd from page 1*)

Charles Root, PhD, President of CodeMap LLC (Schaumburg, IL), says that the current Medicare payment system automatically bundles 23 common chemistry tests into automated test panels (ATPs) reimbursed at discounted rates, thereby eliminating the incentive to create custom panels solely to increase reimbursement. As it stands today, if a lab bills any combination of those 23 tests, Medicare reimbursement is limited to a maximum of $16.64.


Charles Root, PhD

However, starting in 2018, certain combinations of those same 23 tests will result in substantially higher reimbursement. Roots says there are legitimate common lab test orders that will appropriately be paid more, but that there will also be opportunities for less scrupulous labs to reconfigure their test panels to game the system.

Legitimate Reimbursement Hikes from Elimination of ATP Payments

A legitimate example would be when a physician orders a lipid panel (CPT 80061, including total cholesterol, HDL cholesterol and triglycerides) plus tests for Alanine aminotransferase (CPT 84460) and Aspartate amino (CPT 84450). This is a combination of tests frequently ordered to monitor patients taking cholesterol-lowering drugs to check for liver damage, according to Root. Under the current ATP payment system, this group of tests is paid based on four automated chemistry tests under ATP04 at $9.62 plus one non-automated test (HDL cholesterol) paid at its individual CPT code rate of $11.24. Total Medicare reimbursement is $20.86.

Beginning in 2018, this same group of codes (80061, 84460 and 84450) will be paid at the sum of their individual 2018 CLFS rates, which totals $29.46. That represents a 41% increase in payment, but it's appropriate based on the new rules, notes Root.

Another legitimate example is when a physician orders more than one panel of tests. Currently, for instance, an order that includes both a lipid and a metabolic panel for a particular patient is subject to the ATP payment system which results in total reimbursement of $25.73. Next year, Medicare will pay the individual CPT code rates for each panel, which will total $29.57, an increase of 15%.

Sketchy "N-1" Panel Configurations that will Pump Up Reimbursement

Root notes that some labs could take advantage of the elimination of the ATP system by deleting standard chemistry panels on the requisition forms given to ordering physicians, and replacing them with partial panels.

For example, the most commonly ordered chemistry panel—Comprehensive Metabolic (CPT 80053)—includes 14 tests and is currently reimbursed by Medicare at a maximum of $14.49. Under today's ATP system, if a lab bills for a partial Comprehensive Metabolic Panel with 13 tests or fewer they get less reimbursement.

The Medicare rate for a Comprehensive Metabolic Panel is set to decrease by 10% to $13.04 effective January 1, 2018. However, if a lab removes the least useful test (Carbon dioxide) and begins offering a partial Metabolic Panel with 13 tests on its requisition forms, it can then bill Medicare for each of the 13 individual codes for total reimbursement of $76.59.

There are 41.6 million claims for CPT 80053 paid by Medicare each year, including 29 million claims from independent labs and POLs plus 12.6 million from hospitals. Theoretically, if all labs switched to a partial Metabolic Panel (N-1), then Medicare payments would increase from 41.6M x $13.04 = $542 million to 41.6M x $76.59 = $3.2 billion.

If only one-quarter of the 41.6 million annual claims for CPT 80053 were converted to the "N-1" panel format, then that would be enough to wipe out all of CMS's projected $670 million of savings from the PAMA repricing in 2018, notes *Laboratory Economics*.

In addition to the Comprehensive Metabolic Panel, there are five other chemistry panels where the "N-1" strategy could be used to dramatically increase reimbursement (see table below).

Opportunities to Game Medicare through "N-1" Strategy

Test Name and Code	Full Panel Rate, 2018	Partial Panel (N-1) Rate, 2018	% Difference
Comp Metabolic (80053)	$13.04	$76.59	487%
Renal Function Panel (80069)	10.72	51.69	382%
Basic Metabolic with total CA (80048)	10.44	40.91	292%
Hepatic Function Panel (80076)	10.09	37.81	275%
Basic Metabolic with ionized CA (80047)	13.73	50.24	266%
Electrolyte Panel (80051)	8.66	17.30	100%

Source: *Laboratory Economics* from 2018 CLFS

Root says the unintended design of some point-of-care testing systems allows physician offices to selectively perform individual chemistry tests. "The temptation will be there and some POLs may go berserk with this," he adds.

On November 17, when CMS released the final 2018 CLFS, the agency stated, "For CY 2018, payment for tests that were bundled into ATPs will instead be made at the individual HCPCS code level. In other words, we will pay for each appropriately billed HCPCS code based on the CLFS amount for the specific code billed by the laboratory. Moving forward we will continue to consider the efficiencies of ATPs and the appropriate payment methods for these tests under the new private payer rate-based CLFS."

This suggests that the ATP loophole will be open for at least 2018.

However, utilizing an "N-1" strategy could lead to major compliance problems because it utilizes unbundling. And DHHS's Office of Inspector General has published numerous materials over the years that have identified unbundling as fraudulent coding.

The OIG's definition of an unbundled lab test is: *"when a laboratory bills separately for some, or all tests, analyzed simultaneously by a single piece of equipment on a single patient specimen. There are sophisticated versions of this type of false billing. In some cases, laboratories have provided an option for physicians to order customized groupings of tests (called panels and profiles) that do not exactly correspond to the coding principles used by Medicare."* OIG, Medicare Payments for Clinical Laboratory Services: Vulnerabilities and Controls, OEI-05-00-00070, January 2000.

"Any lab that begins offering custom panels to increase reimbursement is asking for trouble," warns Diana Voorhees, President of DV & Associates (Salt Lake City, UT), a coding and reimbursement consulting firm. "Using the N-1 strategy is an invitation for a RAC audit and could easily be construed as an overpayment."

Switch to a Single Unadjusted NLA will also lead to Rate Hikes in Some States
Currently, Medicare pays the National Limitation Amount (NLA) for a lab test, unless the local fee schedule rate is lower. There are 57 local fee schedules across the United States. Generally, most local fee schedules have at least a few tests that are paid below the NLA. Effective January 1, 2018, Medicare is moving to a single national fee schedule for the CLFS. As a result, certain test codes on some local fee schedules currently priced below the NLA may be increased in 2018.

For example, CPT 88175 (cytopath c/v auto fluid redo) is currently set at $36.34, but will decline by 10% to $32.71 in 2018. However, in New Mexico, the local carrier currently pays CPT 88175 at a limit of $25.25. So next year in New Mexico, payment CPT 88175 will rise by 30% from $25.25 to the new uniform NLA of $32.71.

The elimination of local fee schedules and shift to one uniform NLA will have a small positive impact, mostly on more rural states such as Alabama, Idaho, Kentucky, New Mexico, Oklahoma, South Carolina, Vermont, Wyoming, et al.

MolDx Program Continues to Expand Even as Concerns Remain

With the selection of Palmetto GBA as the Medicare Administrative Contractor for Jurisdiction J, three additional states—Georgia, Tennessee and Alabama—will now be subject to the Molecular Diagnostics program (MolDx), which determines Medicare coverage for molecular tests, as well as some additional lab and pathology tests.

More than 30 states and U.S. territories are now covered by MolDx, which Palmetto began in 2011. While the program continues to expand, it is not officially a national program subject to established regulations and transparency and still uses many protocols that are inconsistent with Medicare coverage guidelines, says Lale White, Chief Executive of XIFIN Inc.

Under MolDx, providers are required to register all molecular tests with the Diagnostics Exchange (DEX), which assigns a unique Z-Code to each test. The MolDx team then determines if each test meets the Medicare criteria for coverage.

Georgia, Tennessee and Alabama will come under Palmetto's jurisdiction beginning Jan. 29, 2018, but there will be a transition period to MolDx to give providers time to obtain their Z-Codes. Z-Codes are expected to be required on claims submitted on or after June 1, 2018.

The following CPT codes require a Z-Code for each molecular test prior to claim submission:

Code Category	*MolDx CPT Code Range*
Tier 1 Molecular Pathology Procedures	81161-81383
Tier 2 Molecular Pathology Procedures	81400-81408
Genomic Sequencing and other MAAs	81410-81471
Molecular Multianalyte Assays (MAAs)	81490-81595
MAA Proprietary Codes	0001M-0009M
Immunology	86152-86153
Microbiology	87149, 87150, 87505-87507, 87631-87633
Cytology	88120-88121, 88271-88275
Proprietary Laboratory Analyses (PLA)	All Codes
Not otherwise classified (NOC)	81479, 81599, 84999, 85999, 86849, 87999, 88199, 88299, 88399, 89398

While MolDx was established specifically for molecular diagnostics codes, it has since broadened in scope to include unlisted pathology and lab codes, as well as pharmacogenetics codes, notes White, who says the program has greatly complicated the claims submission and adjudication process across all payers.

Lab Stocks Up 45% YTD

Eighteen lab stocks have risen by an unweighted average of 45% year to date through December 15. In comparison, the S&P 500 Index is up 20%. The top-performing lab stocks so far this year are Exact Sciences, up 286%; Foundation Medicine, up 230%; and CareDx, up 165%. At the two largest public labs, LabCorp is up 24% and Quest Diagnostics is up 8%.

Company (ticker)	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$1.35	44%	$47	NA	1.6	1.5
CareDx (CDNA)	2.70	165%	205	NA	4.4	NA
CombiMatrix (CBMX)*	2.65	136%	18	NA	1.2	3.1
Enzo Biochem (ENZ)	6.94	27%	412	NA	3.8	4.6
Exact Sciences (EXAS)	13.36	286%	6,170	NA	28.9	11.7
Foundation Medicine (FMI)	17.70	230%	2,120	NA	16.0	33.3
Genomic Health (GHDX)	29.39	21%	1,240	NA	3.7	7.1
Interpace Diagnostics (IDXG)	4.40	-79%	25	NA	1.7	0.6
Invitae (NVTA)	7.94	8%	453	NA	8.7	3.4
LabCorp (LH)	128.38	24%	16,190	22.2	1.6	2.7
Myriad Genetics (MYGN)	16.67	101%	2,320	22.2	3.0	2.7
NeoGenomics (NEO)	8.57	7%	738	NA	2.9	4.4
Opko Health (OPK)	9.30	-46%	2,790	NA	2.4	1.3
Psychemedics (PMD)	24.99	-18%	113	18.6	2.8	6.6
Quest Diagnostics (DGX)	91.90	8%	13,492	20.8	1.8	2.8
Rosetta Genomics (ROSG)	5.04	-89%	3	NA	1.0	1.3
Sonic Healthcare (SHL.AX)	21.40	8%	9,730	22.6	1.9	2.5
Veracyte (VCYT)	7.74	-17%	219	NA	3.1	5.1
Unweighted Averages		45%	$56,285	21.3	5.0	5.6

*CombiMatrix was acquired by Invitae on November 15.

Source: Capital IQ

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