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Newly Proposed PAMA Rates for 2018 Confirm Lab Industry's Worst Fears

CMS's newly issued preliminary Clinical Laboratory Fee Schedule (CLFS) for 2018 dashes the lab industry's hopes for PAMA relief by making two things painfully clear:

- There will be no delay in plans to implement the new PAMA payment system for lab tests on Jan. 1, 2018; and
- The agency is sticking to its approach of excluding hospital labs from its pricing formula.

The Context

The idea behind PAMA is to base Medicare payments for particular lab tests on the weighted median of private payor rates for particular tests. Since 2014, CMS has been gathering data from "applicable laboratories" to figure out what those rates actually are. The proposed CLFS for 2018 represents the agency's first cut at setting prices using the new formula.

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Medicare Reimbursements: Part B Lab Payments Slightly Down for 2016, Reports OIG

The OIG released its report on Medicare Part B payments for lab tests in 2016. *The punchline:* Lab payments over the past three years remain incredibly consistent in terms of both amount and reimbursement patterns. Here's an overview of what you need to know about the OIG Report.

The Context

PAMA (the Protecting Access to Medicare Act of 2014) requires the OIG to monitor Medicare Part B payments for lab tests in advance of the new payment system scheduled to take effect on Jan. 1, 2018. 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

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Newly Proposed PAMA Rates for 2018 Confirm Lab Industry's Worst Fears, *from page 1*

While embracing the idea of market-based pricing, the lab industry has objected to CMS for not including hospital and community labs in its definition of "applicable laboratories." Because these labs charge higher rates, excluding their pricing data was bound to artificially skew rates in a downward direction, they insisted.

The CLFS Bloodbath

The CMS's pricing proposal not only confirms the lab industry's concerns but provides for cuts even deeper and more widespread than feared. 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 proposed CLFS:

Reference Labs Suffer the Deepest Cuts

Although the rate cuts would have widespread effects, they fall particularly hard on big reference labs like Quest Diagnostics and Laboratory Corporation of America. 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.

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 an-

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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

alyze 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.

Billing & Coding: Proposed New Molecular Pathology Crosswalk Codes for 2018

The newly proposed 2018 Clinical Laboratory Fee Schedule includes over 130 crosswalked CPT codes, including roughly 30 new codes for molecular pathology tests.

New Crosswalked Molecular Pathology Codes in 2018 Clinical Laboratory Fee Schedule

Test	Crosswalked To
81105 (81X15): Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-1a/b (L33P)	**81227** (CYP2c9 (cytochrome p450, family 2, subfamily C, polypeptide 9) (e.g., drug metabolism))
81106 (81X16): Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-2a/b (T145M)	**81227** (see above for descriptor)
81107 (81X17): Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIb]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-3a/b (I843S)	**81227** (see above for descriptor)
81108 (81X18): Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-4a/b (R143Q)	**81227** (see above for descriptor)
81109 (81X19): Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant (e.g., HPA-5a/b (K505E))	**81227** (see above for descriptor)
81110 (81X20): Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61] [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-6a/b (R489Q)	**81227** (see above for descriptor)
81111 (81X21): Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIb]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], posttransfusion purpura) gene analysis, common variant, HPA-9a/b (V837M)	**81227** (see above for descriptor)
81112 (81X22): Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (e.g., neonatal alloimmune thrombocytopenia [NAIT], posttransfusion purpura) gene analysis, common variant, HPA-15a/b (S682Y)	**81227** (see above for descriptor)
81120 (81X23): IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (e.g., glioma), common variants (e.g., R132H, R132C)	**81227** (see above for descriptor)
81121 (81X24): IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (e.g., glioma), common variants (e.g., R140W, R172M)	**81227** (see above for descriptor)
81175 (81X04): ASXL1 (additional sex combs like 1, transcriptional regulator) (e.g., myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; full gene sequence	**81295** (MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis)
81176 (81X05): ASXL1 (additional sex combs like 1, transcriptional regulator) (e.g., myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; targeted sequence analysis (e.g., exon 12)	**81272** (KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (e.g., gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (e.g., exons 8, 11, 13, 17, 18))

Test	Crosswalked To
81230 (81X30): CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (e.g., drug metabolism) gene analysis, common variant(s) (e.g., *2, *22)	**81227** (see above for descriptor)
81231 (81X31): CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (e.g., drug metabolism) gene analysis, common variants (e.g., *2, *3, *4, *5 *6, *7)	**81227** (see above for descriptor)
81232 (81X32): DPYD (dihydropyrimidine dehydrogenase) (e.g., 5-fluorouracil/5-FU and capecitabine drug metabolism) gene analysis, common variant(s) (e.g., *2A, *4, *5, *6)	**81227** (see above for descriptor)
81238 (81X25): F9 (coagulation factor IX) (e.g., hemophilia B) full gene sequence	**81295** (see above for descriptor)
81247 (81X37): G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice) gene analysis; common variant(s) (e.g., A, A-)	**81227** (see above for descriptor)
81248 (81X38): G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice) gene analysis; known familial variant(s)	**81215** (BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant)
81249 (81X40): G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice) gene analysis; full gene sequence	**81295** (see above for descriptor)
81258 (81X58): HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant	**81322** (PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant)
81259 (81X59): HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence	**81295** (see above for descriptor)
81269 (81X69): HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants	**81294** (MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants)
81283 (81X33): IFNL3 (interferon, lambda 3) (e.g., drug response) gene analysis, rs12979860 variant	**81322** (see above for descriptor)
81328 (81X34): SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (e.g., adverse drug reaction) gene analysis, common variant(s) (e.g., *5)	**81227** (see above for descriptor)
81334 (813XX): RUNX1 (runt related transcription factor 1) (e.g., acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy) gene analysis, targeted sequence analysis (e.g., exons 3-8)	**81272** (see above for descriptor)
81335 (81X35): TPMT (thiopurine S-methyltransferase) (e.g., drug metabolism) gene analysis, common variants (e.g., *2, *3)	**81227** (see above for descriptor)
81346 (81X36): TYMS (thymidylate synthetase) (e.g., 5-fluorouracil/5-FU drug metabolism) gene analysis, common variant(s) (e.g., tandem repeat variant)	**81227** (see above for descriptor)
81361 (813X1): HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (e.g., HbS, HbC, HbE)	**81227** (see above for descriptor)
81362 (813X2): HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)	**81322** (see above for descriptor)
81363 (813X3): HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)	**81294** (see above for descriptor)
81364 (813X4): HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence	**81295** (see above for descriptor)

EHR: Window Closes on Meaningful Use Exemptions as Congress Seeks to Make Future Compliance Easier

October has been a big month for meaningful use compliance.

Oct. 1: Deadline "Hardship" Exemption

Among the victims of the recent natural disasters are first-time participants in the Medicare EHR Incentive Program who must demonstrate meaningful use in the 2016 reporting year or face payment penalties in 2018. The good news for the roughly 171,000 Medicare-eligible professionals facing the meaningful use deadline is that hurricanes and such would be grounds for getting a "significant hardship" exemption from CMS. Unfortunately, the deadline for filing for such exemptions was Oct. 1.

Current laws require the HHS secretary to make meaningful use requirement more "stringent" over time.

Oct. 5: New Bill to Make EHR Compliance Easier

While it won't help the providers who missed out on filing for a hardship exemption, a newly approved House committee bill would make it for providers to avoid EHR and meaningful use penalties in the future.

Explanation: Current laws require the HHS secretary to make meaningful use requirement more "stringent" over time. The thought was that raising the bar would generate significant improvements in EHR use. Unfortunately, it has not gone according to plan. And as providers struggle to meet current requirements, backing away from the keep-making-it-more-stringent mandate seems like a more prudent course of action. And that is precisely what the House bill proposes to do by giving the secretary more leeway in adopting meaningful use rules.

The problem is that the bill is unlikely to pass and is more of a symbolic gesture than an earnest attempt to ease up on EHR rules.

Market Trends: Celebrity Power to Drive Testing Goes Beyond the 'Angelina Jolie Effect'

The rates of genetic testing among women supposedly soared after Angelina Jolie revealed that she had undergone a double mastectomy to reduce her chances of developing breast cancer after learning that she had a mutation in a gene known as BRCA1. But do celebrities really impact testing rates and consumption of diagnostic products? And if so, how can that power be harnessed to improve public health?

The "Charlie Sheen Effect"

These are some of the questions addressed in a new study published in the July issue of *Prevention Science*. The study looks at the "Charlie Sheen effect," or spike in sales of rapid in-home HIV test kits after Charlie Sheen publicly disclosed his positive HIV status. That same week, OraQuick sales rose 95%, the researchers found. Sales remained significantly elevated for four more weeks.

"The public's health decisions are heavily influenced by public figures and reveal an opportunity for the prevention community to target health behaviors when related issues are widely publicized in the media."

— Jon-Patrick Allem, Ph.D.

OraQuick (OraSure Technologies; Bethlehem, Penn.) is the only Food and Drug Administration-approved rapid in-home HIV test kit available in the United States. US sales of OraQuick were evaluated weekly from April 12, 2014, to April 16, 2016, along with Web searches for the terms "test," "tests," or "testing" and "HIV" using Google Trends. Changes in OraQuick sales around Sheen's disclosure based upon expected sales and prediction models using Web searches were assessed.

In total, there were 8,225 more sales than expected following Sheen's disclosure, surpassing orders around the World AIDS Day campaign by a factor of seven. For comparison, OraQuick sales the week of World Aids Day increased significantly, but by only 31%. Following World Aids Day sales returned to expected levels the next week.

Predictive Value of Web Searches

Web searches mirrored OraQuick sales trends, demonstrating their ability to foretell increases in testing. The researchers found that knowing search volumes alone produced sales predictions with an average relative error rate within 7%.

"The public's health decisions are heavily influenced by public figures and reveal an opportunity for the prevention community to target health behaviors when related issues are widely publicized in the media," write the authors led by Jon-Patrick Allem, Ph.D., from University of Southern California in Los Angeles.

Implications for Public Health

The fact increased sales can be predicted by Web searches may provide a future means of planning for public health screening responses to real-time events. The U.S. Centers for Disease Control and Prevention says that untested individuals are responsible for most new HIV infections and that seizing on opportunities to increase testing awareness is the most cost-effective HIV prevention strategy. This study can inform how to capitalize on future opportunities to increase screening.

Takeaway: Web searches immediately following celebrity health-related announcements can be used to capitalize on opportunities to drive screening and predict volume increases.

"Applicable Labs": The Fly in the PAMA Market-Based Pricing Ointment

The lab industry has no objection to basing Medicare payments for lab tests on the actual rates charged to payors in the private market. What has the industry so upset is how CMS has executed the concept.

The "Applicable Labs" Controversy

At the center of the controversy is which labs count as "applicable laboratories" in determining what the actual rates are for particular tests. Specifically, the CMS definition excludes hospital and community-based labs. In addition to being key components of the lab market, these labs have the leverage to command higher rates for tests from payors.

Result: The CMS formula is flawed and yields artificially low rates that do not reflect actual market rates.

CMS Digs in Its Heels

Industry groups like the American Clinical Laboratory Association and major labs like Quest and LabCorp have repeatedly urged CMS to revise its definition of "applicable laboratories," or at the very least delay Jan. 1, 2018 implementation of the PAMA-based Clinical Laboratory Fee Schedule (CLFS) pending further study.

But so far, those appeals have fallen on deaf ears. CMS's only concession has been agreeing to include the very small number of hospital outreach labs that independently enroll in Medicare as labs with their own National Provider Identifier (NPI).

Preliminary Pricing

So the massive rate cuts contained in the preliminary 2018 CLFS issued by CMS on Sept. 22, 2017 were all too predictable. According to the CMS Executive Summary, the proposed fee schedule is based on 1,942 labs broken down as follows:

"Applicable Labs" Submitting PAMA Pricing Data

Type of Lab (NPI)	Total Number of NPIs	Percentage of NPIs
Independent Lab	658	33.9%
Physician Office Lab	1,106	57.0%
Hospital Lab	21	1.1%
Other: Urgent care center, FQHC, etc.	157	8.1%
Total	**1,942**	**100.0%**

Source: CMS, "Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System"

The preliminary rate calculations are flawed and account for only about 34% of the lab market, with two major labs representing 80% of the volume used to calculate the rates, critics contend. The CMS proposal has also been criticized for basing rates on a weighted median cost rather than a weighted average cost resulting in artificially driving down the calculation of market prices for the top 20 tests.

CMS's Ham-Handed Justification

In anticipation of the expected industry criticism, CMS notes in the Executive Summary that it performed a simulation which it claims shows that including more hospital, physician office and independent labs would not have significantly impacted rates. In fact, inclusion would have actually reduced reported rates by around 20%, the Summary contends.

But industry says that the simulation justification is laughable and only confirms just how distorted the CMS formula really is. As an ACLA official notes, to measure the impact of including more hospital labs, CMS multiplied the 21 hospital labs that did submit pricing data by 10. As a result, the simulation included 210 labs, which is a pretty paltry number considering that there are roughly 7,000 hospital labs in the US.

Labs IN COURT

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

Doctor Pleads Guilty for Ordering Unnecessary Tests of Opioid Patients

Case: A 72-year-old Detroit area physician pleaded guilty for his role in a $19 million Medicare fraud scheme. In addition to prescribing medically unnecessary oxycodon and other controlled substances to Medicare patients who did not need them, the physician admitted to requiring his patients, many of whom were drug addicts, to undergo testing at labs in which he had secret ownership interests.

Significance: Labs involved in opioid drug testing need to be on high alert. This summer, the Department of Justice unleashed a potent nationwide crackdown on opioid drug abuse. And while labs and physicians are not the primary target, they continue to get caught up in the dragnet. 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*, Sept. 26, 2017).

OIG Claims Point of Care Test Cup Freebies Cross the Kickback Line

Case: Nearly two years after official settlement, the massive Millennium Laboratories case continues to smolder. The latest collateral defendant is Parallax Center, a New York City drug addiction treatment center which has agreed to settle kickback-related charges with the OIG for $64,203.

Significance: For lab managers, the takeaway from this case is what Parallax provided to Millennium, namely, point of care test cups. The moral is that compensation does not have to be elaborate to establish an illegal referral relationship. And because the referrals were invalid, billing for the resulting claims amounted to false billing.

Kickback, Custom Panel & Standing Order Claims Settled for $2 Million

Case: A South Carolina family medical clinic and its CEO agreed to settle false claims charges for $2 million, $340,510 of which will go to the physician who brought the original whistleblower lawsuit. The controversy centered on the clinic's compensation arrangement that allegedly encouraged physicians to refer Medicare patients to clinic labs. Referring physicians that went along got a percentage of the reimbursement amount while physicians who referred patients to other labs had their compensation cut.

Significance: The government also claimed that the clinic created and pressured physicians to order custom thyroid, hepatic and other disease panels bloated with medically unnecessary lipid tests not typically used for screening or routine testing. Adding fuel to the fire, the clinic created lab standing orders that required staff to automatically perform certain diagnostic tests in response to indications regardless of whether those tests were actually ordered by a physician.

Clinic Owner Jailed, Ordered to Repay $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 made 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.

Court Says Labs Must Verify Medical Necessity of Tests that Physicians Order, *from page 1*

payment rate that will then be updated every three years based on data supplied by labs. Switching to the new system will save Medicare $3.9 billion in lab payments over the next 10 years, the OIG claims.

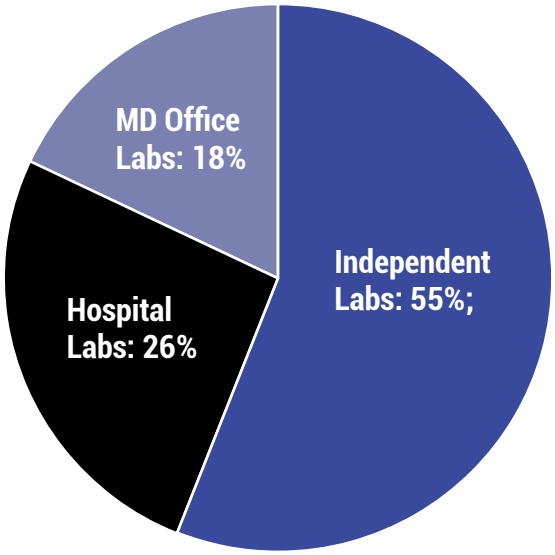
How Medicare Spent Its $7 Billion for Lab Tests in 2016*

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



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:

How Medicare Spent Its $7 Billion for Lab Tests in 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:

- 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

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"

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.

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 insofar as these are newly emerging tests that Medicare only started to cover in 2015. Medicare added 10 new MAAAs to its coverage list in 2016. Howev-

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

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.

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. Still, seven of the top 25 tests for the year were for the newly assigned drug testing codes.

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.