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SPECIAL EXPANDED ISSUE–PART ONE
UNDERSTANDING PAMA'S IMPACT ON LABS

Real Private Payer Lab Price Data Analysis Shows How CMS May Score PAMA Lab Cuts!

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY
FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Medicare Part B Lab Test Prices vs. Budgeted Payment

THERE IS AN IMPORTANT QUESTION THAT lab industry magazines and news sources have failed to address: How many years are left before Medicare officials drop fee-for-service payment for clinical lab testing?

On January 26, 2015, the **Department of Health and Human Services** (HHS) issued a press release declaring an ambitious target. "HHS has set a goal of tying 30% of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as accountable care organizations (ACOs) or bundled payment arrangements by the end of 2016 and tying 50% of payments to these models by the end of 2018," stated the agency.

In March of this year, HHS announced that it had achieved the goal of moving 30% of fee-for-service payments to quality or value a full year ahead of schedule. It said the 30% goal was met at the end of 2015 instead of 2016.

One way that Medicare officials can minimize Part B fee-for-service payments to providers is to encourage Medicare beneficiaries to enroll in Medicare Advantage plans (Part C). Currently almost one in three Medicare beneficiaries are in Medicare Advantage plans. That is 17.6 million people, up from 9.7 million in 2008. The Medicare program pays the health insurers operating Medicare Advantage plans a budgeted payment for each enrollee. The health insurer then contracts with hospitals, physicians, clinical labs, and other providers, often using capitated arrangements to reimburse those providers.

Meanwhile, Medicare officials are working to convert more Part B services away from fee-for-service and over to bundled reimbursement. This winter, it rolled out the Comprehensive Care for Joint Replacement (CJR) model in 67 markets. Medicare pays a bundled fee which must be split among all the providers. Another example is the Comprehensive Primary Care Plus program. When implemented, this initiative will start with 20,000 primary care physicians who will be paid monthly fees for selected patient management services, and they will get reduced fee-for-service payments.

The actions by officials at HHS and the Medicare program make it timely for pathologists and lab administrators to begin giving this question more attention: How much time remains before Medicare officials drop fee-for-service payment for clinical lab testing? TDR

10% PAMA Fee Cut Lowers Pay to Labs by $400 Million

New OIG report provides clues as to how cuts to CLFS prices will reduce payments to clinical labs

CEO SUMMARY: Just eight weeks remain before certain clinical laboratories must begin submitting private payer lab test price data to the federal Centers for Medicare & Medicaid Services. A new report by the Office of the Inspector General makes it possible to estimate how CMS may implement fee cuts in 2018. The Dark Report's calculations show that a 10% cut to the top 25 tests identified by the OIG would produce a $400 million fee cut in 2018. Successive yearly cuts could bring that to $1.2 billion by 2020.

PROBABLY NO SINGLE FACTOR has the potential to be as financially disruptive to the clinical laboratory industry as the impending repricing of the Medicare Part B clinical laboratory fee schedule (CLFS).

Blame it on the Protecting Access to Medicare Act of 2014. One of the six sections of that law dealing with clinical laboratory matters mandates that the federal **Centers for Medicare & Medicaid Services** gathers lab test market price data from certain clinical labs and uses the data to establish new prices for the CLFS.

Thus, a significant repricing of the CLFS is just 14 months away. As of Jan. 1, 2018, expectations are that CMS will institute deep cuts to the prices of the clinical lab tests which cost it the greatest amount of money.

This expectation of lower prices is based on the statements CMS officials have made and reports released by CMS and the OIG. For more than 30 years, Medicare officials have pushed to drive down the prices of the clinical laboratory fee schedule.

For these reasons, the popular wisdom is that CMS will accept the market price data from those labs required to report, then set significantly lower prices for the 2018 CLFS. How much lower? Under PAMA, CMS cannot lower the price of individual tests by more than 10% in the years 2018, 2019, and 2020. PAMA then allows price cuts of a maximum 15% in 2021, 2022, and 2023.

These price cuts will bite deeply into the operating margins of all of the nation's clinical laboratories. CMS and OIG have

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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made it clear that the price-cutting will focus on the 25 lab tests on the CLFS that represent 59% of Medicare's spending in this category for last year.

$7 Billion Lab Spend In 2015

In its report "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data," the OIG stated that Medicare Part B payments for lab tests totaled $7.0 billion in 2015. Of that amount, $4.1 billion—or 59%—of that spending went to the top 25 tests listed in the OIG's report.

These numbers allow THE DARK REPORT to estimate the financial impact that fee cuts imposed in 2018 will have across the clinical lab industry. Assume that Medicare uses the market price data to justify implementing a 10% cut in each of the fees for the top 25 tests for 2018.

That would mean all the nation's labs will be paid about $400 million less in 2018, compared with payments from prior years. Assume that Medicare implements a 10% fee cut in each of three consecutive years. By 2020, such a cut would mean that all the nation's labs would be paid *$1.2 billion less per year* than the baseline year of 2017, before the fee cuts commenced!

Look at this in another way. In its report, the OIG said that 1% of labs (which would be 2,921 of the 29,211 labs the OIG considers the relevant universe) collected 25% of the 2015 Medicare payments for the top 25 tests, or $1 billion.

Labs Paid $250 Million Less

Therefore, in 2018, these labs would get $250 million less for the same volume of tests that year. By 2020, these labs would be paid $750 million per year less than what they were paid in 2015, based on information in the OIG report.

This is a huge amount of money to remove from the cash flow of the nation's laboratories. And remember, this analysis is based on the top 25 tests that the OIG said represents 59% of CLFS spending in 2015. CMS is expected to enact similar cuts to other tests on the CLFS. Thus, in 2018, the nation's clinical laboratories would probably see an overall reduction in Medicare Part B revenue greater than the $400 million example presented above.

Which labs survive and which labs go out of business if this scenario plays out in the coming years? The two biggest lab companies, **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**, should survive, with one caveat.

For two decades, LabCorp and Quest Diagnostics have given national health insurers deeply-discounted lab test prices in exchange for managed care contracts that exclude competitors. Financial analysts have observed that, because these prices are near or below marginal costs to perform these tests, the two blood brothers lose money on this segment of their test business. But they offset these losses on managed care contracts with the revenue from Medicare Part B fee-for-service payments, among other sources.

Upset Financial Balance?

Could the expected cuts in Medicare lab test fees upset this financial balance? If so, it would require these two lab companies to renegotiate higher rates for their biggest managed care contracts. These are issues that will be resolved over time.

Meanwhile, what about the other segments of the clinical laboratory industry? How would consecutive cuts of 10% in the fees for the top 25 lab tests on the CLFS affect their financial stability?

For the nation's hospital laboratories, these cuts would trigger a major assessment of whether the hospitals want to continue providing lab testing services to office-based physicians in their communities.

This testing is beneficial for many reasons, such as these: local physicians get their testing services from local labs, turnaround times are faster, and the hospital labs can often provide office-based

In Implementing PAMA, Is CMS Following the Letter of the Law and the Intent of Congress?

AFTER THE DRAFT RULE for PAMA lab test price market reporting was posted in September 2015, by the federal Centers for Medicare & Medicaid Services, there was much consternation in some quarters of the clinical laboratory industry.

Language in the Protecting Access to Medicare Act of 2014 directs CMS to collect private health insurer prices for clinical laboratory tests from the labs that received these payments. CMS will then use that data to reset prices on the Part B clinical lab fee schedule.

However, as pathologists, lab administrators, and their legal and business advisors read the language in the draft rule CMS published, they recognized major problems. One problem was—and remains—the biggest issue. Critics of the draft rule pointed out that, as written, CMS will not get an accurate picture of the average price *all* insurers—large or small—pay to *all* labs, ranging from physician office labs to independent labs and hospital outreach labs.

The critics next pointed out that, because of how CMS excluded a large number of labs from reporting, the agency will base its pricing decisions on a biased sample of pricing data.

They also noted that the data sets would be dominated by the large national laboratories that perform a substantial proportion of Medicare Part B lab test volume. The proposed rule excluded many higher-cost labs from the reporting requirement. For example, hospital laboratories, which are generally paid more by private insurers for their services, would have been excluded from submitting market price data to CMS.

This criticism was not successfully addressed when CMS issued the final rule on June 17, 2016. Many types and sizes of laboratories were excluded from the reporting requirement. Since that date, lab professionals have repeatedly pointed out that, by excluding these labs with higher-priced tests from reporting, CMS would be working with a biased set of data.

These same lab professionals and their associates have reported to CMS and to members of Congress that, by starting with a biased set of data, CMS will then end up with an analysis that does not accurately reflect what the private health insurer market pays for clinical laboratory tests. Moreover, they argue that, as written, the final rule is not consistent with the language of the PAMA statute, nor does it fulfill the intent of Congress when the law was drafted and passed.

Upset Financial Balance?

There is now credible evidence to back up these criticisms about the bias that is built into the final rule on PAMA market price reporting. On pages 12-23 of this special issue, THE DARK REPORT presents an analysis of private payer pricing that was developed by **XIFIN, Inc.**, of San Diego, from the actual private payer data its lab clients will report to CMS starting Jan. 1, 2017.

XIFIN analyzed data from four sectors of lab testing. It determined that private payers pay significantly more for clinical laboratory testing than the current Medicare clinical laboratory fee schedule pays in all categories but one.

It calculated a weighted average price paid by private payers for these four lab sectors compared to Medicare fees as follows:

- Independent labs are paid 19.6% less.
- Hospital labs with NPIs are paid 25.6% more.
- Molecular and genetic testing labs are paid 27.3% more.
- Pain management and toxicology labs are paid 50.4% more.

This analysis may give the lab industry a useful tool to go back to Congress and show lawmakers how and why the planned implementation of market price reporting has flaws that need to be corrected.

physicians with a complete record of their patients' lab test data. That's because the hospital lab did all the testing in inpatient, outpatient, and outreach settings. These are clinically useful features that the two blood brothers cannot easily match. Also, as the integration of clinical care moves ahead, physicians will want access to a single lab that has *all* the lab test data on their patients.

But yearly cuts to the Medicare fees of the top 25 lab tests that these hospital labs perform on their patients would cripple many community hospital lab outreach programs for a simple reason. These hospital labs use their lab equipment to test outreach specimens in the evening, after testing for inpatients ends and when only stat testing is done.

Although hospital labs don't have the economies of scale and lower average cost-per-test of LabCorp and Quest, by using their lab equipment in the evenings, these labs have margins from the outreach business that are sufficient to sustain the cost of lab-to-doctor's office interfaces and the courier services needed to serve these clients.

Nursing Homes

Also, nearly all hospital labs with an outreach program serve nursing homes in their regions. The outreach revenue from lab testing is essential to cover the hospital lab's costs to send phlebotomists and couriers to these sites, where nearly all the patients are Medicare beneficiaries.

Where hospitals truly benefit is that the added outreach volume, run on the evening shift, contributes to improved patient care in two ways. First, the added outreach volume helps the hospital lower its overall average cost-per-test for all testing, including the inpatient testing.

Second, the added outreach volume enables those labs to set up and run tests in-house that they would otherwise refer to outside labs. That benefits patient care because it means the lab can deliver faster results for tests run on inpatients. All of these elements benefit Medicare patients, including hospital inpatients, patients served in physicians' offices, and patients in nursing homes.

There is another category of clinical laboratories that will rapidly go to the chopping block if the expected cuts happen to the Medicare CLFS. These are the nation's community laboratories.

Community Labs Are Small

These labs are generally located in smaller communities or on the rural/suburban fringe of larger metros. Community labs provide much testing for Medicare beneficiaries because they are willing to provide lab testing services to nursing homes, SNFs, and rehab centers that public lab companies abandoned as unprofitable clients in the 1990s.

Medicare beneficiaries make up as much as 60% of their total patient mix. (By contrast, LabCorp and Quest Diagnostics report that about 15% to 20% of their total testing is done for Medicare patients, very few of whom are in nursing homes).

Community labs are typically very small operations and have profit margins of 3% to 5%. Clearly, this class of clinical labs will be extremely vulnerable to Medicare cuts to the CLFS. Drop Medicare fees by 10% on a community lab that has 60% Medicare patients and a 3% profit margin, and that lab will be forced to close or go into bankruptcy. As that happens, Medicare patients in these communities lose access to the only local laboratories that may have served them for decades.

These are basic insights about why the downward repricing of the CLFS has the potential to wreak financial havoc across key sectors of the clinical laboratory industry. The problem for Congress and CMS rests on a simple fact: once an established lab disappears from a community, it cannot be easily replaced. For these reasons, lawmakers and CMS should act carefully before they destroy local labs that are assets to their communities. TDR

Labs Have Heavy Burden to Report Lab Price Data

Under new law, CMS requires each lab to choose if rules apply; then, which payments to report

CEO SUMMARY: Clinical labs must assess their responsibilities to report lab test market prices to CMS as part of the Protecting Access to Medicare Act. A panel of three experts took up this topic at a recent webinar hosted by THE DARK REPORT. On June 23, the federal Centers for Medicaid & Medicare Services published a final rule and later issued more guidance setting out a complicated series of requirements that labs must follow to determine if they are required to report and, if so, what lab price data they must submit.

CLINICAL LABS WILL FACE SIGNIFICANT challenges in coming weeks to report lab test price data to the federal **Centers for Medicare & Medicaid Services**, starting January 1, 2017. Labs that fail to comply with this new law can be hit with stiff penalties.

That's the opinion of lab industry experts who spoke during a recent DARK REPORT webinar. "Pathologists and clinical lab directors seeking to avoid these penalties need to know that PAMA requires CMS to revise how it pays for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS)," emphasized Mark Birenbaum, PhD, Administrator for the **National Independent Laboratory Association** (NILA).

In the webinar, Birenbaum's goal was to explain the rule and its complexities to help pathologists and clinical lab managers tasked with learning the new terms and policies under PAMA and ensuring that their labs comply with those rules. "We also want to assist you in avoiding pitfalls, mistakes, and penalties," added Birenbaum.

"On June 23, CMS published the final rule implementing the PAMA clinical lab reimbursement framework," he continued. "Next, on Sept. 14, CMS posted a Clinical Laboratory Fee Schedule Data Reporting Template and a Quick User Guide to the template."

Lower Payments Expected

From the presentations during the webinar, it was clear that clinical laboratories must deal with significant challenges as they follow the steps required to report the necessary market price data under the law. "The reality is that the end result is expected to be lower payments for Part B clinical laboratory test fees," stated Julie Scott Allen, who represents NILA and is Senior Vice President at the **District Policy Group** in Washington, D.C. Rounding out the webinar panel of experts was attorney Jeffrey J. Sherrin, President of **O'Connell & Aronowitz**, in Albany, N.Y. and an adviser to NILA.

"Through all of what's been said about PAMA, CMS' goal is to reduce what it pays under the clinical laboratory fee

schedule," stated Allen. "This is what the agency has said before PAMA came to be, and it's what it says now. CMS officials even said so specifically in a recent meeting. They point out that the intention of PAMA is to reduce Medicare rates for these tests."

"CMS intends to reduce what it pays for clinical diagnostic laboratory tests (CDLTs) and for Advanced Diagnostic Laboratory Tests (ADLTs) by collecting data on what private commercial insurers pay labs for these tests," observed Birenbaum. "CMS will then use that data to reduce current Medicare reimbursement rates for these tests."

Price, Volume Data Needed

Under the final rule CMS issued to implement the law, certain clinical labs will be required to report private payer payment rates for laboratory tests and the corresponding volumes of tests. CMS will then use those private payer rates as the basis for revising Medicare payment rates for most laboratory tests on the CLFS beginning in January 2018. For some 1,300 CDLTs, CMS pays about $7 billion each year. *(See TDR, July 5, 2016.)*

STEP ONE: Which Labs Report?

Birenbaum began the webinar by explaining which clinical labs would be required to submit lab test price data and how they would do so. And he warned labs that they need to pay attention to the definitions CMS has set out in the PAMA final rule.

"Your lab needs to determine if it is 'applicable' as defined in the final rule for the purpose of reporting the data to CMS, because the penalties in the statute and in the regulations could be significant," cautioned Birenbaum, adding that, "It is important to note that CMS is not planning to assess or notify a laboratory whether it must report data to the agency.

"Thus, step one is to answer this question: Does your lab need to report its private payer rates?" stated Birenbaum. "In other words, is your lab what CMS calls an 'applicable laboratory?'

"To determine that, you must answer two questions: Between January 1 and June 30, 2016, did your laboratory receive from the CLFS more than $12,500 in Medicare revenue? That's called the low expenditure threshold." commented Birenbaum. "If the answer is no, then your lab would be excluded from reporting as an applicable laboratory.

"If the answer is yes, then you need to answer the second question: Was 50% of your individual laboratory's total Medicare revenues received from the CLFS or the Physician Fee Schedule (PFS)?" he continued. "This assessment is based on each laboratory's national provider number (NPI). Thus, if you have multiple laboratories and they have individual NPIs, each NPI must conduct this assessment.

"An applicable lab must report total Medicare revenues received by each lab NPI from Jan. 1, 2016, through June 30, 2016," noted Birenbaum. He said that the final rule defines these as as fee-for-service payments under:

- Medicare Parts A and B
- Medicare Advantage (Part C) payments
- Prescription Drug Payments (Part D)
- Medicare beneficiary deductibles and coinsurance under the CLFS or PFS.

CLFS And PFS Calculations

"All of those figures for your clinical laboratory must be added together to come up with the denominator in the calculation," noted Birenbaum. "If that numerator (CLFS and PFS revenue together) is more than 50% of your laboratory's total revenue, then the answer is yes, your lab needs to report.

"If your lab answers no to either one of these questions, then you don't have to report your private payer rates," he said. "But even if you don't have to report, your

lab will have to live with the weighted medians that are calculated from the data that other labs submit. All laboratories paid on the CLFS are subject to the new prices.

"Now, if you're an individual, independent lab, and you have just one type of business, your lab's NPI is probably just for your business," he explained. "But if you're a bigger company and you have multiple entities with unique NPIs, then you have to do these calculations for each NPI in your corporation.

Hospital Laboratories

"A hospital outreach laboratory must determine whether it operates under the hospital's general NPI or whether it has its own unique NPI when billing Medicare," commented Birenbaum. "If the hospital outreach lab uses the hospital's NPI, then it would likely never be an applicable laboratory. That's because the hospital gets a sizeable amount of Medicare revenue from sources other than the CLFS and the PFS and would not meet the 50% threshold outlined under the law.

"Hospital outpatient laboratories are excluded from reporting under the regulation, even if they receive a majority of their Medicare revenues under the CLFS or PFS," he added. "CMS argued in the rule that most hospital laboratory payments are bundled under the outpatient payment schedule, so would not qualify for the purposes of reporting. This is despite the fact that many outpatient hospitals regularly bill under the CLFS for some laboratory tests.

"Now, who reports the data to CMS?" he asked. "The NPI doesn't report the data and the CLIA lab doesn't report the data to CMS," explained Birenbaum. "Whoever holds the taxpayer identification number (TIN) associated with all the NPIs in your business is the entity that is required to report the private payer data to CMS. If you consider this confusing, then you are not alone!"

New CLFS Prices Become Effective on Jan. 1, 2018

"UNDER THE FINAL PAMA RULE, the Medicare program will be required on or after January 1, 2018, to pay an amount equal to the weighted median of what private payers pay for CDLTs," explained Mark Birenbaum, Administrator for the National Independent Laboratory Association (NILA).

"That means just 14 months remain before these new rates go into effect," he said. "Then, CMS will recalculate the weighted medians every three years.

"Most labs were unaware that the first reporting period under PAMA has already past," continued Birenbaum. "The reporting period reflects payments labs received from payers between January 1 and June 30 of this year. Labs required to report must submit their data between January 1 and March 31, 2017.

"CMS will use that data to set payment rates beginning in 2018," said Birenbaum. "The next data collection period is expected to be January 1 to June 30 of 2019.

"It's important to keep in mind that once the weighted medians are calculated, there will be no updates or adjustments to the CLFS as there are now," warned Birenbaum. "There will be no increase tied to the Consumer Price Index and there will be no decrease tied to any productivity factors. CMS will set lab test prices only by the weighted median—or by gapfill or crosswalk when no data is provided for a test through the PAMA assessment process."

How CMS decided to define the type of laboratory that must report price data is a point of major contention by many who have studied the draft rule and the final rule. "One major issue of concern to NILA is how CMS chose to identify applicable clinical laboratories," noted Birenbaum. "Originally CMS proposed identifying applicable labs by tax ID numbers. But in the final rule, CMS changed that to the NPI number.

STEP TWO:

What Data Must Labs Report?

Next, Birenbaum explained the challenges every clinical lab faces to report its price data. "Assume that you are an applicable lab, what do you need to report?" he asked. "Your lab must report each private payer rate for which a final payment has been received.

"The final payment has to be received in the six-month period between Jan. 1 and June 30 of this year," continued Birenbaum. "Your lab reports only payments received during those dates regardless of the original date of service, but not claims submitted and unpaid.

What Data to Report

"Here is the data that must be reported," he stated. "1) the associated volume of the tests that correspond to each private payer rate; and, 2) the specific HCPCS code associated with each test as outlined in CMS' list of HCPCS codes for collecting and reporting applicable information from the six-month period Jan. 1, through June 30, 2016."

Birenbaum next explained that, "toward the end of August, CMS issued guidance on the more than 1,200 HCPCS codes, and those are the test codes labs must report.

"Labs are not to report payments made on a capitated basis, nor partial payments for which a final payment on a per-test basis cannot be determined," added Birenbaum. "But your lab does report if it did out-of-network, non-contracted work for private insurers—in those cases where the final payment was received in the six-month period between January 1 and June 30, 2016.

"Also report lab test rates that are the final amount paid for a CDLT after all private payer price concessions are applied," he noted. "These price concessions can be volume discounts, prompt-pay discounts, cash discounts, chargebacks, rebates, even those free goods contingent on any purchase requirements. So, for example, if the test is priced at $10 but your lab gives a $1 discount for prompt payment, then you report $9, not $10.

"In addition to what must be reported, there are some things not to report," he continued. "If your laboratory did not receive the final payment because of, say, post-payment activity or appeal, or if there is a dispute about what the actual payment should be and that hasn't been resolved by June 30, 2016, do not report that. If a claim is under review, it is not reported until the laboratory has the final payment.

What Not To Report

"Do not report a payment that cannot be correlated to a specific HCPCS code," Birenbaum said. "This part is confusing because some 'test-level' payments can be grouped into a 'claim-level' payment instead of using individual HCPCS codes.

"When a lab claim is denied and there's no payment, do not report a zero amount. Simply don't report it," he explained.

Another issue involves patient cost-sharing amounts. "Labs should include deductibles and coinsurance in the private payer rates," Birenbaum said. "If a rate is $10 and there's a 20% patient copay and the private insurer pays your lab $8, you don't report $8; you report $10. A lab does so whether it received the $2 from the patient or not.

How To Handle Deductibles

"For deductibles, if the private payer rate is $10 and the patient hasn't met her deductible, your lab still reports $10," he explained. "We plan to get confirmation from CMS on the deductible and coinsurance issues."

One last issue to consider is how CMS defines a private payer as a health insurance issuer. "This definition includes any Medicare Advantage plan, Part C; or Medicaid managed care organization," observed Birenbaum. "If your lab gets Medicaid payments on a fee-for-service

Critics of CMS and Final PAMA Reporting Rule Object to Exclusion of Hospital Outreach Labs

"BECAUSE THE PRICE DATA from many hospitals will be excluded, as outlined in the regulation, this will bias the data collected by CMS in ways unfavorable to the clinical lab industry," asserted Mark Birenbaum, Administrator for National Independent Laboratory Association (NILA).

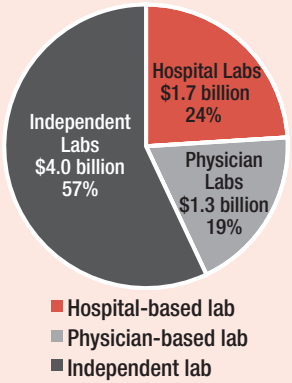
He also believes that CMS is not interpreting the PAMA statute as written and as Congress intended. "What's important about hospital lab data is how it might affect calculations for weighted medians," he said. "NILA has a breakdown showing Part B payments in 2014 to independent labs, hospital labs, and physician office labs. Hospital labs accounted for about one-fourth of the total payments. *(See pie charts below.)*

"This means, that—without hospital lab data—what the two big labs report dominates the calculation of weighted medians because they have the biggest testing volume, which constitutes over 54% of the data from the non-hospital volume," he warned.

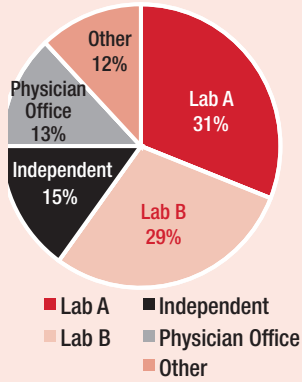
"Under PAMA, the hospital inpatient data is excluded because they are not paid under the CLFS, and CMS excluded hospital outpatient data, because they argue that it is primarily bundled into Medicare's outpatient prospective payment system," stated Birenbaum. "CMS says hospital outreach testing data should be included, but we are very skeptical about how much of that data will actually find its way into the calculations since most hospital outreach labs do not have their own NPI."

How Hospital Private Payer Rates Will Affect the Calculations of Weighted Medians

Medicare Part B Payments for Lab Tests by Setting in 2014



Non-Hospital Lab Market (estimated)



basis that is not part of Medicaid managed care, such a situation does not fall under the definition of private payer, so you don't report that amount. Report it only if it comes from a Medicaid managed care organization.

"Also, do not include payments your lab gets as cash from direct-to-consumer sales," concluded Birenbaum. "Consumers are not included in CMS' definition of private payers, so revenue from this source is not be be reported." TDR

—Joseph Burns

Contact Mark Birenbaum 314-241-1445 or NILA@NILA-USA.org; Julie Scott Allen at 202-230-5126 or Julie.Allen@dbr.com; Jeffrey Sherrin at jsherrin@Oalaw.com or 518-462-5601.

CEO SUMMARY: In a new analysis of data its lab clients will use to report market prices to CMS, XIFIN Inc., reports private payers paid independent labs a weighted average price that was 19.6% less than what Medicare pays for 20 of its highest-volume tests. By contrast, private payers paid hospital labs with NPIs a weighted average that was 26.5% greater than what Medicare pays. Did CMS exclude hospital labs without NPIs from reporting because it would skew CMS payments higher?

Study Based on Hundreds of Millions of Lab Test Claims

XIFIN Analysis of Its Price Data Shows Hospital Lab Price Effect

IN JUST EIGHT WEEKS, certain clinical labs will begin reporting their PAMA lab test market price data to CMS. Those reports will set off a series of events that could trigger the single most financially-disruptive event to hit the clinical laboratory industry in the past three decades.

That event would be Medicare's implementation, as of Jan. 1, 2018, of substantial price reductions to the highest-volume tests that the nation's community laboratories and hospital outreach lab programs depend on for financial stability. Experts predict such reductions could force many labs into bankruptcy.

Officials at the **Federal Centers for Medicare & Medicaid Services** are implementing the Protecting Access to Medicare Act, which includes a requirement to use private market lab test prices to establish a new Part B clinical laboratory fee schedule, effective on Jan. 1, 2018, just 14 months from now.

The potential for large swathes of the clinical laboratory industry to undergo financial crises should the 2018 CLFS impose deep cuts on existing prices of lab tests is a significant concern for those labs. If many labs close, large numbers of Medicare patients may lose access to medical lab testing in their communities that have served them for decades. Related to that is the longer-term problems Congress and CMS could face if a large number of community labs and hospital lab outreach programs went out of business, concentrating even more market share in the hands of these two lab industry oligopolists.

How deep might the price cuts be? Until now, only CMS has had access to the range of price data that would provide even a partial picture of what Medicare pays for lab tests versus what private health insurers pay.

But that has changed. In this issue, THE DARK REPORT presents the lab industry's first look at actual price data that four sectors of the clinical lab industry are preparing to submit to CMS.

The analysis was conducted by **XIFIN, Inc.**, of San Diego. XIFIN describes itself as a "health economics optimization platform that is a connected health solution that facilitates connectivity and workflow automation for accessing and sharing clinical and financial diagnostic data." It provides revenue cycle management services and laboratory information services to more than 200 laboratory clients.

XIFIN handles between 200 million and 300 million lab claims each year and is electronically connected to all of the nation's payers. Its client mix includes the nation's largest lab companies, independent labs, hospital labs with NPI numbers, molecular/genetic labs, and pain management/toxicology labs.

XIFIN tapped its data base to look at the data that its client labs will report to CMS for 20 high-volume lab tests. It calculated a weighted average price that private payers paid for these four lab sectors when compared with what Medicare pays, as follows:

- Independent labs are paid 19.6% less.
- Hospital labs with NPIs are paid 25.6% more.
- Molecular and genetic testing labs are paid 27.3% more.
- Pain management and toxicology labs are paid 50.4% more.

This real price data is derived from tens of millions of private payer payments and shows two things. First, large independent labs are paid less, according to the weighted average, than the Medicare CLFS prices.

Second, private payers pay hospital labs with NPIs a weighted average price that is significantly more than what Medicare pays under the CLFS. Private payers also pay more than the Medicare CLFS pays to molecular/genetic labs and to pain management/toxicology labs.

One conclusion drawn from these basic findings is that CMS is about to significantly reduce its costs by targeting price cuts so

as to pay significantly less to the limited number of the biggest labs performing the highest volume of tests that represent the biggest share of the money paid annually for Medicare lab test claims.

Focus on Most-Used Tests

"It's important to recognize that Medicare is focused on the top tests because that's where it incurs much of its spending," observed Lâle White, Founder and CEO of XIFIN. "Plus, the lower end tests are more esoteric and so don't represent the bulk of what the Medicare program pays."

The question, then, is how will the data from XIFIN translate the results CMS will derive from the PAMA exercise? To answer this question, White explained that some of the data XIFIN reviewed were based on the same top 20 tests that the **Office of Inspector General** analyzed in a recent report on what CMS might save as a result of implementing PAMA.

"We were trying to concentrate on some of that same data that OIG reviewed because this is where labs will feel the majority of the impact from PAMA," she explained. "In our analysis, we collected data on the top 20 tests selected by the OIG and reviewed private payer data against Medicare Part B payments in 2016. Many of our top 20 tests are the among the OIG's top 25 tests.

"When you look at the OIG report, you see that the OIG came to conclusions that were similar to our findings," she added. "When we looked at the top 20 clinical lab tests, we saw that there would be a fairly significant decrease of 19.6% for independent labs. And a large portion of our clinical database represents data from the larger labs.

Part B Lab Payments

"This is important when you look at the OIG report. The report says that 1% of labs (292 out of 29,101 labs) received 54% of all Medicare Part B payments for the top 25 lab tests last year. These labs received an average of $7.6 million each in 2015.

"The OIG said new payment rates for lab tests will be based on data provided by a projected 5% of labs, and these labs received 69% of Medicare payments in 2015," she said. "Also, OIG said that for the top 25 tests, 79% of payments go to the top 4% of labs.

"That means that CMS will use data reported by 5% of all labs to set new payment rates which accounted for 69% of Medicare payments for lab tests in 2015."

On the pages that follow, THE DARK REPORT presents four tables that show how XIFIN calculated a weighted average of private payer prices for 20 of the top 25 tests that incurred the highest costs to Medicare in 2016. These data were compared with the Medicare National Limit price for each of the 20 lab tests.

Accompanying each of the four tables are comments from our editors and White. The commentaries provide insights about the actual payer data used in the analyses, the mix of lab types that contributed data, and some conclusions to draw from the information provided in each table.

Question To Be Answered

There is one question that is not addressed in this intelligence briefing regarding CMS and its plan to implement the lab test price market reporting section of the PAMA statute.

These critics question whether the CMS plan for market reporting is consistent with the language of the PAMA law and the intent of Congress when this bill was passed in 2014. One reason they raise this question is because CMS administrators, since the early 1980s, have regularly come forward with plans to make significant cuts to the Medicare CLFS. And, just as regularly, Congress has stepped in to stop or moderate those efforts.

—Joseph Burns

Contact Lâle White at 858-436-2908 and lwhite@xifin.com.

OIG Desribes How CMS Is Preparing to Implement PAMA Laboratory Test Market Price Reporting

Figure 5. Which Labs Will Be Required to Report Their Private Payer Data?

INDEPENDENT LABS	PHYSICIAN OFFICE LABS	HOSPITAL LABS
Independent labs that received at **least $12,500** from Medicare Part B for lab tests during the first half of 2016 or any labs that perform advanced diagnostic lab tests will be required to report	Physician-office labs that received at **least $12,500** from Medicare Part B for lab tests during the first half of 2016 will be required to report	Generally, no hospital labs will be required to report, because 50% or **less of their Medicare revenue** is for Clinical Laboratory Fee Schedule or Physician Fee Schedule services
1,398 out of 3,211: Estimated number of labs that will be required to report	**11,149 out of 235,928:** Estimated number of labs that will be required to report	**0 out of 6,994:** Estimated number of labs that will be required to report (excludes hospital outreach labs, which function as independent labs)
$3.8 billion out of $3.9 billion: Medicare payments to reporting labs	**$1.0 billion of$1.4 billion:** Medicare payments to reporting labs	**$0 of $1.7 billion:** Medicare payments to reporting labs

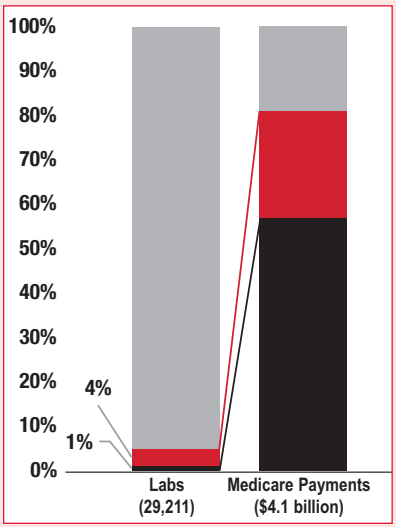
Source: OIG analysis of Medicare Part B lab test payments, 2016. See endnote 10 for more information about the criteria identifying applicable laboratories, i.e., laboratories that will be required to report.

Note: Figures regarding how many labs will be required to report are estimates. We assumed that all independent labs and physician office labs will receive more than 50 percent of their Medicare revenue from the Clinical Lab Fee Schedule or Physician Fee Schedule.

Figure 5 is provided by the Office of the Inspector General in its September report, "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data." It shows how CMS and OIG analyze the clinical laboratory test market and provides information about the proportion of Medicare lab test payments going to each of these three categories of clinical laboratories.

Figure 2.

Medicare Payments for the Top 25 Lab Tests Were Unevenly Distributed Among Labs in 2015



Source: OIG analysis of Medicare Part B lab test payments, 2016.

Figure 2 is also a graphic provided the Office of the Inspector General in its September report, "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data."

This graphic shows how CMS and OIG are using Pareto's Law to analyze the clinical laboratory testing marketplace. OIG wrote that 1% of labs (292 out of 29,101 labs) received 54% of all Medicare Part B payments for the top 25 lab tests in 2015. The next 4% of labs accounted for 25% of Medicare payments for the same tests. By contrast, the remaining 95% of labs accounted for just 21% of payments for the top 25 lab tests.

Market Price Data from: Independent Clinical Labs

EDITOR: When XIFIN analyzed the actual private payer price data that its independent clinical laboratory clients would report to CMS under the PAMA market price reporting rule, why did it select the 20 tests listed in the table on the facing page?

WHITE: The goal was simple. Both CMS and the OIG have identified the small number of lab tests that make up the largest cost for lab testing in the Medicare Part B program. CMS officials regularly state that they intend to make cuts to those tests, which are typically the high-volume, highly-automated assays that make up a large proportion of every independent lab's test volume.

EDITOR: What did your analysis of the actual data your client labs would submit to CMS tell you?

WHITE: When we looked at what private payers had paid independent labs for the 20 types of test, we determined that they were significantly lower prices. The weighted average was 19.6% less than the Medicare National Limit.

EDITOR: What types of lab clients does XIFIN have that are independent labs?

WHITE: Currently XIFIN has more than 200 lab clients and handles between 200 million and 300 million lab test claims per year. XIFIN has electronic interfaces with every health insurer in the United States. This is relevant because it means that XIFIN is capturing all the claims information electronically, in a form that allows us to do these types of analyses.

EDITOR: What is the range in size for XIFIN's independent lab clients?

WHITE: We serve most of the nation's largest independent labs. For some of the bigger lab clients, we handle only a portion of their claims. Collectively, we believe that the lab data that was part of the analysis shows a good mix of what CMS will see when all of the independent labs submit their full sets of market price data.

EDITOR: I'd like to drill down farther on that point. Since the nation's largest independent labs—whether it's the two biggest or the 10 biggest—perform such a substantial proportion of the total volume of test claims, do you believe that the actual claims data that XIFIN analyzed represents what CMS will see from the independent lab marketplace?

WHITE: We think that is correct. It shows that the private health insurers are paying a weighted average of 19.6% less than Medicare for this list of 20 tests. This is relevant when you look at the OIG report. The authors of the report say that "new payment rates for lab tests will be based on data provided by a projected 5% of labs; these labs received 69% of Medicare payments in 2015."

EDITOR: Your point is that CMS will use this handful of very large labs—that have the economies of scale to offer a low price per test to payers—as the basis to reset the Medicare CLFS. Thus, every lab in the nation will be stuck with Medicare lab test prices that do not allow them—with their smaller volume and higher costs—to survive. That would further concentrate market share held by the largest lab companies.

WHITE: That is certainly the common belief, but the mix of hospital labs in the data set will be the primary factor in the degree of the cuts. Many will be watching to see how those fee cuts affect the access Medicare patients have to lab testing in their communities.

Limited Sample of Market Pricing: Clinical Laboratories

Potential Impact on PAMA Price Analysis: -19.6%

Procedure Code	Test Code	Private Payer Weighted Average Rate	Medicare National Limit*	Variance	Percentage Increase / Decrease
80048	Metabolic panel total ca	11.26	11.52	-$0.26	-2.2%
80053	CMP	11.40	14.39	-$2.99	-20.8%
80061	Lipid Panel	16.37	17.73	-$1.36	-7.7%
82306	Vit D	28.45	40.33	-$11.88	-29.5%
82542	Chromotography quant	17.80	24.60	-$6.80	-27.7%
82607	B12	15.09	20.54	-$5.45	-26.5%
82728	Ferritin	13.61	18.57	-$4.96	-26.7%
82746	Folic acid serum	14.81	20.03	-$5.22	-26.1%
83036	Glycosylated hemoglobin	11.16	13.22	-$2.06	-15.6%
83880	Natriuretic peptide	38.41	46.24	-$7.83	-16.9%
83970	Parathormone	44.59	56.23	-$11.64	-20.7%
84153	PSA	19.35	25.06	-$5.71	-22.8%
84439	Thyroxine	9.54	12.28	-$2.74	-22.3%
84443	TSH	18.44	22.89	-$4.45	-19.4%
85025	Complete CBCw/auto diff wbc	8.11	10.59	-$2.48	-23.5%
85027	Complete CBC automated	7.28	8.81	-$1.53	-17.3%
85610	Prothrombin time	4.37	5.36	-$0.99	-18.4%
87086	Urine culture/colony count	8.27	11.00	-$2.73	-24.8%
87491	Cytopathology, Auto	38.17	47.80	-$9.63	-20.1%
88175	Chlamydia, Amp. Probe	36.39	36.09	$0.30	0.8%

* Medicare prices as of 2016

Source: XIFIN, Inc., San Diego, Calif.

- This private payer price data was gathered from XIFIN's database, for payments between Jan. 1, 2016 and June 30, 2016.
- Data comes from approximately 200 labs and between 200 million and 300 million lab test claims.
- Listed above are the top 20 tests for which the Medicare program spent the most money during 2015.
- The table shows how the "private payer weighted average rate" compares to the Medicare National Limit for each test.
- The variance, in dollars, and the percentage increase or decrease over the Medicare National Limit is shown in the far right column.
- XIFIN's calculations, based on real price data to be reported by independent clinical laboratories, indicate that CMS would get price data for this group of tests that would show private payers pay labs a cumulative 19.6% less than the Medicare National Limit.

Market Price Data from:
Hospital Labs with NPI Number

EDITOR: The analysis XIFIN has done of hospital lab market price data will be of high interest, not just in the lab industry, but also among legislators and healthcare policy experts. That's because your analysis uses a large set of data and this data presents the actual prices private payers paid to hospital labs from Jan. 1, 2016, through June 30, 2016.

WHITE: I agree. We have over 22 hospital labs as clients and most of them have quite large lab businesses.

EDITOR: Do all of these hospital labs have national provider identifiers (NPIs)?

WHITE: Yes, all of them do.

EDITOR: Your data set represents hospitals labs that are required to report their PAMA market data to CMS. What did your analysis reveal?

WHITE: When these hospital labs with NPIs report their data to CMS, it will show that they were paid a weighted average of 25.4% more than Medicare by private payers for that list of 20 tests.

EDITOR: Of the approximately 5,000 hospitals in the United States, how many hospital labs have their own NPI numbers?

WHITE: A cursory look at the NPI database indicates that probably only a couple of hundred hospital labs actually have NPIs. That being said, our subset probably represents less than 10% of the ones that have NPIs, but they're among the biggest ones. What that means is that the volume of testing our hospital lab clients do each year probably makes up a higher percentage of the overall number of lab tests performed by hospital labs with NPIs.

EDITOR: This is useful information. If I were to apply Pareto's Law (the 80/20 rule that says roughly 80% of the effects come from 20% of the causes) to your analysis, is it reasonable to assume that XIFIN's hospital lab clients with NPIs, as 10% of the 200 hospital labs with NPIs, probably handle 50% of the lab test volume coming from this segment of the lab industry? That adds credibility to your determination that private payers pay these labs a weighted average of 25.6% than Medicare.

WHITE: Yes. And we don't see the prices that private health insurers pay to those hospital labs that don't have NPIs because they are not our clients. The PAMA final rule excludes those hospital labs from reporting.

EDITOR: Here's another assumption. Would it be reasonable to assume that private payers pay hospital labs more because they serve communities and regions where the larger national lab companies have few or no patient service centers to enable patient access?

WHITE: Yes, that is definitely a fair assumption. I would add that, even in communities where a major lab company has good coverage, bigger hospitals in that same city have payer contracts. So this is not just about patient access.

EDITOR: These are important insights. That's because, since CMS issued the draft PAMA lab test market price reporting rule earlier this year, experts have intuited that hospital lab prices are significantly higher than the Medicare Part B clinical lab test fee schedule. XIFIN's analysis of the market price data its clients will report to CMS demonstrates that this assumption is correct. In fact, Medicare already pays lower lab test prices than many private health insurers.

Limited Sampling of Market Pricing Hospital Laboratories with NPI numbers

Potential Impact on PAMA Price Analysis: +25.6%

Procedure Code	Test Code	Private Payer Weighted Average Rate	Medicare National Limit*	Variance	Percentage Increase / Decrease
80048	Metabolic panel total ca	12.36	11.52	0.84	7.3%
80053	CMP	18.83	14.39	4.44	30.8%
8006	Lipid Panel	22.30	17.73	4.57	25.8%
82306	Vit D	51.29	40.33	10.96	27.2%
82542	Chromotography quant	29.41	24.60	4.81	19.6%
82607	B12	26.50	20.54	5.96	29.0%
82728	Ferritin	24.16	18.57	5.59	30.1%
82746	Folic acid serum	27.49	20.03	7.46	37.2%
83036	Glycosylated hemoglobin	17.83	13.22	4.61	34.9%
83880	Natriuretic peptide	53.97	46.24	7.73	16.7%
83970	Parathormone	68.37	56.23	12.14	21.6%
84153	PSA	32.14	25.06	7.08	28.3%
84439	Thyroxine	16.84	12.28	4.56	37.2%
84443	TSH	28.38	22.89	5.49	24.0%
85025	Complete CBCw/auto diff	13.67	10.59	3.08	29.1%
85027	Complete CBC automated	10.39	8.81	1.58	17.9%
85610	Prothrombin time	6.57	5.36	1.21	22.5%
87086	Urine culture/colony count	14.41	11.00	3.41	31.0%
87491	Cytopathology, Auto	46.33	47.80	(1.47)	-3.1%
88175	Chlamydia, Amp. Probe	47.03	36.09	10.94	30.3%

* Medicare prices as of 2016

Source: XIFIN, Inc., San Diego, Calif.

- This data was gathered from the lab clients of XIFIN, for payments between Jan. 1, 2016 and June 30, 2016.
- Data comes from more than 22 large hospital labs with NPI numbers and tens of millions of lab test claims.
- Listed above are the top 20 tests for which the Medicare program spent the most money during 2015.
- The table shows how the "private payer weighted average rate" compares to the Medicare National Limit for each test.
- The variance, in dollars, and the percentage increase or decrease over the Medicare National Limit is shown in the far right column.
- XIFIN's calculations, based on real price data to be reported by hospital labs with NPI numbers, indicate that CMS would get price data for this group of tests that would show private payers pay labs a cumulative 25.6% more than the Medicare National Limit.

Market Price Data from: Molecular/Genetic Labs

EDITOR: When you did this analysis of molecular and genetic testing labs, what caught your attention?

WHITE: The issue for us is that Medicare made significant cuts in molecular and genetic test prices, but the private sector has not necessarily done so.

EDITOR: Anything else?

WHITE: Because these are primarily molecular labs and not routine clinical labs that may perform some genetic tests, they spend a lot of time appealing claims where reimbursement is low. Many of these genetic labs are making a big push with the private payers to get better reimbursement rules; some of them are out of network. So a good portion of payments are not contracted prices. Keep in mind that these are generally labs with specialty molecular and genetic tests. Thus, their test mix is not the type of "routine" molecular assays that some of the larger lab companies perform.

EDITOR: This study is based on price and not on volume. Is it correct to assume this is where Medicare might be spending the most money on molecular and genetic tests—lower volume, but higher prices?

WHITE: These are the top 20 molecular tests that represent the most dollars spent by Medicare for this category of tests paid to labs specializing in genetic testing.

EDITOR: What this data shows is that private payers continue to be willing to reimburse labs for molecular and genetic tests at prices that are notably higher than what Medicare pays. By contrast, Medicare has spent several years attempting to drive down what it pays for these same molecular tests.

WHITE: There is another fact about private payer pricing that we must recognize. XIFIN sees that these molecular labs are getting paid only about 25% of the dollars for which they bill, when they get paid! The balance of the time, which is 75%, they don't get paid because they are out of network. So these unpaid claims won't be reported to CMS under the PAMA final rule.

EDITOR: This is an interesting dichotomy.

WHITE: Yes, it is, because, for the most part, molecular labs are not being paid for the majority of their test claims. When they get paid, they get paid fairly well. Where claims are not paid, these labs will appeal and, once they do, they get better payments.

EDITOR: So they spend a lot of time trying to get payment for their claims. How does that affect their overall finances?

WHITE: When molecular labs do get paid, the payments they get are good. But this is not the majority of testing and claims they submit. However, for the larger genetic labs, the payments they receive generate enough revenue to support the entire menu of lab testing.

EDITOR: That is a crazy way to operate a laboratory that provides test results that physicians use to diagnose and treat patients.

WHITE: Unfortunately, this is the current system. This is particularly true since the molecular and genetic labs that are clients of XIFIN and generated this market price data are performing proprietary and specialty tests that physicians are using daily in patient care. Pathologists and clinical lab managers should know that these labs pay attention to compliance. We see this as our team helps them with different issues involving coding, billing, and collections. It is important to also note that some of these tests are also performed by independent clinical labs that do not specialize in molecular testing, but provide some version of these tests, either directly or through a reference lab partner. These labs have not been included in this analysis.

Limited Sample of Market Pricing: Molecular/Genetic Laboratories

Potential Impact on PAMA Price Analysis: +27.3%

Procedure Code	Test Code	Private Payer Weighted Average Rate	Medicare National Limit*	Variance	Percentage Increase / Decrease
81490	Autoimmune rheumatoid arthr	811.31	574.77	$236.54	41.2%
81211	seq & cBRCA1&2 om dup/del	2,573.29	2,180.22	$393.07	18.0%
81545	Oncology thyroid	3,616.72	3,135.07	$481.65	15.4%
81213	BRCA1&2 uncom dup/del var	548.99	581.84	-$32.85	-5.6%
81226	CYP2D6 gene com variant	736.55	450.91	$285.64	63.3%
87507	LADNA-DNA/RNA probe 12-25	221.98	567.75	-$345.77	-60.9%
81225	CYP2C19 gene com variants	422.89	291.36	$131.53	45.1%
87633	Resp virus 12-25 targets	194.30	567.75	-$373.45	-65.8%
81317	PMS2 gene full seq analysis	740.54	780.12	-$39.58	-5.1%
81292	MLH1 gene full seq	729.86	645.26	$84.60	13.1%
81291	MTHFR gene	129.59	59.46	$70.13	117.9%
81401	MoPath Tier 2	262.27	134.40	$127.87	95.1%
80061	Lipid panel	43.86	17.73	$26.13	147.4%
81298	MSH6 gene full seq	666.32	287.40	$378.92	131.8%
81400	MoPath Tier 2	305.47	117.60	$187.87	159.8%
81528	Oncology colorectal scr	502.45	508.87	-$6.42	-1.3%
81295	MSH2 gene full seq	501.63	151.48	$350.15	231.2%
81227	CYP2C9 gene com variants	280.50	174.81	$105.69	60.5%
81404	MoPath Tier 2	315.39	163.96	$151.43	92.4%
81381	HLAi typing 1 allele hr	300.90	128.84	$172.06	133.5%

* Medicare prices as of 2016

Source: XIFIN, Inc., San Diego, Calif.

- This private payer price data was gathered from the lab clients of XIFIN, for payments between Jan. 1, 2016 and June 30, 2016.
- Data comes from more than 20 specialty molecular labs and tens of millions of lab test claims.
- Listed above are the top 20 molecular and genetic tests for which the Medicare program spent the most money during 2015.
- The table shows how the "private payer weighted average rate" compares to the Medicare National Limit for each test.
- The variance, in dollars, and the percentage increase or decrease over the Medicare National Limit is shown in the far right column.
- XIFIN's calculations, based on real price data to be reported by its molecular labs, indicate that CMS would get price data for this group of molecular and genetic tests performed by labs specializing in this type of testing that would show private payers pay labs a cumulative 27.3% more than the Medicare National Limit. The degree to which some of these tests will be diluted by submissions from larger labs will determine the final impact.

Market Price Data from:
Pain Management/Toxicology Labs

EDITOR: Before we discuss XIFIN's analysis of what PAMA market price reporting will look like for labs involved in pain management testing and toxicology, I think it is appropriate to recognize that there has been substantial fraud and abuse in this sector. That can affect the policies private payers use to adjudicate claims for this category of lab tests.

WHITE: To that point about the policies of private payers regarding pain management and toxicology lab test claims, readers should understand two things about this analysis. First, the data is from 2016. Thus, it represents payments from payers who have implemented policies to address illegal or unethical billing practices by some labs offering these tests and who have adopted the G codes. In that regard, the data represent current reimbursement levels from private payers.

EDITOR: And your second point?

WHITE: The second point is that the data are from XIFIN lab clients and these labs have demonstrated to us that they have appropriate compliance policies and programs in place.

EDITOR: Keeping those two points in mind, how should this data be interpreted?

WHITE: It is necessary to understand a few things about the G codes. Early on, the Medicare program initiated severe cuts to the G codes. At the same time, across the board, private health insurers have not fully accepted use of G codes for these types of lab test.

EDITOR: That is interesting. How are things changing? Are private payers more willing to accept the G codes?

WHITE: We've seen a slow, but steady growth in the number of private payers that have adopted the G codes. It should be noted, however, that the volume of G codes in pain management that private payers use is not large.

EDITOR: Is there a pricing trend for pain management and toxicology testing that you see with private payers?

WHITE: This data set reflects the G codes where they've been adopted by private health insurers and, while it doesn't represent a big volume, payment is significantly higher than Medicare rates. Looking at both the G codes and some of the 8xxxx codes that pain management/toxicology labs use, this data shows a 50.4% higher payment rate than what is paid by Medicare.

EDITOR: What is changing with the 8xxxx codes that are used in pain management and toxicology testing?

WHITE: It is interesting that the majority of this 2016 data set were paid in the old 8xxxx codes and these are not going to be part of the PAMA lab test market price reporting. By the way, these codes were also paid at high rates by private payers compared to the Medicare program.

EDITOR: Have CMS officials given an indication as to how they might change current guidelines and reimbursement levels involving pain management and toxicology test codes?

WHITE: During recent meetings conducted by CMS, Medicare officials have made statements that show some recognition that the federal agency had gone too far in the cuts for pain management testing and the G codes specifically. There are indications that CMS may be preparing to do an upward adjustment in 2017.

Limited Sample of Market Pricing: Pain Management/Toxicology Laboratories

Potential Impact on PAMA Price Analysis: +50.4%

Procedure Code	Test Code	Private Payer Weighted Average Rate	Medicare National Limit*	Variance	Percentage Increase / Decrease
G0482	Drug test def 15-21 classes	243.87	166.03	$77.84	46.9%
G0483	Drug test def 22+ classes	458.14	215.23	$242.91	112.9%
G0481	Drug test def 8-14 classes	167.39	122.99	$44.40	36.1%
G0479	Drug test presump not opt	102.26	79.25	$23.01	29.0%
G0480	Drug test def 1-7 classes	111.95	79.94	$32.01	40.0%
81226	CYP2D6 gene com variants	410.04	450.91	-$40.87	-9.1%
82542	Column chromo quant	22.41	24.60	-$2.19	-8.9%
84311	Spectrophotometry	8.94	9.52	-$0.58	-6.1%
82570	Assay of urine creatinine	6.67	7.05	-$0.38	-5.4%
81291	MTHFR Gene	50.46	59.46	-$9.00	-15.1%
80184	Assay of phenobarbital	12.00	15.60	-$3.60	-23.1%
83986	Assay ph body fluid nos	4.62	4.88	-$0.26	-5.4%
83789	Mass spectrometry quant	35.87	24.60	$11.27	45.8%
80171	Drug screen quant gabapentin	15.58	18.06	-$2.48	-13.8%
81003	Urinalysis auto w/o scope	2.70	3.06	-$0.36	-11.8%
81225	CYP2C19 gene com variants	256.72	291.36	-$34.64	-11.9%
81401	MoPath Tier 2	125.99	137.20	-$11.21	-8.2%
81400	MoPath Tier 2	326.23	120.54	$205.69	170.6%
81227	CYP2C9 gene com variants	191.84	174.81	$17.03	9.7%
83655	Assay of lead	10.56	16.49	-$5.93	-35.9%

* Medicare prices as of 2016

Source: XIFIN, Inc., San Diego, Calif.

- This private payer price data was gathered from the lab clients of XIFIN, for payments between Jan. 1, 2016 and June 30, 2016.
- Data comes from multiple pain management/toxicology labs and tens of millions of lab test claims.
- Listed above are the top 20 pain management/toxicology tests for which the Medicare program spent the most money during 2015.
- The table shows how the "private payer weighted average rate" compares to the Medicare National Limit for each test.
- The variance, in dollars, and the percentage increase or decrease over the Medicare National Limit is shown in the far right column.
- XIFIN's calculations, based on real price data to be reported by this pool of its lab clients, indicate that CMS would get price data for this group of pain management/toxicology tests that would show private payers pay labs a cumulative 50.4% more than the Medicare National Limit. Again, this data set does not include pricing for the same tests preformed by Independent Clinical Labs and Hospital Labs, and will alter the weighted median average based on the mix of data submitted across various labs.