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Special! Part 2 of PAMA FINAL RULE!

What All Labs Must Know about reporting data, Medicare fee 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

Could Community Labs Become Extinct after PAMA?

IN THE PURSUIT OF IMMEDIATE COST SAVINGS, our federal government may be about to tinker with an essential clinical service in ways that will severely harm patients in rural areas and small towns throughout the United States.

Specifically, will the final rule to implement PAMA lab test market price reporting turn out to be a financial death blow to a sizeable number of community labs, rural hospitals, and community hospitals (who depend on outpatient and outreach lab test revenues for financial stability)?

Our editor makes that argument in this DARK REPORT, which is our second special issue devoted to helping lab executives understand why implementation of the PAMA market price reporting rule has the potential to be the single most financially-disruptive event to the clinical lab industry in three decades.

Why are community labs, along with rural and community hospitals, at financial risk because of PAMA? As our editor explains, these labs are typically paid higher prices by private payers for three reasons (reasons that are not addressed by CMS in its final rule for PAMA). First, in many towns and regions, health insurers need access to lab testing that these labs provide. So payers keep those labs in network to provide that access.

Second, because these labs have smaller specimen volumes, they also have a higher average cost per test. Payers recognize this fact and thus agree to prices that are higher than Medicare Part B prices so that these labs have adequate revenue to stay in business.

Third, private payers know that the nation's largest public labs won't provide comparable access and lab testing services to these rural areas and towns that community labs, rural hospitals, and community hospitals serve. This factor is another reason private payers continue to pay higher-than-Medicare prices and keep these labs in their networks.

Given that these small labs and hospitals operate on razor-thin margins, deep cuts in Medicare Part B lab test fees—as Medicare officials have predicted are coming—cause the owners of these organizations to understand that their ability to stay in business will be compromised, putting their labs at high risk of financial collapse. Several lab groups and experts have predicted this scenario, saying they fear that coming cuts in Medicare lab prices could trigger the extinction of labs that provide essential access to rural communities and small towns. TDR

Why Small Labs, Hospitals Are at Risk from PAMA Cuts

Could PAMA's Medicare price cuts kill off the nation's smallest—but vital—clinical labs?

CEO SUMMARY: Clinical lab executives and experts who have studied the final rule for PAMA lab test market price reporting are seriously concerned that the design of this rule may put many of the nation's smallest, but still essential, clinical labs at great risk of financial distress, if not outright failure. In this exclusive analysis, THE DARK REPORT shows why excluding the reporting of the higher prices private insurers pay to clinical labs who get 31% of Part B fees could eventually cause many labs to go out of business.

IN JUST FOUR WEEKS, Medicare officials will begin accepting private payer lab test price data from those labs required to report under the PAMA final rule to implement the Protecting Access to Medicare Act of 2014. Some lab administrators expect that implementing PAMA could be the single most financially-disruptive event to hit the clinical lab industry in three decades.

As was widely reported on these pages and by many lab industry professional societies and associations, officials at the federal **Centers for Medicare & Medicaid Services** have stated on multiple occasions that the agency's study of private payer lab test price data will result in price cuts to the Medicare Part B fees. CMS estimates of $5.4 billion in savings over the first 10 years of those price cuts have been reported.

The estimate of $5.4 billion in savings shows that the agency may be going beyond the intent of Congress when it passed PAMA two years ago, according to critics of how CMS is implementing the law's market price reporting requirement. When PAMA was signed into law, the **Congressional Budget Office** (CBO) scored this part of the bill as projected to deliver $2.4 billion in savings over 10 years. *(See TDR, April 7, 2014.)*

These critics are troubled by the fact CMS now projects savings that are more than double the original CBO estimate of savings expected over 10 years. They point out that, since CMS has not yet seen and analyzed the private payer price data, its prediction that costs for lab testing will decrease Medicare lab test spending by $5.4 billion demonstrates that the federal agency

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may not be making a good faith effort to execute the language of PAMA. That's because its target is to cut lab test fees by an amount that is more than double the savings that was budgeted by Congress when the bill was scored and passed.

Bias in Report Methods?

Some lab industry experts argue that CMS structured the final rule to exclude classes of labs known to get higher prices from health insurers. CMS arranged the final rule so that the majority of the private payers' price data that labs report will consist of the much lower prices that health insurers pay to the nation's largest commercial labs in exchange for exclusive network status that excludes smaller lab competitors, the critics assert.

CMS established requirements that guaranteed that the majority of private payer price data will come from those clinical laboratories that get the lowest prices from private payers, the critics argue. But these labs also perform the highest volume of tests and thus have lower costs.

At the same time, because of the types of clinical laboratories excluded from the final rule, the private payer price data won't be reported from labs that represent 31% of the total payments paid out annually under Medicare Part B. These types of labs are known to get higher prices from private insurers.

One Third of Data Excluded

The **Office of Inspector General** confirms this fact in its report of *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data*, issued in September. OIG wrote, "...we estimate using data from 2015 that 5% of labs (12,547 labs) will be required to report their private payer data to CMS. CMS will use data reported by these labs to set new payment rates for lab tests. These labs accounted for 69% of Medicare payments for lab tests in 2015. The other 95% of all labs (248,977) accounted for the remaining 31% of Medicare payments in 2015." *(See TDR, Nov. 7, 2016.)*

The OIG's findings are significant because they show that the price data the nation's largest lab companies report is the result of having extended deeply-discounted lab test prices to major insurers in exchange for exclusive or near-exclusive network status. Those labs will make up the largest proportion of the data submitted to CMS starting in January.

By excluding such data, CMS is putting some of the nation's clinical labs at risk of significant erosion in their financial condition. Specifically, small labs (often the only independent labs serving nursing homes in their regions), community hospitals, and rural hospitals will take a financial hit that may put them out of business.

Why Pay Higher Prices?

Further, private health insurers pay these higher prices for important reasons. First, they are often the only labs (or hospitals) that provide beneficiaries with access to lab tests in their communities and rural areas.

Second, private payers recognize that these labs have greater costs because of their much lower lab test volume. Thus, private insurers understand that a higher lab test price is necessary for these labs to remain in business and provide lab testing services to the private payers' patients in these communities.

Third, if these smaller lab test providers are the only source for lab testing and they go out of business, private health insurers recognize that it is highly unlikely that the nation's largest independent labs would step in to serve these communities.

There is some irony in this situation. Currently, the nation's largest labs do not serve these rural areas because it's not feasible financially, given the mix of prices that private insurers and Medicare pay. Thus, lower Medicare Part B lab test fees would make it even more difficult for big-

There Is Long History of Medicare Officials Taking Steps to Cut Part B Lab Test Prices

GIVEN THE SEVERAL STATEMENTS of the estimated savings of $5.4 billion to come from cuts to the Medicare Part B clinical laboratory fee schedule from officials of the Centers for Medicare & Medicaid Services, there should be no surprise when CMS finally publishes the lower fees late in 2017 that will become effective on Jan. 1, 2017.

Assuming that CMS does succeed in implementing deep price cuts to the CLFS, it will be the culmination of a price-cutting effort that began as long as 35 years ago. It was in the early 1980s that certain Medicare officials began to publicly discuss the use of competitive bidding as a way to cut clinical lab test fees.

Competitive Bidding Model

CMS (then known as the **Health Care Financing Administration**, or HCFA) engaged outside contractors to develop a model for conducting competitive bidding. In 1987 and again in 1989, **Abt & Associates** of Cambridge, Massachusetts, did this type of work for CMS.

Efforts continued. THE DARK REPORT wrote, "During 1996-97, **Research Triangle Institute** (RTI) completed a contract with HCFA to produce a detailed plan for a laboratory competitive bidding demonstration project. RTI published the results of this work in the form of a paper titled *Medicare's Demonstration of Competitive Bidding for Clinical Laboratory Services: What It Means for Clinical Laboratories*. This paper appeared in *Clinical Chemistry* (44:8, 1728-1734 [1998]). *(See TDR, Dec. 31. 2007.)*

Nothing came of these efforts. For CMS, it was an idea that refused to die. One Congress after another Congress was given a recommendation by Medicare officials to authorize the federal agency to proceed with a competitive bidding project involving clinical laboratory tests. That was true throughout the 1990s and into the 2000s.

The big change happened in 2003. That was when Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This authorized CMS to organize and conduct demonstration projects for the competitive bidding of clinical laboratory services.

CMS again engaged RTI and, by 2007, it announced a demonstration project for competitive bidding of lab testing for the San Diego-San Marcos Metropolitan Statistical Area. Only a lawsuit in a federal court with several laboratories as plaintiffs stopped this competitive bidding project in 2009. *(See TDRs, Aug. 14, 2006; Dec. 31, 2007; Jan. 21, 2008; March 3, 2008.)*

Did that kill the competitive bidding idea? No! In the spring of 2012, a study authored by experts at RTI was published in the *Medicare & Medicaid Research Review* (MMRR, 2012: Volume 2, Number 2). The study was titled *The National Market for Medicare Clinical Laboratory Testing: Implications for Payment Reform*." In their abstract, the authors stated, "national competitive bidding for non-patient laboratory tests could result in cost savings for Medicare." *(See TDR, Sept. 17, 2012.)*

Studies of Lab Prices

Officials at CMS next engaged the **Office of the Inspector General** (OIG) to further study the prices of clinical lab tests. In 2013, the OIG issued: *Comparing Clinical Laboratory Test Payment Rates: Medicare Could Achieve Substantial Savings*. Using a subjective methodology, the authors concluded that CMS could save $910 million annually if it could lower Part B lab test fees to the prices of 20 high-volume tests as paid by state Medicaid programs. *(See TDR, June 17, 2013.)*

As documented above, administrators at CMS have shown bulldog tenacity for 35 years in their attempts to slash Part B lab test prices. The PAMA final rule may be the fulfillment of this long-standing wish.

ger labs to fill the vacuum left after the existing, smaller labs stop serving these communities.

Important data published in THE DARK REPORT's special coverage of PAMA lab test price reporting shows why it matters that hospital labs and smaller independent labs submit their data. That analysis was based on the data that labs will report to CMS, based on several hundred million lab test claims that **XIFIN, Inc.**, of San Diego, processed for its almost 200 clinical laboratory clients. *(See TDR, November 7, 2016.)*

The XIFIN data shows evidence of the bias that CMS is accused of building into the PAMA final rule. As we reported, XIFIN calculated that for 20 of the lab tests for which CMS pays the most money, private payer payments were above or below Medicare's 2016 fees by the following percentage, on average, for the following four categories of labs:

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

➤Concerns About PAMA Rule

This analysis supports the comments of CMS' critics about how and why CMS wrote the final rule for market price reporting. XIFIN's analysis of the private payer price data its clients will submit to CMS demonstrates that private health insurers regularly pay significantly higher prices than the Medicare program pays to every sector of the lab industry except one: the commercial lab sector dominated by **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**.

Thus, if Congress intended for Part B lab test fees to be reset based on what private health insurers pay to *all* clinical labs, whether they are independent, hospital, molecular and genetic, toxicology and pain management, or physician office labs, then CMS apparently is failing to meet Congress' intention, as specified in PAMA.

Given that it takes years and substantial capital to rebuild clinical laboratory capacity after it disappears from a community, it would be wise for lawmakers, Medicare officials, and laboratory industry leaders to reconsider all the potential consequences of implementing the final rule for PAMA market price reporting as it is written. TDR

Small and Rural Hospitals Also at Risk from Fee Cuts

FOR COMMUNITY HOSPITALS, PARTICULARLY THOSE IN RURAL AREAS, revenue from outpatient and outreach laboratory testing often sustains these hospitals' finances. Therefore, the expected cuts to Medicare Part B clinical laboratory test fees will be a severe financial hardship for many of these hospitals.

Congress and healthcare policymakers do not realize how important even small volumes of outreach lab testing can be to smaller or rural hospitals. In 2012, Michelle McEwen, FACHE, President and CEO of 25-bed **Speare Memorial Hospital** in Plymouth, N.H., told THE DARK REPORT, "The funds generated by performing these [outpatient] lab tests are used to support the cost of providing laboratory services to all patients 24/7, including stat lab testing for emergency patients and inpatients. These funds also help support other services in the hospital where losses are typically incurred, such as the emergency room and obstetric programs." *(See TDR, April 2, 2012.)*

There has not been much discussion of how the price cuts from PAMA lab test market reporting will affect the nation's smaller community hospitals and rural hospitals. It could be that the CEOs and administrators of these hospitals are unaware that CMS is preparing to implement significant cuts to Medicare Part B lab test fees in 2018.

Should Labs File Challenge To PAMA Price Report Rule?

In 2008, several labs sued HHS and obtained an injunction that stopped competitive bidding

CEO SUMMARY: Just four weeks remain before CMS begins collecting private payer clinical laboratory test price data. Many lab industry executives have charged that Medicare officials are not following the language of the PAMA statute or the intent of Congress. At stake are $5.4 billion in Part B fee cuts that CMS plans to introduce. Has the time come for the clinical laboratory industry to act together by challenging the rule-making in federal court?

By Robert L. Michel

OVER THE PAST THREE DECADES, the clinical laboratory industry and the house of laboratory medicine have seldom spoken with a unified voice about critical issues.

That situation exists because the clinical and business objectives of each sector of the lab industry will often diverge. For instance, public lab companies often have different business interests than private clinical labs.

Another large segment of the lab industry are hospital labs. But they are part of the hospital industry, which has its own agenda. As clinical professionals, pathologists need to protect their professional interests, which often diverge from the interests of clinical labs. And, labs specializing in molecular diagnostics and genetic testing have separate business interests.

Today, however, the clinical laboratory industry and the house of laboratory medicine face a common threat: the looming, substantial cuts to the Medicare Part B clinical laboratory fee schedule that the federal **Centers for Medicare & Medicaid Services** will implement in January 2018.

For this reason, leaders from all sectors of the clinical laboratory industry and the pathology profession should come together, without delay, to act as necessary to ensure that the PAMA statute is executed in a way that is consistent with the language of the law and the intent of Congress. There are several actions that labs can take, ranging from administrative appeals and reviews to court action.

Lawsuit In Federal Court

Filing suit in federal court against the **Department of Health and Human Services** (HHS) is the most direct way to obtain a restraining order that would at least temporarily stop CMS from moving forward with implementation of the PAMA market price reporting rule. That would then give both parties to the lawsuit time to put their arguments before a judge.

If such an injunction were to be obtained before January 1, 2017, that would mean labs would not submit pri-

vate payer market price data to CMS until a ruling by the federal judge overseeing the case. Such a ruling would prevent CMS from reviewing that market price data, pending a decision in this court case.

Who should be the plaintiffs in this court case? It would be smart to include several community labs that serve nursing homes primarily. Medicare patients make up as much as 50% to 70% of the patient mix for community labs, which typically provide the only lab testing services in the towns and rural areas they serve. In front of a federal judge, these labs could make a compelling case about the financial harm and loss of access Medicare beneficiaries would suffer if CMS implemented the PAMA price reporting rule as written.

It would also be beneficial to include as plaintiffs some small hospitals and rural hospitals. Associations such as the **Texas Organization of Rural & Community Hospitals** (TORCH) can identify small hospitals that have the greatest financial risk that would result from these cuts in Part B lab test fees. These hospitals also provide important access to Medicare beneficiaries that Congress would want to continue.

Hospital Labs With No NPIs

A third group of plaintiffs would be hospitals and health systems that have significant clinical laboratory outreach programs, but do not have NPI numbers. Private health insurers typically pay these labs more than these labs get under Medicare Part B (a fact that CMS officials know), but these labs have been excluded from reporting under the final rule. Lab test revenues are important to the budgets of these hospitals and, as plaintiffs, they would provide strong evidence that their exclusion from market price reporting under the final rule violates the language of the statute and the intent of Congress.

In our most recent issue, we published an analysis of the actual lab test data to be reported for four classes of laboratories. That data came from **XIFIN, Inc.**, of San Diego, which based its analysis on hundreds of millions of private payer lab test payments. *(See TDR, Nov. 7, 2016.)*

The analysis showed, for example, that hospitals with NPIs are paid substantially more than Medicare fees—25.6% more! Yet CMS officials are effectively excluding almost all hospital laboratories from reporting price data.

Do Labs Have Strong Case?

A careful study of the comments, concerns, and objections to the PAMA market price reporting rule that lab industry leaders and experts made at CMS public hearings and in various news stories indicates that the lab industry may have a strong case against CMS.

Use of a lawsuit in a federal court against HHS on a lab-related issue has a precedent. In 2008, several plaintiff labs sued HHS in federal court in San Diego. The labs challenged the manner in which the federal agency was implementing a federal law authorizing a competitive bidding demonstration project for Part B clinical laboratory testing.

A federal judge ruled in favor of the plaintiff labs on several key points and issued a preliminary injunction to stop the bidding demonstration project. HSS chose not to appeal the judge's decision and didn't proceed with the project. *(See TDR, March 3, March 24, and April 14, 2008.)*

New Congress And President

Facing CMS' estimate that it will cut $5.4 billion from lab testing fees—an amount that is more than double what the PAMA law was scored to save at the time Congress passed it—and using a method that multiple lab experts say does not fulfill the language of the PAMA statute, it would seem to be a smart move to use the federal courts to slow or stop this program, at least until the new Congress and administration reviews the concerns of the clinical laboratory industry. TDR

Medi-Cal Update

California's Lab Price Data Project Cuts Lab Test Prices by 10.5%

In rate changes effective July 1, state slashed pay for 252 lab tests; most were cut by 0.1% to 25%

COLLECTING LAB TEST PRICE DATA is not limited to PAMA and the federal **Centers for Medicare & Medicaid Services**. California's **Medi-Cal** program is in its second year of requiring clinical labs to submit private payer lab test price data.

However, in both the first and second year of requiring clinical labs to report lab test prices paid by private payers, the **California Department of Health Care Services** (DHCS) has received price data from only 9% and 10.1%, respectively, of the total number of labs required to report.

After the first year's submission of lab price data, DHCS reported a drop in fee-for-service Medi-Cal spending on clinical lab tests from 2014 to 2015 of $29.4 million, or 10.5%.

This deep cut in payment came because DHCS slashed what its Medi-Cal program pays labs for 252 lab tests. Most of those tests (229) were cut by 0.1% to 25%, DHCS said. The rate adjustments were effective as of July 1, 2016, the first day of the state's fiscal year. Medi-Cal is California's Medicaid program.

"The overall expenditures for Medi-Cal FFS clinical lab services slightly decreased, from $278,566,000 in calendar year 2014 to $249,185,000 in calendar year 2015," DHCS reported in answer to questions from THE DARK REPORT. That decline of $29.4 million equals a drop in payment of 10.5%.

Earlier this year, THE DARK REPORT covered the first phase of California's data-collection effort, revealing that only 9% of clinical laboratories in California submitted data in 2015 for DHCS' rate-setting program. The data submitted in 2015 was based on what third-party payers paid the labs in 2014. *(See TDR, April 11, 2016.)*

This year, 56 clinical laboratories provided data in the second-phase of the state's initiative. This number represented 10.1% of the 553 labs required by DHCS to submit data for the second annual rate-setting process, DHCS reported. "The labs that submitted the requested data continue to represent a majority of the total fee-for-service (FFS) claims for these services," DHCS added.

Majority of Claims Submitted

Last year, DHCS required 742 labs to submit data in phase one and only 66 individual labs submitted the requested data, DHCS said, adding that those 66 labs represent most of the total claims for services.

"DHCS expected to receive a higher number of data submissions; however, the data received continues to represent the majority of FFS claims for these services," the agency said.

Earlier this year, Michael Arnold, Legislative Advocate and Executive Director of the **California Clinical Laboratory Association**, said he did not know why most California labs were not submitting data to DHCS except that

some labs have said the process is difficult and expensive. "We have suggested to CCLA members that more data would be better and have encouraged our labs to participate," stated Arnold. "For labs, it's probably a cost and time issue."

Prediction About PAMA

Earlier this year, Mark S. Birenbaum, PhD, Administrator, of the **National Independent Laboratory Association** (NILA), made a comment about California's experience with the collection of lab price data that turned out to be prescient. "We believe that the California data reporting clearly indicates that the PAMA reporting will be difficult and complicated," he commented in April. PAMA is the Protecting Access to Medicare Act of 2014.

DHCS choose the clinical labs required to submit data based on total claims paid and submitted. Lab providers with 2015 Medi-Cal utilization reflecting paid claims totaling $100,000 or greater, or claim counts totaling 5,000 or greater, were required to submit fee schedule data.

To get more labs to participate, DHCS implemented several strategies to alert labs. But the state agency did not extend the date to submit data beyond the deadline of March 18, 2016.

Steps To Build Participation

"DHCS has implemented several methods focused on increasing participation, such as updating the DHCS Clinical Laboratory web page in November 2015 to provide advance notice of the affected NPIs and codes," DHCS said. "The agency also directly mailed the affected providers to notify them of the data submission requirements and deadline. It continues to notify the lab stakeholders of the request for 2015 lab data so they can encourage their provider's participation, and the agency has posted provider bulletins to notify the public and providers of the 2015 lab data request and deadline.

"DHCS expects that these efforts will help to increase the number of provider data submissions for the third annual rate-setting process, which recently started for the July 1, 2017, rate adjustments," the agency said.

"DHCS did not impose any fines to providers," the agency reported. "DHCS has authority to suspend providers for not complying with the data submission request, but in order to avoid any potential access issues as a result of suspending providers, the department is first looking to other methods of increasing data submissions. Again, the data submitted for the past two rate-setting processes continue to represent a majority of the total FFS claims for these services."

Law Requires Data Collection

California's Department of Health Care Services (DHCS) is required under state law, Assembly Bill 1494, to develop a new rate-setting methodology for clinical laboratory or laboratory services based on the average of the lowest prices other third-party payers are paying for similar services. The new rate-setting methodology was effective July 1, 2015.

The new method requires a 10% payment reduction for clinical laboratory and laboratory services until CMS approves a new rate-setting methodology, DHCS said. Lab testing services under the Family Planning, Access and Treatment (FPACT) program and outpatient hospital services, effective July 1, 2012 through June 30, 2015, are excluded from this reporting requirement.

The low rate of clinical laboratories submitting private payer price data as required by California state law is a sign of how complex and time-consuming it is for the majority of labs to comply with this type of requirement. TDR

—Joseph Burns

PAMA Update

Will Coming Medicare Fee Cuts Reduce Access to Lab Tests?

ACLA is concerned key PAMA implementation issues remain unaddressed, urges congressional oversight

SEVERAL IMPORTANT clinical laboratory associations are concerned that the lab test price reporting under the Patient Access to Medicare Act of 2014 will have a negative effect on diagnostic innovation and on Medicare beneficiaries' access to lab testing services.

The **American Clinical Laboratory Association** wants to ensure that the new Medicare Part B clinical laboratory fee schedule rates established by the **Centers for Medicare & Medicaid Services** under PAMA do not threaten access to laboratory services for Medicare beneficiaries. ACLA also wants Congress to ensure that the new rates do not limit innovation among diagnostic testing laboratories, Julie Khani, ACLA's Executive Vice President, told THE DARK REPORT. ACLA is concerned about how the regulations under PAMA define "applicable labs" that must report lab-test-price data to CMS.

"While the 'applicable lab' definition in the final rule is an improvement from the proposed rule, we are monitoring implementation closely to ensure that PAMA results in market-based rates," Khani said. "We urge Congress to exercise its oversight authority to ensure that the new reimbursement rates do not limit diagnostic innovation or threaten Medicare beneficiary access to clinical laboratory services."

In addition, ACLA is concerned about the challenges clinical laboratories face as they prepare to report their price and volume data to CMS starting in January.

"Collecting and certifying private payer data to submit to CMS is very challenging, especially since labs are going through it for the first time," Khani said. "Challenges include determining those codes for which applicable information is to be reported, reviewing the large amounts of data that will be reported, pulling the necessary data from laboratory systems, and collecting and reporting information on automated multi-channel chemistry tests. We are also still awaiting guidance from CMS on the advanced diagnostic laboratory test (ADLT) application process.

"We continue to work closely with Congress and CMS on PAMA implementation," she added.

How Will New Congress Act?

One factor that adds uncertainty to the implementation of PAMA market price reporting is the effect a new president and new Congress will have when they take office in January. New members of the executive and legislative branches may be receptive to arguments from the clinical laboratory industry about how CMS has interpreted the PAMA statute and is implementing the market price reporting section of the law. TDR

—Joseph Burns

Contact Julie Khani at 202-637-9466 or jkhani@ACLA.com.

CEO SUMMARY: In its work with more than 200 lab clients, XIFIN, Inc., of San Diego, sees the best and worst of problems in how labs submit claims to lab tests and how payers process these claims. In this exclusive interview, Lâle White, XIFIN's Founder and CEO, identifies the systemic sources of problems in the filing and settlement of lab claims. Because CMS will engage outside auditors to find errors in the data that labs report under the final rule for PAMA market price reporting, it is imperative that lab billing teams learn how to identify and fix payer errors.

Labs warned that payers' information full of errors

Expert Explains Why Payer Errors Skew Labs' PAMA Price Data

ACROSS THE NATION, clinical laboratories required to report their lab test market price data to the **Centers for Medicare & Medicare Services** are scrambling to gather that data, ensure it is accurate, and package it for submission to the federal agency starting on Jan. 1, 2017.

However, one expert in lab coding, billing, collections, and managed care issues says that the clinical lab industry is working with payer data that is full of significant errors and inaccuracies.

Because of this fact, labs are at risk of submitting market price data to CMS that, when later checked by auditors incentivized to find errors, will prove to be full of inconsistencies and problems that can cause federal regulators to assess the onerous penalties that are part of the Protecting Access to Medicare Act (PAMA).

In this exclusive interview with THE DARK REPORT, Lâle White, Founder and CEO of **XIFIN, Inc.**, of San Diego, discusses why lab test billing data is rife with errors and inaccuracies. She offers insights and suggestions on how labs can identify and correct these errors before submitting their PAMA market price data to CMS.

The information which follows should be given high credibility, for a very good reason. XIFIN, which describes itself as a "health economics optimization platform and a connected health solution that facilitates connectivity and workflow automation for accessing and sharing clinical and financial diagnostic data," provides revenue cycle management 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 laboratories.

The common theme to White's insights and recommendations to labs as they gather the data they need to report to CMS is that the incoming data from payers is peppered with errors. This didn't matter in past years, as labs accepted that status quo, deposited the checks, and filed appeals on unpaid claims as a normal order of business.

But the stakes have changed. Now, if labs submit data to CMS that contains errors, inaccuracies, and other problems, downstream audits that uncover these problems can subject the lab to substantial penalties as defined in the PAMA statute. White has much to say about this situation and what steps labs should take to fix the problems, thus allowing them to have confidence that the information submitted to CMS can withstand rigorous audits in subsequent years.

Lab Claims Rife With Errors

"One major issue that all labs reporting price data need to address is the accuracy of the data they get from payers," stated White. "There is much inconsistency in this data and that is why it is important for labs to understand two things about payer data.

"We know that payers make a lot of mistakes. There's no question about that. That's the first problem labs face when compiling data on lab test payment," she said. "But the second problem is that even with electronic payments, there are many errors in the way claims are processed on both the lab side and the payer side.

"Both facts make it important for every lab to have people trained to recognize these errors," explained White. "These individuals must regularly audit the data to understand the specific types of errors that can occur. Errors occur in a wide variety of ways, and since XIFIN began work for its lab clients to prepare accurate data for submission under PAMA, we have identified some of the most common errors labs will experience.

"Here's just one example. Anytime there are multiple units of a single procedure code returned on an electronic remittance advice (ERA), there's a high potential error rate," White said. "There is a very high chance that the units aren't being reported properly on the ERA. Your lab could be submitting payment for five units and the payer could return the payment for only one unit, or the payer could pay for 10 units. We've seen big

errors, such as when one unit is billed and the ERA reports 1,000 units. This means that for a $17 test, the per-unit price is now $0.017.

Payer Recoupment

"Another common source of errors comes anytime a payer does either a recoupment or an adjustment. For recoupment and adjustments, there's usually a high error rate in the way payers report the allowable price," she said. "Sometimes they change the payments, but they don't change the allowable. Sometimes they restate the new allowable, rather than increasing, decreasing or reversing the original allowable.

"Under PAMA, labs are supposed to report the allowable," she explained. "This is significant because the OIG recommends auditing the data labs submit and it intends to use outside contractors for this purpose, much as Medicare currently uses contractors for its other program integrity and fraud audits.

"If Medicare uses outside contractors, those audit contractors will have a financial incentive to find errors, and there will be plenty of errors to find," White warned.

"That's why the issue of accuracy in determining allowables is critical for labs to understand," she added. "Electronic payment-posting systems that auto-allocate tend to have a higher percentage of errors at the individual-allocated CPT code level than those that require line item entry. That can be a big problem in the way labs report payments because then the lab would actually be reporting an overbooked allowable for some CPT codes and under-reporting others.

"Another important issue related to allowables is that in the ASC X-12 v.5010 specification there is a formula for calculating the allowable," she said. "Billing systems processing ERAs are supposed to calculate the allowable from the fields on the ERA instead of taking the allowable that the payer has pre-calculated and populated in the ERA.

"The calculation produces an accurate allowable, while payers that pre-populate do not always use the calculation and can make errors in the allowable reported on the ERA or EOB," noted White. "Further, many payers do not populate the allowable field in the ERA, so lab systems must use the 5010 calculation to determine allowables when posting these ERA, making it a more standard exercise if all ERA allowables are calculated in the same manner.

"Also, keep in mind that pre-populated allowables are net of the sequestration amount," she added. "Where sequestration is applicable, a lab would be under reporting allowables if it took the pre-populated allowable rather than performing the calculation and excluding sequestration.

"While these are some of the problems labs face when using electronic payment posting, manual payment posting is fraught with even more errors," she warned. "We've seen an error rate of almost 10% when a lab's clerical staff posts payments.

Interpreting A Complex ERA

"That's because the clerical staff is trying to interpret what's on the ERA and sometimes they pick up a miscalculated allowable," White cautioned. "In some cases where the EOB does not reflect exactly what was submitted and has been re-bundled by the payer, the clerical staff will try to interpret a complex ERA and cannot make decisions accurately.

"The way to address this problem is to make sure your lab keeps the source documents (the electronic remittance advice and explanation of benefits) so that you can verify the original tests and billing amount," she advised. "We recommend keeping the source documents because many labs post payments and then report price data for PAMA based on what they posted into the billing system.

"But what's on the ERA or EOB source documents and what's in the billing system may not match" she said. "Too often the lab doesn't have the source documents

XIFIN's Lessons Learned Following Two Years Of Gathering PAMA Lab Test Market Price Data

FOR TWO YEARS, A NUMBER OF COMPANIES that advise clinical laboratories on best business practices have been preparing to assist their client laboratories in how to report test-price data under the Protecting Access to Medicare Act.

One of those companies is XIFIN, a company in San Diego that specializes in revenue cycle management for clinical labs. Lâle White, XIFIN's President and CEO, has identified five of the most important lessons learned as a result of preparing for PAMA since 2014.

"The first, most obvious, lesson is that any lab that has a managed care contract where the lab's payment is based on getting a percentage of Medicare prices has a significant problem that can cause it to be paid less money by the payer," said White. "Since labs had plenty of notice before the data collection period, XIFIN advised clients to renegotiate contracts with this language before the PAMA collection period was finalized.

"However, if labs were unable to renegotiate prices in their managed care contracts prior to the current collection period," she stated, "it becomes even more important to do so before the new, lower Medicare prices go in effect in 2018 and before the next collections period. After those dates, labs with payer contracts that tie payment to a percent of Medicare prices will experience an unintended downward spiral on reimbursement.

"The second lesson is that all labs should ensure that they are billing the correct amount," stated White. "Labs will need to do the financial analysis necessary to understand that—where the billed amount equaled the allowed amount for a given payer plan—they were billing below the payer fee schedules and need to review their lab fees to make sure their billing price is adequate and represents appropriate market rates.

"The third lesson is to optimize your lab's electronic transactions and eliminate all manual payments," she explained. "Labs should absolutely make sure that they process every bill electronically. Payers are required to give you electronic transactions and labs should take steps to ensure that they are enrolled to receive those electronic transactions.

"The fourth lesson is to have a financial system that allows your lab team to audit your data," added White. "That includes retaining the source data so that when your lab does an audit, you can confirm the audit results against the source data in an automated fashion.

"The fifth lesson is to have a system that has financial, accounting, and referential integrity," she explained. "That's important because your lab will need to produce an accurate, auditable financial report to manage your business and to review and negotiate your payer contracts properly.

"Such a system should be able to create audit trails for reported data, as well as data that was not reported by unreportable category since penalties apply for unreported as well as misreported data," said White. "This will also help you document the accuracy of your lab's PAMA lab test market price data reporting whenever CMS has auditors visit your lab."

and payers generally do not store source documents for more than two weeks for providers. So if your lab doesn't retain them, you have no recourse.

"Labs need to retain these documents for audit purposes," she said. "When labs go back to the original ERA to recalculate payments, they often find errors. We recommend auditing your payments because even billing systems that process payments well will have some level of errors resulting from either payer mistakes or clerical overrides to the posting process.

"As we cross checked payments against original ERAs, we learned that having the source document made it much easier to identify potential errors," she explained. "It's the most reliable way to audit the data.

"As part of the auditing process, labs should be able to create a number of data integrity reports, including reports identifying different allowables from the same payer plan," she continued. "A single payer may have multiple payer plans with different allowables, making it imperative to be able to identify payments by payer plan.

Lab Paid Incorrectly By Payer

"Discrepancies in payments from the same plan may indicate that the lab has been incorrectly paid and that either an appeal or a redetermination request needs to be filed" she noted. "This determination is not possible if the billing system does not differentiate between payer plans and simply lumps them all together under a single payer category.

"In a case where all payers are lumped together, a lab will end up reporting all payments at the different levels without the ability to pull out payments for underpaid claims." White added. "Therefore it's critical that labs have a system that can identify claims by payer plan. If you have that, you can create reports that show different payments on the same CPT code by payer plan. That would allow you to spot payment errors easily.

"If your lab has a system that dumps out different payments for the same payer because you're not segregating by payer plan, and you've got 100 different payments for the same exact test from one payer, you would have no way to identify errors versus correct payments," she said. "So you would not know if you have a contract problem or the payer is paying incorrectly.

"Remember that labs need to submit PAMA data accurately and to do that you have to determine that you got paid correctly and in full," she cautioned. "If you can't verify that you got paid accurately, then your lab will be submitting data that may be understated.

"I say all this to point out that the integrity of your financial system will be a crucial differentiator between labs that can report test-price data accurately and those that cannot," she concluded. TDR

—Joseph Burns

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Managing Audit Risk From PAMA Market Data

"LABS NEED TO RECOGNIZE THE RISKS they face under the PAMA market price reporting requirement," noted Lâle White, Founder and CEO of XIFIN. "CMS plans to use outside auditors—much like it currently does with Medicare fraud audits—to visit labs and audit the data it used to produce its PAMA market price report.

"Labs should anticipate that when the auditor shows up, it is incentivized to find errors in the lab's reported data—and, for all the reasons explained earlier, there will be plenty of errors to find!" she warned.

White doesn't believe that the audit risk to labs submitting PAMA market data will be immediate. "CMS will have its own learning curve during year one," she pointed out. "And the agency will not have a basis for enforcing an audit on a retroactive data collection period during which time the lab could not have known the audit requirements.

"But eventually, auditors incentivized to find errors will fan out to audit labs," she said. "Given the high rate of errors baked into payers' remittance amounts and ERAs that we've already discussed, there will be plenty of errors for them to find.

"This is one reason why we recommend that every lab take the extra step of creating an actual report out of its financial system," continued White. "This allows you conduct your own internal audits of the data that your lab will report to CMS.

"This report is critical for another reason," she added. "This is the report your lab will use when someone arrives to audit your data. That report, along with the source data, must all be retained and must be easy to access for auditing purposes."

PAMA Reporting Update

Labs Discover Much Complexity In Their Lab Test Price Data

Reporting prices paid by payers for tests such as chemistry panels proving to be very complicated

DON'T EXPECT IT TO BE EASY AND STRAIGHTFORWARD when reporting the prices of chemistry panels as the final rule for lab test market price reporting rule requires. Instead, labs should expect the process to be complex and troublesome.

Also, labs should be concerned that Medicare officials have threatened to make deep cuts to chemistry panel prices if labs do not submit market price data as required.

These are two warnings from Julie Scott Allen, Senior Vice President of the **District Policy Group** in Washington, D.C. Allen represents the **National Independent Laboratory Association** (NILA) and she has first-hand knowledge of how the Protecting Access to Medicare Act of 2014 was written and became law.

Allen offered those two admonitions during a recent webinar about PAMA and the final rule for lab test market price reporting. Conceptually, it sounds simple to ask a clinical laboratory to report, for each test, what it was paid by each payer and what the volume was for each test.

However, what many independent labs are learning is that matching different payers' payments to one type of test can be a complex undertaking. The additional complexity inherent in paying for panels of tests or in receiving bundled payment for panels of patients makes the analysis much more challenging.

During a webinar for THE DARK REPORT about the Patient Access to Medicare Act, Allen, an expert in payment policy for clinical labs, explained some of the challenges labs face in reporting data on chemistry panel tests.

"There are variants in how payers pay for tests and this is true for chemistry panels," stated Allen. "There are sometimes inconsistent and different ways that health plans pay for tests—even across different plans from one payer.

"On top of that, there are inconsistencies in how laboratories manage these variants from payers," Allen cautioned. "The big concern, of course, is that laboratories will not be able to provide accurate data that the agency can use when assessing payments to different labs and from different payers.

"Automated test panels are relevant to the discussion because the federal **Centers for Medicare & Medicaid Services** has recently highlighted the issue of automated test panels as an area of focus and concern," Allen said. "Suddenly the agency has recognized an important fact: the way labs bill for lab testing does not always align with the information labs get back from payers.

"As a result, CMS is considering strategies to revise payments for tests when labs do not get data back from payers on specific tests, and therefore, cannot report data to the agency under PAMA," she explained. "Some NILA members have encountered problems when seeking to report on certain types of tests, such as automated muti-channel test panels (ATPs) or chemistry tests and other tests that payers bundle together.

CMS Seems Ready to Target Chem Panels for Deeper Cuts

Public statements by officials from the federal Centers for Medicare & Medicaid Services indicate an interest in making deep cuts to the reimbursement for certain highly-automated, high-volume chemistry tests.

"At a recent public meeting, the National Independent Laboratory Association asked CMS about these issues," stated Julie Scott Allen, Senior Vice President of the District Policy Group. "It became clear that the agency has an agenda regarding those chemistry tests that are most frequently billed under Medicare and it wants to find a way to make some drastic cuts in payments outside of the Protecting Access to Medicare Act of 2014.

"When looking for areas to cut payments, CMS has always had a focus on chemistry tests," she explained. "Now with PAMA, CMS reasons that if labs are paid for a bundle of chemistry tests, those rates are typically reduced—meaning labs don't get a full payment amount on each test in that bundle. But CMS also reasons that if it paid for each test separately, through an individual test submission, and reimburses on each test directly, then the agency pays more.

"Now the agency is asking if it's correct to pay one rate under a bundle and another rate if paying for each test separately," continued Allen. "We believe the agency intends to reduce lab payment rates, even beyond the cuts that are coming under PAMA—meaning CMS is now considering strategies to target chemistry tests directly. One strategy CMS could use is to remove the code that exists now and provide a temporary code, so that the agency then can cross-walk a new set of rates."

Allen is discussing an emerging issue that has not gained much attention within the clinical laboratory industry. Because these tests are among the highest volume assays reimbursed under Part B, CMS sees an opportunity to cut its costs further by enacting more restrictive guidelines, independent of how it uses market data to cut the prices for these tests.

"As labs know, there are variants in terms of how labs bill for some tests and what they're paid for those tests. There are also variants in how labs apply those payments in their systems," continued Allen. "Those variations create challenges associated with how your lab reports that information in line with the requirements of the PAMA Final Rule.

CMS Reporting Instructions

"Currently, there are 23 CPT codes for chemistry analytes that CMS pays as panels," she added. "CMS has argued that these are not specific CPT codes. In the subsequent material that CMS provided through guidance, the agency listed the HCPCS codes that labs need to report on. CMS is asking that labs break out the tests in some of the panels (hepatic and lipid) and report that information to the agency.

"This means that, for example, hepatic or lipid tests are reported individually to the agency," Allen explained. "Such a requirement is an obvious concern to NILA members because typically clinical labs do not bill for the individual tests in these chemistry panels.

"When your lab gets a payment, you certainly don't apply the payment to the individual tests," she said. "You apply payments as you receive them, whether they apply to a panel or not. You wouldn't split out the individual payments unless, of course, you were paid a clean claim on one of those individual tests. The problem for labs is that their systems are not designed to break out the individual tests in a given panel.

"There is also complexity in terms of how your lab bills payers, such as when you respond to a physician order and have several panels of tests and individual tests to perform for an individual patient," she added. "When you submit all that to a payer, many times the payer will submit a lump-sum payment back to your lab. When that happens, the lab applies those payments in the best way it can to

Complexity of Reporting Price Data Is Illustrated By CMS Instructions for Automated Chem Panels

DURING THE WEBINAR ON PAMA LAB TEST MARKET PRICE REPORTING, Julie Scott Allen, Senior Vice President of the District Policy Group, presented this slide illustrating guidance the federal Centers for Medicare & Medicaid Services issued on how labs should report price data for different chemistry panels and tests. It demonstrates why labs do not have the full guidance needed to have confidence that they are compliant with the reporting requirements.

The CMS Guidance listing all the reportable HCPCS codes instructs labs to "use another code" for the following:

- 80050 General Health Panel Includes:
  Comprehensive metabolic panel (80053)blood count, complete (CBC), automated and automated differential WBC count (85025, 85027, 85044)
  OR Blood count, complete (CBC), automated (85027)
  AND Appropriate manual differential WBC count (85007 or 85009)
  Thyroid Stimulating Hormone (TSH) (84443)

CMS' "Key to Medicare Status Indicators" instructs that when the list indicates "use other codes" do the following:

- "…use another comparable HCPCS code(s) payable under the CY 2016 CLFS. For example, HCPCS code 80050 (general health panel) is not payable under the CY 2016 CLFS. However, each component test included in the description for 80050 has a separate HCPCS code and is payable under the CLFS.

Left unanswered is how a lab would allocate payment amounts for each of these component HCPCS codes.

justify in their data systems that they have been paid for those tests.

"Labs apply the panel payments when paid on the panel and sometimes will prorate the data across other tests for which they billed because the payer didn't provide a specific payment rate for those tests," Allen said.

A Bundle of Questions

"In the final rule, CMS stated explicitly that, if a payer pays in a bundle in a way that's not tied to specific tests (meaning the payer is lumping together other test reimbursements into one payment in a way that makes it impossible to put a final payment rate on each test in that lump-sum payments), then your lab doesn't need to report that data," Allen said. "So, on the one hand, CMS is telling labs they don't have to report on a test-by-test basis when payers lump payments together. But, on the other hand, CMS is telling labs to break apart panels on a test-by-test basis to report it, despite the fact that it not always possible for a lab to do that.

Waiting For CMS To Answer

"We have asked CMS how to resolve these questions and are waiting for an answer," she stated. The experience of NILA member labs in collecting their market price data demonstrates that CMS faces its own challenge to analyze this data in an objective and fair manner and in a way that meets the language and intent of Congress as set out in the language of the PAMA law. TDR

—Joseph Burns

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OIG PAMA Update

OIG Comments on PAMA Plan and Exclusion of Many Labs

Inspector general says results will be skewed because CMS won't require data from certain labs

ON THE SUBJECT OF LAB TEST MARKET PRICE REPORTING as required under PAMA, many clinical laboratory executives, pathologists, and industry experts see deep flaws in the process the federal **Centers for Medicare & Medicaid Services** has established. Yet, CMS itself seems blind to these flaws.

Fortunately, the clinical lab executives are not alone. The **Office of the Inspector General** has issued a report calling attention to the flaws in how CMS will implement the section of the Protecting Access to Medicare Act (PAMA) that requires some labs to report market price data.

Unfortunately, the OIG does not comment on whether CMS officials are interpreting the PAMA statute as Congress intended. Many clinical laboratory professionals who have read the law believe that CMS is acting contrary to the language of the statute and the intent of Congress.

OIG Has Concerns

What OIG does explain is its concern about the way CMS has included certain classes of labs in the reporting mandate, while deliberately excluding a class of labs that are paid higher prices by private health insurers and would thus tend to move the weighted market price average calculated by CMS higher than agency officials would like.

Excluding this class of clinical laboratories from the pool of reported private payer price data will skew the results downward in a way that favors CMS, experts say. But that's just one important criticism.

Another criticism is that CMS will base its new payment rates for lab tests on data from only 5% of labs, again creating the probability of skewed market data. Those 5% of labs got 69% of Medicare payments for clinical laboratory tests in 2015, OIG said in its Data Brief, *Medicare Payments for Clinical Laboratory Tests in 2015: Year 2 of Baseline Data.*

Another problem the OIG cited is that about half of all independent labs will be required to report what private payers paid them for clinical laboratory tests, but only a small portion of physician office labs and only a few hospital labs are required to report such data.

"Thus, new payment data will be based primarily on private payer data from independent labs," the OIG reported.

Pathologists and lab administrators will find that the OIG report contains an impressive collection of data about what CMS pays under Medicare Part B for the clinical laboratory tests. The most interesting facts in the report involve how CMS' data-collection efforts under PAMA will skew the data. The report also makes the following key points:

1. The drug-testing business is booming: Medicare paid 19% more for toxicology tests in 2015 than it did in 2014.
2. Medicare payments for molecular pathology tests declined in 2015 by 44% over what CMS paid in 2014.

3. Although the total amount that CMS pays for lab tests is expected to drop overall, what CMS pays for some tests will rise in some parts of the country.
4. Certain aspects of the new payment system will require ongoing monitoring. *(See sidebar at right.)*

On the issue of how CMS' data-collection effort will skew the results, the OIG report is clear. Not only will CMS exclude about half of the nation's independent labs from reporting private payer price data, but the federal agency will also exclude most physician office labs and almost all hospital laboratories from reporting this data.

CMS Excludes Some Codes

What OIG calls "specific test procedure codes" also will be excluded. For example, those clinical labs required to submit price data to CMS do not need to report payments if a patient receives a clinical lab test and other medical services and a private health plan makes a single payment for the clinical laboratory test and the other services combined.

After listing all the reasons some data will be excluded from the data-collection process, and just before the conclusion to the report, the OIG adds this one ominous sentence without any more elaboration: "If the data that are not reported are systematically lower than the data that CMS will use to set new payment rates, the decreases in Medicare payment rates under the new payment system could be limited." This comment implies the opposite of the criticisms made by many in the clinical lab industry, that the exclusion of these labs from reporting means CMS will not get data from labs which are paid higher prices by private payers than the Medicare CLFS.

Another reason for the OIG's concern is that the new rates will be based on data paid to only 5% of labs, and these 5% of labs (12,547 labs) got 69% of CMS' CLFS payments last year. However, that leaves the labs that got 31% of Medicare Part B payments—and a comparable proportion of private payer lab test payments—excluded from the reporting requirements. The OIG acknowledged that fact, stating, "The other 95% of all labs (248,977 labs) got the remaining 31% of CMS' CLFS payments last year."

OIG Report: Monitoring Of PAMA Will Be Needed

FOR THE FEDERAL CENTERS FOR MEDICARE & MEDICAID SERVICES to get the most from its data-reporting initiative under PAMA, it will need to monitor three areas of the program closely, the Office of Inspector General said in a recent report.

The first area that will need monitoring involves what Medicare could pay for some lab tests by changing to a single national fee schedule, the report said. "Despite expectations that the new payment system will result in lower national rates for most tests, the new rates will nonetheless cause payments to increase in locations where Medicare currently pays rates that are lower than the new national rate for that test," the report explained. Also, median prices from private payers could be higher than what Medicare pays for some tests. If so, then the new Medicare payment rates for those tests will be higher in all areas, OIG said.

Second, under the new system, Medicare may pay more for those lab tests than it pays under "bundled" rates because it will no longer use those rates. For example, CMS limits current payments for some blood test profiles to the lower of the profile rate or the total of what it would pay for all the individual tests together. But under the new system, payment will be based on the weighted median of private payer rates.

Third, the OIG said that the lack of prices from private payers could limit the cuts CMS makes in lab test payments because certain labs will not be required to report their private payer data, including about half of independent labs, most physician office labs, and virtually all hospitals.

Although what CMS paid labs for tests overall in 2015 was mostly unchanged from what it paid in 2014, payments for pain management and toxicology tests increased considerably as more health insurers and physicians became concerned about drug abuse for therapeutic drugs, such as opiates, and other illicit drugs, such as methamphetamine.

For all drug tests, CMS paid 19% more in 2015 than it did the previous year. In 2014, CMS paid $910 million for these tests, and last year it paid $1.1 billion for those tests. For 18 different drug tests, CMS payments rose by at least $1 million each, the report said.

While payments by Medicare for drug tests rose, payments for molecular pathology tests declined by 44% in 2015 versus what CMS paid for these tests in 2014. Payments dropped from $466 million in 2014 to $259 million last year. This decrease was largely concentrated in payments for three tests (which the report did not name).

25 Lab Tests, 59% of Spend

Most of what CMS paid for Part B clinical lab testing went to just 25 lab tests. For these 25 tests, CMS paid a staggering $4.1 billion in 2015, slightly less than the $4.2 billion it paid for these tests in 2014. This $4.1 billion amount represents 59% of Medicare payments for all lab tests under the CLFS last year.

Lab administrators should note the importance of this fact: Changes in the Medicare payment rates for these 25 tests could have a significant effect on overall Medicare spending for Part B lab tests when the new payment system mandated by PAMA goes into effect in 2018.

Of the top 25 tests, CMS spent more than $200 million on each of the top eight in 2015. "Combined, these eight tests totaled $2.7 billion and accounted for about two-thirds of Medicare payments for the top 25 tests," the report said. "The remaining 17 tests totaled $1.4 billion and accounted for the remaining one-third of payments."

Some Medicare Test Prices Will Rise to Match NLA

WILL ALL LABS SEE MEDICARE PART B PRICE CUTS GOING FORWARD? At least in the short term, labs in some regions of the United States may actually see increases in prices CMS pays for some tests, the Office of Inspector General reported.

Payments will rise for those labs in areas that have lab test prices lower than that of the National Limitation Amount (NLA), the OIG said. The change to a single national rate will cause those test prices to increase in certain areas under the new payment system, OIG reported.

"For example, in 2015 Medicare paid $58.79 for a given drug test in Ohio, whereas in most areas of the country, it paid the NLA of $98.96," the report stated. "Under the new payment system, Medicare's rate for this test in 2018 can decrease by no more than 10% from the 2015 NLA of $98.96—i.e., to $89.06. When CMS implements the single fee schedule in 2018, Medicare will pay at least 51% more in Ohio for this drug test than it does under the 2015 rate in the current payment system (an increase from $58.79 to $89.06—potentially more)."

OIG reported that Medicare payments will rise in some areas for 22 of the top 25 lab tests. In 38 states, Medicare payment rates for at least one of the top 25 tests will increase. In some states, Medicare payment rates will rise for seven of the top 25 tests, ranging from 2 cents to $30.27 per test, the report said.

The OIG also pointed out that a small proportion of labs collected most of the payments for the top 25 clinical laboratory tests: Last year, only 1% of labs (292 out of 29,101 labs) got 54% of all Medicare Part B payments for the top 25 lab tests and each of these 1% of labs got an average of $7.6 million, the report said. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent weeks, two different lab transactions were announced. One involved a hospital laboratory management contract and the other was a potential merger of two anatomic pathology lab companies. The first announcement came on October 31, when **Lovelace Health System** of Albuquerque, New Mexico, released news that it entered into an "inpatient and outpatient laboratory management service" contract with **TriCore Reference Laboratories**, also based in Albuquerque. The new management services pact takes effect on February 21, 2017. This transaction is a setback for **Quest Diagnostics Incorporated**, which had held the hospital laboratory management services contract with Lovelace since 2012, when it acquired **SED Laboratories**, then owned by Lovelace. *(See TDR, January 9, 2012.)*

MORE ON: *Lab Deals*

The second transaction involves two pathology lab companies in Seattle. On November 4, **Pacific Institute of Pathology** (PSIP) and **CellNetix, Inc.**, disclosed a memorandum of understanding to explore a merger of their respective pathology businesses. Currently 17 pathologists work at PSIP while 50 pathologists are at CellNetix. If this merger takes place, it will represent further consolidation of private practice pathology groups in Washington state.

FDA TO DELAY LDT GUIDANCE

The recent election is apparently one reason that the **Food and Drug Administration** (FDA) will not release final guidance to regulate laboratory-developed tests (LDTs) until it has worked with the new Congress and other stakeholders on this issue. The agency issued this statement on November 18.

TRANSITIONS

- **Rosetta Genomics** of Philadelphia, Penna., named Mark R. Willig as Chief Commercial Officer. Willig has served at **CardioDx**, **Agendia**, **Exiqon**, **Thermo Fisher Scientific**, **Cleveland Heart Lab** (**Prognostix**), **Specialty Laboratories**, **Myriad Genetics**, and **Abbott Diagnostics**.
- David C. Weavil joined the board of directors of **Acuamark Diagnostics**, of New York, NY. Weavil is currently CEO of **Solstas Lab Partners, LLC**, a division of **Quest Diagnostics Incorporated**. He has held executive positions with **Specialty Laboratories**, **Unilab Inc.**, **Laboratory Corporation of America**, and **Roche Biomedical Laboratories**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...a new collaboration involving **IBM Watson Health** and other entities that want a solution to unstructured data. The focus will be on radiology images, but pathology data will also be studied as part of this effort.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 19, 2016.