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For Clinical and AP Laboratories and Pathology Practices

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Upcoming Events

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Lab Reimbursement Summit 2018
December 8, 2017
Holiday Inn Airport (South)
Atlanta, GA
www.lableadershipsummit.com

PAMA-Geddon: Proposed 2018 Lab Pay Rates Are a Bloodbath

- There will be no delay; and
- And hospital labs will remain excluded from "applicable laboratories" on which supposed market rate payments for lab tests will be based.

Those were the first two things we learned on Sept. 22 when CMS issued its preliminary Clinical Laboratory Fee Schedule (CLFS) for 2018. And it got even worse for those with the stomach to look at the proposed rates.

The Market Rates Controversy

PAMA is supposed to base Medicare payments on market rates. Starting Jan. 1, 2018, CMS will determine the prices for particular lab tests based on the weighted median of private payor rates for particular tests. So, how does CMS know what those rates are?

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Brief Your CEO: The 4 Key Takeaways from the OIG 2016 Part B Lab Payments Report

As PAMA payment system D-Day creeps closer, the OIG issued its report on 2016 Medicare lab payments. *Spoiler Alert:* It was more of the same in 2016. Part B payments for lab tests over the past three years have remained incredibly consistent in terms of both amount and reimbursement patterns. Here are the four things lab managers need to ensure their CEOs know about the OIG Report.

1. The Whole PAMA Context

Make sure the CEO understands that the reason the OIG is issuing these reports is that PAMA (the *Protecting Access to Medicare Act of 2014*) requires it to monitor Medicare Part B payments for lab tests in advance of the new payment system scheduled to take effect on Jan. 1, 2018. (See the related article above). The September 2017 Report covers 2016, Year 3 of Baseline Data under the OIG PAMA monitoring mandate. Starting in 2018, CMS will update the Clinical Laboratory Fee Schedule (CLFS) using the median of private payer rates, weighted by test volume, to establish a new payment rate that will then be updated every three years based on data supplied by labs.

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PAMA-Geddon: Proposed 2018 Lab Pay Rates Are a Bloodbath, *from page 1*

To answer that crucial question, CMS has been gathering data from "applicable laboratories" since 2014. The lab industry is perfectly fine with that approach. The problem is the execution, namely, CMS's determination to exclude hospital and community labs in its definition of "applicable laboratories." In addition to being key components of the lab market, these labs have the leverage to command higher rates for tests from payors. Consequently, excluding their pricing data was bound to artificially skew rates in a downward direction.

Deep Cuts in the CLFS

At least that is what the lab industry has been arguing. And, based on the deep and widespread cuts proposed, the industry appears to have been right. The 2018 CLFS would cut the rates of approximately 75% of lab tests. The only saving grace is that 58% of the rate cuts will be phased in due to CMS's 10% per year cap on reductions from 2018 to 2020. CMS claims that the new rates will save Medicare Part B about $670 million in CY 2018.

"If these draft rates were finalized, the impact would be devastating," according to American Clinical Laboratory Association President Julie Khani. "We fear the impact on laboratories serving the most vulnerable Medicare beneficiaries, laboratories serving rural areas, and those with high Medicare volumes would be the most severely impacted."

Here's an overview of the key things lab managers need to know about the proposal.

Reference Labs Suffer the Deepest Cuts

Although the rate cuts would have widespread effects, they hit big reference labs like Quest Diagnostics and Laboratory Corporation of America especially hard. In a note to investors, Piper Jaffray analyst William Quirk writes that the expected revenue decline of approximately 8% in the first three years is even worse than Wall Street's initial expectations of a 6% drop in 2018 followed by a flat 2019-2020. So it is hardly surprising that word of the CLFS sent the share prices of both firms sharply down.

Both labs have also issued statements criticizing the preliminary rates as not being market-based because they exclude payment data from hospital labs. According to Quest CEO Steve Rusckowski, "hospitals and physician office labs comprise half of Medicare clinical lab fee schedule volume and lab spending, but only accounted for 8.5% of the reported lab volume used by CMS to calculate the rates."

Mixed Bag for Molecular Dx

Newfangled proprietary tests offered by a limited number of labs fared better than reference lab tests provided by large numbers of hospital and reference labs. A notable example is molecular diagnostic tests. Thus, while a few molecular tests did suffer deep cuts (including tests for Lynch syndrome (CPT 81435) and TRB gene rearrangement direct probe (CPT 81341)), molecular assays were hit with generally smaller declines and even a few rate increases.

G2CA

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Molecular DX Test Winners & Losers

Test	Proprietary Manufacturer(s)	2017 Rate	Proposed 2018 PAMA Rate
CPT 81519 (Oncotype DX for breast cancer recurrence)	Genomic Health	$3,443.36	$3,873
CPT 81525 (Oncotype DX for colon cancer recurrence)	Genomic Health	$3,126	$3,116
CPT 0008M (Prosigna for breast cancer recurrence)	Nanostring	$3,443	$900
myRisk Hereditary Cancer (based on CPT 81211 and 81213)	Myriad Genetics	$2,781	$2,949
CPT 81490 (Vectra DA rheumatoid arthritis test)	Myriad Genetics	$591	$841
CPT 81450 (hematological malignancies)	--	$541.81	$648.40
CPT 81445 (targeted next-generation sequencing of 5 to 50 genes panels)	--	$602.10	$597.91
CPT 81432 (Invitae hereditary cancer panel)	Invitae	$931	$838
CPT 81528 (Cologuard colon cancer screen)	Exact Sciences	$512	$509
CPT 81420 (prenatal testing)	Illumina, Natera, et al.	$802	$759
CPT 81435 (Lynch syndrome test)	--	$802	$38

Advanced Diagnostic Laboratory Tests (ADLTs)

Another category of tests to dodge the axe are the newfangled ADLTs, i.e., tests developed and offered by a single lab that use a unique algorithm to analyze multiple DNA, RNA or protein markers, and which provide new clinical diagnostic information that cannot be obtained by any other test. Two key ADLT test codes to get increases included:

- CareDx's AlloMap for cardiac transplant rejection risk (CPT 81595): from $2,841 to $3,240; and
- Veracyte's Affirma Gene Expression Classifier for classifying thyroid nodules (CPT 81545): from $3,222 to $3,600.

Crosswalk Codes

CMS also issued crosswalk- and gapfilling-based preliminary rates for 58 HCPCS codes for which it received no private payor data.

Takeaway: CMS is taking public comments on the proposed rates through Oct. 23 with the expectation of issuing final rates in November. In the meantime, the lab industry has not given up on its efforts to persuade the agency to change the pricing formula to include hospital labs or at least delay the new PAMA rates from taking effect on Jan. 1.

OIG Work Plan Monthly Review: October 2017

Drugs continue to command the OIG's attention with three of this month's five new Work Plan items dedicated to the issue. Although none of the new items specifically address lab services, four of them could have an indirect impact on some labs, particularly the item targeting Medicare payments for bariatric surgeries.

1. Medicare Payments for Bariatric Surgeries

Concern: A Comprehensive Error Rate Testing program's special study of certain HCPCS codes for bariatric surgical procedures found that approximately 98% of improper payments lacked sufficient documentation to support the procedures.

What OIG Will Investigate: The OIG will review the supporting documentation to determine whether the bariatric services billed for under Medicare Parts A and B met coverage requirements.

2. Specialty Drug Coverage and Medicaid Reimbursement

Concern: Medicaid spending on specialty drugs, the definition of which varies from state to state, has sharply increased in recent years.

What OIG Will Investigate: The OIG will review how states define and pay for specialty drugs under Medicaid, how much they pay for them and what strategies they use, e.g., formularies, cost sharing, step therapy and prior authorization to manage those costs.

3. FDA Oversight of Prescription Opioid Abuse Risk Evaluation & Mitigation Strategies

Concern: A 2007 law gives the FDA authority to require pharmaceutical companies to develop Risk Evaluation and Mitigation Strategies (REMS) if the agency thinks the risk of using a drug outweighs its benefits.

What OIG Will Investigate: The OIG will review how the FDA uses this authority with regard to opioid drugs, specifically how it determines the need for opioid-related REMS and holds manufacturers and sponsors accountable for mitigating risks of opioid misuse, addiction, overdose and serious complications due to medication errors.

4. Drug Traceability Test

Concern: The Drug Supply Chain Security Act (DSCSA) gives the FDA new powers to keep diverted, counterfeit, imported and other potentially harmful drugs from getting into the supply chain and to spot and remove any that are already there. Those powers include requiring trading partners to exchange drug product tracing information when they take ownership of drugs.

What OIG Will Investigate: The OIG will determine the extent to which DSCA records can be used to trace drugs from the dispenser back to the manufacturer.

OIG Calls on CMS to Do Better at Medicare Collecting Overpayments

The system Medicare uses to detect and recover overpayments isn't working as well as it should be, according to a new OIG report.

The Overpayment Collection System

CMS relies on special contractors called program safeguard contractors (PSCs) and six zone program integrity contractors (ZIPCs) to detect overpayments and refer them to Medicare administrative contractors (MACs) for collection. After discovering that most of the overpayment money wasn't being collected, CMS tinkered with the system. The OIG report looks at how well the PSCs, ZIPCs and MACs performed in FY 2014.

Findings

Not so well, it turns out:

- **$559 million:** Total Medicare overpayments PSCs and ZIPCs referred in FY 2014;
- **$482 million:** Amount MACs attempted to collect;
- **$96 million:** Amount MACs actually did collect;
- **80%:** Amount of overpayments that went uncollected.

Although a 20% collection rate is pretty lousy, it's still better than the 7% rate of 2010, the report notes.

OIG's 5 Recommendations

CMS is already transitioning from PSCs and ZIPCs to unified program integrity contractors (UPICs). Other things the OIG recommends that CMS do to improve overpayment collections:

1. Get the individual PSCs and ZIPCs to share best practices with each other, which would rectify the notable disparity in performance from contractor to contractor;
2. Work with MACs to come up with effective collection strategies;
3. Establish standard report formats for both overpayment referral reports and overpayment collection reports;
4. Require ZPICs, UPICs and MACs to use a unique identifier for each overpayment; and
5. Implement the surety bond requirement for home health providers and consider the feasibility of doing the same for other providers, which could include labs, based on their level of risk.

Case of the Month: Lab Tests Play Key Role in $19 Million Detroit Opioid Scheme

A physician just pleaded guilty to ordering millions in medically unnecessary lab tests? So what else is new? Please pass the butter. . .

Granted, stories like the Oct. 12 guilty plea of that physician in Michigan are old hat. But what makes the case highly significant is not the storyline but its playing out within the context of an opioid drug scheme.

The takeaway from the Michigan case is its providing another illustration of how the current opioid drug epidemic is influencing the direction of federal health care fraud enforcement.

The Case

The defendant in this case was a 72-year-old physician who admitted to conspiring with two other Detroit-area providers, including the owner of the Tri-County Network, in carrying out an opioid drug scheme that generated roughly $19 million in fraudulent Medicare billings. The doctor's role:

- Prescribing medically unnecessary oxycodone, opana and hydrocodone to Medicare patients, many of whom were drug addicts;
- Directing physicians to make Medicare patients who wanted an opioid prescription to first undergo medically unnecessary facet joint injections and lab tests; and
- Telling physicians to refer those services to labs, clinics and other facilities in which he had secret ownership interests.

Same Rules, New Context

The takeaway from the Michigan case is its providing another illustration of how the current opioid drug epidemic is influencing the direction of federal health care fraud enforcement. This summer, the Department of Justice unleashed a potent nationwide crackdown on opioid drug abuse, both illegal and prescription.

Labs and physicians are not necessarily the primary target. However, they are well within the range of potential suspects to the extent that urine testing plays a key role in detecting prescription opioid abuse. Doctors contend that medical guidelines require screening tests when prescribing pain pills. But critics contend that there is too much screening testing. And, of course, the more frequently the tests are ordered, the more they cost.

None of these concerns are novel. Illegal billing of drug tests by labs, physicians and addiction treatment centers is a perennial issue for the OIG and Justice Department and played a key role in the Millennium Health case which settled for $256 million in 2015.

But the volume and pace of these cases is and will continue to increase for as long as opioid drug abuse remains a centerpiece of federal policy. Recent examples include genetic testing company Proove Biosciences whose Southern California HQ was raided by the FBI in a Takedown case targeting illegal dispensing of oxycodone and opioids by Physicians Primary Care (PPC) in

Indiana, and urinalysis lab Confirmatrix, which was allegedly involved in a Tennessee opiate pill mill scheme. (See "Labs In Court," *NIR*, September, 2017).

Takeaway: If your lab is involved in opioid drug testing, you need to be on ultra-high compliance alert.

Compliance Quiz: Spot the HazCom Mistake

SITUATION

Health and safety director Matt Hazard is responsible for keeping the lab compliant with OSHA HazCom rules. He takes inventory of all the hazardous substances the lab uses in the workplace. He verifies that there's a complete, up-to-date Safety Data Sheet (SDS, previously known as MSDS for Material Safety Data Sheet) from the chemical's manufacturer or supplier for each one. He assembles all of the SDSs into a loose leaf binder and keeps it in his office. Although Matt keeps the office locked, he goes out of his way to remind lab workers that he'll gladly give the binder to anybody who asks to see it.

QUESTION

What did Matt do wrong?

A. He didn't independently verify the accuracy of the information listed in the SDS

B. He used the manufacturer's SDS instead of preparing a lab version

C. He kept the SDS binder in his locked office

D. He kept the SDSs in a paper binder rather than a computer system

ANSWER

C. Matt did everything right except for keeping the SDS binder behind a locked door

EXPLANATION

OSHA HazCom (short for "Hazard Communication") standards require employers, including labs, to make the SDS readily accessible to any worker who may be exposed to hazardous chemicals and substances. Although it doesn't specify an exact method, OSHA interprets "readily accessible" to mean that workers should have access to the SDS when they're in work areas during work shifts. Workers should have access to that information themselves and not through somebody else. Keeping SDSs in the office of a safety director (or any other individual for that matter) is problematic because:

- The office may be far from the work area or even off the premises;
- The office is likely to be kept locked during certain shifts; and
- Workers must be able to see the SDS without having to ask anybody for permission or making an appointment

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WHY WRONG ANSWERS ARE WRONG

A is wrong because labs are allowed rely on SDS information they get from their chemical manufacturers or suppliers without having to evaluate the substance independently.

B is wrong because labs are allowed to use the manufacturer or supplier SDS—they only have to write their own SDS if they produce the chemical themselves.

D is wrong because old fashioned loose leaf paper binders are perfectly fine. While making SDS sheets available to lab workers via computer terminal is an option, it isn't mandatory.

(For more on how to comply with OSHA Hazcom rules, see *GCA*, Nov. 2, 2015)

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Free Point of Care Test Cups Results in $64K Kickback Settlement Bill

Case: The embers from the Millennium Laboratories case, which settled in 2015, continue to smolder. The latest collateral defendant is Parallax Center, a New York City drug addiction treatment center which has agreed to pay the OIG $64,203 to settle kickback-related charges.

Significance: For lab managers, the takeaway from this case is what got Parallax into trouble, namely, providing Millennium, free point of care test cups. The OIG has made it abundantly clear that compensation need not be elaborate to cross the line; something as seemingly trivial as free cups may have enough value to establish an illegal relationship between the lab and referral source. And if the referrals are tainted, billing for the resulting claims amounts to submitting a false claim under the False Claims Act.

Judgment Day for BLS Bribery Strip Club Doctors

Case: Among the three dozen doctors that have so far been convicted for taking bribes from now defunct Parsippany, NJ, Biodiagnostic Laboratory Services LLC (BLS), the Staten Island brothers treated to lap dances at strip clubs may be the most notorious. Now they and one other physician have received their sentences:

Name	Practice	Allegations	Sentence
George Roussis	Pediatrician, Staten Island, NY	Accepted $175K in BLS cash payments for roughly $1.7 million in lab referrals from Oct. 2010-April 2013; BLS also paid for strip club trips, lap dances and sexual favors	37 months' prison, one year supervised release + $7,500 fine
Nicholas Roussis	OBGYN Staten Island, NY	Accepted $175K in BLS cash payments for roughly $1.7 million in lab referrals from Oct. 2010-April 2013; BLS also paid for strip club trips, lap dances and sexual favors	24 months' prison, one year supervised release + $5,000 fine
Ricky J. Sayegh	Internal medicine, Yonkers, NY	Accepted roughly $400K in cash bribes for generating roughly $1.4 million in lab business from Feb. 2010-April 2013	30 months' prison, one year supervised release + $10,000 fine
Yousef Zibdie	Internal medicine, Woodland, NJ	Accepted $80K worth of monthly bribe checks for generating roughly $930K in illegal lab business for BLS	

Significance: The latest BLS scoresheet: 50 convictions, 36 of them doctors and over $13 million recovered via forfeiture. At least two more doctors are also awaiting sentencing. Stay tuned...

Clinic Owner Must Pay Back $1.1 Million in Unnecessary Services

Case: The owner-operator of a Burbank medical clinic was sentenced to 37 months in prison after pleading guilty to two counts of falsely billing Medicare for medically unnecessary office visits and diagnostic tests. The owner admitted that "many, if not all" of the people who came to her clinic were lured by promises of free equipment, services or food offered by her "marketer" co-schemers.

Significance: One of the distinctions of this otherwise rather ordinary case is that the clinic owner also agreed to make restitution payments of $1.711 million to cover what CMS paid out to reimburse the clinic for the medically unnecessary services involved in the scheme.

Brief Your CEO: The 4 Key Takeaways from the OIG 2016 Part B Lab Payments Report, From Page 1

2. The 2016 Medicare Lab Payments by the Numbers

There are some key payment statistics you'll want to include in your briefing. In 2016, CLFS payments for lab tests totalled $6.8 billion, down slightly from the $7.0 billion Medicare paid in each 2015 and 2014. CLFS payments accounted for roughly 2% of all Part B payments made in 2016, as opposed to 3% in 2015. You might want to give the CEO a copy of the table below showing where that money went.

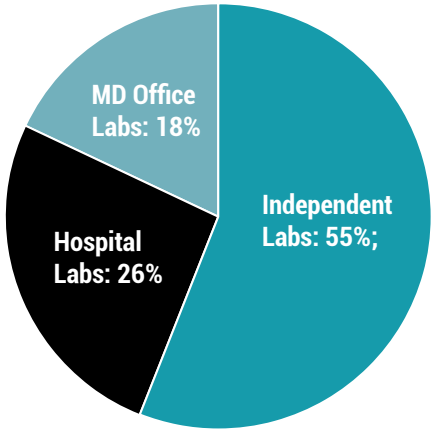
How Medicare Spent Its $7 Billion for Lab Tests in 2016*

Tests	Beneficiaries	Labs	Providers
437 million: total tests billed **3.4:** average number of tests received by beneficiaries per day **17:** average number of tests per day for top 1% of beneficiaries	**28 million:** beneficiaries that received at least one test **16:** average number of tests per beneficiary **86:** average number of tests per beneficiary among top 1% of beneficiaries	**58,593:** labs that received Medicare payments **$115,546:** average payments per lab **$1.1 billion:** payments to top three labs	**635,773:** providers that ordered lab tests **485:** average tests ordered per provider **6,176:** average tests ordered by top 1% of providers

Source: OIG "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016"
***Note:** For a comparison to 2015 data, see *NIR*, Oct. 28, 2016, page 1

The chart below shows the breakdown of payments by type of lab:

Medicare Part B Payments to Labs by Lab Type



3. What Medicare Paid for Top 25 Lab Tests

As required by PAMA, the OIG report includes detailed analysis of the 25 most frequently ordered lab tests. While the top 25 tests always generate the lion's share of payments, that trend was even more pronounced in 2016:

Payments for Top 25 Lab Tests 2014-2016

Year	Total	Percentage of All CLFS Payments
2016	$4.3 billion	63%
2015	$4.1 billion	58%
2014	$4.2 billion	59%

Other Report findings for the top 25 to relate to your CEO:

- 17 of the top 25 tests have been in the top 25 for all three years of the review;
- The top 6 tests accounted for $2.4 billion, or 35% of all payments for lab tests in 2016;
- Payments generated by the top 6 have increased by at least $2 million per year each year;
- The rankings of the top 6 tests have not changed in three years.

Here's another table you can copy and give to the CEO showing payments for the top 10 lab tests.

Top 10 Lab Tests Based on Medicare Part B Payments in 2016

Rank	Test Description and Procedure Code	National Limitation Amount	Number of Tests (in millions)	2015 Medicare Payments (in millions)	Changes from 2015 Payments (in millions)
1	Blood test, thyroid-stimulating hormone (TSH) (84443)	$22.89	21.5	$482	+$7.4
2	Blood test, comprehensive group of blood chemicals (80053)	$14.39	41.6	$470	+$11.7
3	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	$10.59	42.0	$433	+$5.5
4	Blood test, lipids (cholesterol and triglycerides) (80061)	--	29.0	$411	+$31.7
5	Vitamin D-3 level (82306)	$40.33	9.0	$350	+$13.3
6	Hemoglobin A1C level (83036)	$13.22	19.3	$250	+$9.8
7	Drug test(s), definitive, 22 or more drug class(es), including metabolite(s) if performed (G0483)	$215.23	1.2	$241	New code in 2016
8	Drug test(s), presumptive, any number of drug classes, per date of service (G0479)	$79.25	3.0	$221	New code in 2016
9	Blood test, basic group of blood chemicals (80048)	$11.52	13.7	$133	-$0.7
10	Drug test(s), definitive, per day, 15-21 drug class(es), including metabolite(s) if performed (G0482)	$166.03	0.8	$127	New code in 2016

Source: OIG "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016"

4. The 4 Key Payment Trends

Although total lab test payments changed little from the previous year, the Report cites significant year-to-year variances in payments for four particular types of tests. Make sure you relay these to the CEO.

Trend 1. Multianalyte Assays with Algorithmic Analyses (MAAA) Way Up

Payments for MAAAs combining multiple test results with other patient information to yield a predictive score, e.g., cancer recurrence risk or drug response, were up 665% year-over-year. The spike is not really surprising since these are newly emerging tests that Medicare only started to cover in 2015. Medicare added 10 new MAAAs to its coverage list in 2016. However,

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the Report also points out that at an average $890 per test, MAAA tests are the most expensive category of CLFS tests.

Trend 2. Microbiology Tests Consistently Up

Payments for tests to detect and identify infection-causing microorganisms have climbed consistently in the past three years:

- 2014: $472 million;
- 2015: $517 million;
- 2016: $570 million.

Trend 3. Drug Tests Go from Up to Down

After increasing 19% to $1.1 billion the previous year, drug tests made a U-turn dropping to $880 million in 2016. Probably not coincidentally, CMS changed its payment formula for drug tests in 2016. Rather than paying separately for each drug class tested for, the agency paid a set amount for multiple tests, regardless of drug class targeted by testing. Even so, seven of the top 25 tests for the year were for the newly assigned drug testing codes.

Trend 4. Molecular Pathology Tests Continue to Decline

Medicare payments for molecular pathology tests analyzing genetic material to determine how patients will respond to treatment decreased 44% from $466 million to $259 million in 2015. The trend continued in 2016 with payments falling to $165 million. The decline coincides with OIG efforts to prevent medically unnecessary genetic testing, the Report adds.