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Special Expanded Issue!

CMS Publishes 2018 Lab Fees—We Analyze!

NEWS FLASH: AHA, AMA, Others Join Labs to Request CMS Administrator Suspend Medicare Lab Fee Cuts

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Attention All Lab Professionals: It's Time to Act!

AT THIS MOMENT, THE ENTIRE CLINICAL LABORATORY INDUSTRY STANDS on the precipice of the most financially disruptive development in the past three decades. On Jan. 1, the federal **Centers for Medicare and Medicaid Services** will implement deep cuts to the Medicare Part B Clinical Laboratory Fee Schedule.

There is additional unwelcome news. CMS now says that, in 2018, these fee cuts will total $670 million, an increase of almost 70% over the $400 million in fee cuts that CMS and the federal **Office of Inspector General** said to expect in September 2016.

With just 83 days remaining between now and Jan. 1, every lab manager and pathologist has a chance to influence government officials about the need to forestall the scheduled implementation of the Medicare Part B clinical laboratory test fee cuts.

THE DARK REPORT recommends that all clinical laboratory scientists and managers, along with their hospital and health system administrators, take two actions. The first action is, before the Oct. 23 deadline, they should submit comments to CMS that point out the problems with how CMS collected private health insurer lab test price data and describe the negative consequences that will occur because of the deep fee cuts CMS proposed. Those negative consequences are the financial erosion labs will experience and the reduction in testing services and staffing that will result. Labs also should describe the ways that any probable cutbacks will deprive Medicare beneficiaries in your communities of access to high quality lab testing services.

The second action is to notify each senator and representative about why they need to intervene with CMS and suspend the fee cuts to allow time for CMS and the lab industry to work through the problems. To make this easier, you can share the same comments you submitted to CMS. It is important that letters to elected officials describe how labs could be forced to close, which would eliminate well-paid jobs in their districts, and the disruption in access Medicare beneficiaries will experience in their districts.

As you submit comments and letters, you will have influential allies in this effort. Be sure to mention that major healthcare associations, including the **American Hospital Association** and the **American Medical Association,** are collaborating to fix the problems with the proposed lab fee schedule. TDR

AMA, AHA Join Labs to Request Delay, Fix

22 healthcare associations come together, ask CMS to delay Medicare Part B lab fee cuts

CEO SUMMARY: In what may be a first for the clinical lab industry, the American Medical Association and the American Hospital Association joined with 20 other healthcare associations to ask CMS Administrator Seema Verma to address the problems with the CMS proposal involving Medicare Part B fees. Specifically, the associations asked Verma to delay implementing the Medicare Part B Clinical Laboratory Fee Schedule, which CMS plans to implement Jan. 1, 2018.

IN A SIGNIFICANT EVENT FOR THE CLINICAL laboratory industry, 22 healthcare associations issued an important warning to the federal **Centers for Medicare and Medicaid Services** that the fee cuts proposed for implementation on Jan. 1 will disrupt patient care by restricting Medicare beneficiaries' access to clinical lab tests.

In a letter sent Oct. 6 to CMS Administrator Seema Verma, the **American Medical Association** and the **American Hospital Association** joined 20 other lab and healthcare associations asking Verma to correct numerous substantial problems with the market study that CMS conducted into private payer lab test prices.

The decision of the AMA and the AHA to join with other healthcare associations on an issue involving Medicare regulation of Part B clinical laboratory testing is without precedent in the past 25 years. It is a milestone event and a powerful statement to Medicare officials that physicians and hospitals recognize why the Medicare Part B clinical lab test fee cuts to be implemented Jan. 1 will interfere with the provision of healthcare in hospitals and physician clinics.

"We urge the Centers for Medicare and Medicaid Services to take immediate action to address the significantly deficient data collection process used to establish new clinical laboratory payment rates, which resulted in unreliable and unsustainable rates that fall short of Congress' goal of establishing a market-based system," the associations wrote in the letter. "We urge CMS to suspend

implementation of the draft payment rates until these deficiencies can be addressed."

Serious Deficiencies Cited

Among the problems the association cited was a flawed process to collect market-based price data on clinical laboratory tests. "The payment data collected by CMS for tests on the Clinical Laboratory Fee Schedule (CLFS) does not result in an accurate weighted median of private payer rates for most tests on the CLFS, as required by the Protecting Access to Medicare Act (PAMA). We believe the data used to set the proposed rates would not stand up to statistical validity review," the letter stated.

"The data sources used to determine the preliminary rates do not appear to reflect the various market segments, which CMS has the authority to consider in order to validate the data submitted," the associations wrote. "It is also clear from our review that the overly burdensome regulatory requirements resulted in the submission of inaccurate and incomplete laboratory payment data that is not reliable for use in its current form."

Many times over the past two years, the lab and healthcare associations expressed concerns to CMS, HHS, and Congress about the final PAMA regulation, including the serious limitations in lab test data collection and the "skewed" proposal that resulted, the letter stated.

Significant Harm to Patients

"The proposed CLFS rates will now result in significant harm to the nation's surveillance network for emergent public health issues, job losses across the United States, and significantly reduced access to clinical laboratory testing for Medicare beneficiaries, particularly those in rural geographic and post-acute care settings," the letter stated.

The associations asked Verma to prevent the disruption in care and the financial turmoil that will befall independent labs, hospitals providing lab testing, and physician office labs.

"We stand together in our position that before CMS proceeds with making any revisions to the CLFS, the agency must first:

- "Modify the PAMA regulation to address data integrity concerns and market exclusion through a statistically valid process that is least burdensome on providers;
- "Ensure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market (national independent, community and rural independent, hospital outreach, and physician office laboratories); and,
- "Provide a transparent process to allow for the validation of the data collected by CMS."

Fast Action Requested

The associations' comments are consistent with those of the clinical laboratory profession in its comments to HHS, CMS, and Congress about the final market price reporting rule that CMS issued last year. "In light of these significant concerns, we call on CMS to take swift action to engage in a constructive dialogue with stakeholders on ways to improve the PAMA data process and calculation, and establish a clear path forward for the clinical laboratory community and the Medicare beneficiaries who rely on its services. We urge CMS to suspend implementation of the revised payment rates while this path forward is determined."

It is noteworthy that the coalition of associations signing the letter represent most hospitals, physicians, and clinical laboratories. In the past 25 years, this is a coalition without precedent in the clinical lab industry.

Medicare officials appear to have designed a flawed and biased study of the

market prices that private health insurers pay to clinical labs. They did so by excluding from reporting those hospital labs, physician office labs, and community labs that insurers value and thus reward with higher fees for lab tests.

Insurers do so because they recognize that these labs have higher costs and serve communities and rural areas that would otherwise not have access to lab services.

In addition, Medicare used a weighted median—not a weighted average—when producing the lab test price data. This factor biased the results of the analysis still further.

Tough Fight Ahead?

Certainly the AMA, AHA, and the lab associations united in this coalition have a tough fight to persuade government officials to suspend implementation and fix the deficiencies in the final market price reporting rule and in the CLFS for 2018.

At the same time, it would be foolish of Congress, HHS, and CMS to not recognize this fact: Although clinical lab testing represents only about 3% of what the government spends on healthcare, lab test data makes up 70% or more of a patient's permanent health record.

What's more, lab tests play a role in more than half of all diagnoses, in decisions on how to treat, and in monitoring patient care. Thus, if Medicare officials deprive the nation's labs of adequate funds, they could see almost every aspect of medical care deteriorate or suffer as a consequence.

Flawed, Biased Price Study

The letter sent to CMS is just the most recent development in this important story. Following the release of the proposed Medicare Part B Clinical Laboratory Fee Schedule by CMS on Sept. 22, many lab associations and experts have issued public comments. This special, expanded issue of THE DARK REPORT provides detailed coverage and analysis of these developments. TDR

—Robert L. Michel

Hospitals, Physicians, Labs Unite in Response to CMS

THESE ARE THE 22 HEALTHCARE ASSOCIATIONS that signed the Oct. 6 letter to the administrator of the Centers for Medicare and Medicaid Services:

- AdvaMedDx
- American Academy of Family Physicians
- American Association for Clinical Chemistry
- American Association of Bioanalysts
- American Clinical Laboratory Association
- American Hospital Association
- American Medical Association
- American Medical Technologists
- American Society for Clinical Laboratory Science
- American Society for Clinical Pathology
- American Society for Microbiology
- Association of American Medical Colleges
- Association of Public Health Laboratories
- Clinical Laboratory Management Association
- COLA
- College of American Pathologists
- Medical Group Management Association
- National Association for the Support of Long Term Care
- National Independent Laboratory Association
- New York State Clinical Laboratory Association
- New York State Society of Pathologists
- Point of Care Testing Association

Medicare Update

For Top 20 Tests, CMS to Cut Payment by 28% in 2018-2020

Medicare officials move one step closer to destroying beneficiary access to lab tests

On Sept. 22, Medicare officials released the draft prices for the 2018 Clinical Laboratory Fee Schedule. The bad news for the lab industry is that the fee cuts are deeper than the federal **Centers for Medicare and Medicaid Services** had predicted earlier.

The price cuts to clinical laboratory test fees will total $670 million in 2018. This amount is almost 70% greater than the $400 million in fee cuts the federal agency had predicted in statements it published last year.

Moreover, that $400-million figure was almost double what the **Office of Management and Budget** scored for projected savings when Congress passed the Protecting Access to Medicare Act (PAMA) in 2014. OMB had predicted savings of $2.4 billion over 10 years, or $240 million annually.

For community lab companies and most hospital labs, the financial erosion from the proposed 2018 Medicare Part B fee schedule will be particularly difficult because of another development: CMS will impose even deeper fee cuts than expected on the 20 clinical lab tests that labs run most frequently, and which make up the largest volume of lab tests that the nation's smaller laboratory companies and hospitals perform.

In an analysis of the draft fee schedule, **XIFIN,** a healthcare IT company serving clinical labs, shows that CMS will cut the fees of the 20 highest volume tests by an average of 28% by the end of 2020 (with a maximum cut of 10% for each test during each of the three years 2018, 2019, and 2020). That exposes community laboratories and hospital labs to fee cuts of almost one-third for the 20 high-volume, automated tests that make up the highest proportion of their total test volume.

The comment period on the proposed 2018 Part B Clinical Laboratory Fee Schedule will end Oct. 23. The Dark Report recommends that all pathologists and clinical laboratory professionals submit comments to CMS. As documented in previous issues of The Dark Report, the process CMS is using to collect and analyze private payer lab test price data has fundamental flaws.

As lab industry experts have explained, CMS is using a biased process to set fees in a manner that—if implemented as written in the proposed fee schedule—will be destructive to the healthcare system in two ways.

Many Labs At Risk

First, the pending Part B lab fee cuts will undermine the financial stability of three types of laboratories that operate on the razor's edge of profitability. A substantial reduction in what Medicare pays these labs for the 20 high-volume tests would tip these labs into the red. Finding themselves unable to cover operating costs, these labs could go out of business, either by selling, closing their doors, or liquidating their labs through bankruptcy.

(Story continues on page 8.)

Michigan Hospital Lab Leaders Express Concern Over Bias, Flaws in Proposal

IN MICHIGAN, THE LEADERS OF TWO REGIONAL HOSPITAL LABORATORY NETWORKS say their members are worried about the cuts in lab test fees that CMS proposed Sept. 22.

At **Joint Venture Hospital Laboratory Network** (JVHL), CEO John Kolozsvary said Michigan's hospitals serve 70% of the office-based physicians in the state with outreach lab testing services. Included among these hospitals are the 120 JVLH member laboratory facilities.

CMS Misses Key Price Data

"Since our network, plus the outreach programs of another 25 or 30 hospitals, holds a significant share of outreach lab testing in Michigan, how can CMS conduct an accurate, representative market study of what private insurers pay for lab tests in Michigan if it doesn't collect data on what private payers reimburse hospital lab outreach programs in Michigan?" he asked.

"We've said all along that any reductions to the CLFS—without sampling the entire national lab market—could create a fee schedule with rates that are not sustainable to the small market providers, such as rural hospitals," Kolozsvary added. "In certain instances, this will cause rural hospitals to significantly scale back—if not completely eliminate—their outreach laboratory programs simply because they can no longer afford the cost to provide those services.

"The end result from CMS' 2018 Part B clinical lab test fee cuts will be to create barriers to access for Medicare beneficiaries who rely on those hospitals as their sole source of testing," he added. "Another consequence will be on local economies in Michigan's smaller communities as these hospital laboratory workforces are potentially reduced or eliminated. Further, these medical technologists have well-paid jobs that are not easily replaced."

The second lab organization is **Great Lakes Laboratory Network**, (GLLN) which includes 40 hospital labs in Michigan and Northwest Indiana and collaborates with JVHL. After an initial review of the fees CMS published in the proposed 2018 CLFS, many of GLLN's hospitals lacked the resources to analyze the financial effects the proposal would have on their labs and parent hospitals, Executive Director Mike Hiltunen told THE DARK REPORT.

"The majority of our network members are smaller community hospitals," he said. "The consensus is that their finance departments are not equipped to perform a detailed analysis of the proposed PAMA rates, especially before the CMS comment period ends on Oct. 23.

"Following a cursory review of the proposed rates, many GLLN hospital members said they were concerned about the drastic decrease in revenue their outreach programs will sustain," Hiltunen noted.

Patients Will Lose Access

Hiltunen also discussed the potential loss of patient access. "In Michigan and Northern Indiana, many of these laboratories serve a large geographic area with a lower population base and don't have a Quest or a LabCorp drawsite in their catchment area," he explained. "Our hospital members are concerned that they may have to close some of their distant patient service centers or scale back their lab outreach operations due to the loss of revenue. The fear is they may no longer be able to provide lab tests to their patients in the communities they serve."

Kolozsvary's comments about the fact that hospital laboratories in Michigan hold a 70% market share of outreach lab testing for office-based physicians in the state, yet were not required to submit private payer market price data to CMS, demonstrates the truth to the criticism voiced by many that the market price study performed by CMS failed to conform to the PAMA law.

The three classes of labs are: community laboratory companies, smaller and rural hospitals, and physician office labs (POLs). Typically, these labs serve towns and rural areas and are the sole providers of lab tests in these regions.

The second destructive consequence of the CMS fee cuts will be the loss of access among Medicare beneficiaries in rural areas, small towns, and on the suburban fringes of some metropolitan areas. This outcome would be contrary to the PAMA statute and the intent of Congress.

Furthermore, once the officials at CMS enact these fee cuts, they are going to discover a well-established fact of the clinical laboratory business: Once a laboratory shuts down, it is nearly impossible to replace it. The capital costs to develop and equip a medical laboratory are significant and finding and recruiting the medical technologists and clinical chemists needed to operate today's high-complexity clinical laboratories is challenging.

Patients Lose Access

The lab industry has watched this process play out over 25 years. When a national lab acquires a strong local lab company, the core lab often is closed, the med techs laid off, many specimen collection sites are closed, and the specimens are then sent to one of the acquiring lab's huge regional facilities. Physicians and patients lose access to local, high quality clinical laboratory testing and it takes longer for physicians to get their lab test results.

It's not clear if CMS knew about these market dynamics when it wrote the final rule to implement the PAMA private payer lab test market price reporting requirement on June 23, 2016.

Yet, when discussing these issues with CMS officials, representatives of the clinical lab industry identified four areas of concern that they related to officials at CMS and at the federal **Department of Health and Human Services**, as well as to members of Congress.

First, CMS is failing to implement the PAMA law as written and as Congress intended.

Second, the process CMS established to collect and analyze private payer market price data was inherently biased. By design, CMS excluded from reporting several categories of clinical laboratories to which private payers pay higher fees than Medicare pays because the insurers recognize that these labs have higher costs, in part because they serve small communities and rural areas that the nation's big commercial labs do not serve.

Two Additional Forms of Bias

Third, under PAMA, CMS was required to use weighted-median costs (and not the average or weighted-average costs) when analyzing the private payer price data. The weighted-median costs introduced another source of bias in the agency's analysis of how much private health insurers pay clinical laboratories for clinical laboratory tests.

The fourth criticism is based on the information CMS released in the proposed fee schedule. CMS reported that only 1,942 labs (or 0.07% of the nation's total number of labs) submitted private payer price data. Consider that the HHS **Office of Inspector General** reported that 61,040 labs received Medicare payments in 2015. In its final rule, CMS identified 12,547 labs that were required to report. But it received data from only 1,942 labs.

A fifth criticism is similar in that it comes from the proposed Clinical Laboratory Fee Schedule and is equally as troubling. The number of labs that actually reported data to CMS is substantially lower than what the agency required to report. That means the actual number of labs, and the volume of price data CMS received, is substantially lower than what it planned to use. This fact means the data CMS is using to establish fees does not represent the full marketplace that CMS is required to survey. TDR

—Robert L. Michel

XIFIN CEO White Analyzes Medicare 2018 Fee Cuts

As most experts predicted, CMS will cut lab test prices deep enough to hurt many labs

CEO SUMMARY: If the draft lab rates that CMS published Sept. 22 for the Clinical Laboratory Fee Schedule for 2018 go into effect Jan. 1 as proposed, then clinical labs will see a cut of 28% in what they get paid for the top 20 most common tests, according to a recent analysis. The rates that CMS proposed were set under the PAMA law's requirements that CMS collect data on what private health insurers pay labs for clinical laboratory tests and an analysis by Xifin shows that the market-price data collection effort was deeply flawed.

EARLIER THIS YEAR, EXPERTS PREDICTED that what the federal **Centers for Medicare and Medicaid Services** would pay clinical labs beginning Jan. 1 would be about 24% lower for the top 20 most common tests compared with what CMS is paying for those tests this year. That prediction was wrong. What CMS will pay will be about 28% less than what CMS is paying this year, according to an analysis from **XIFIN Inc.**, a healthcare IT company serving clinical labs.

Xifin reviewed the draft laboratory rates that CMS published Sept. 22 for the 2018 Clinical Laboratory Fee Schedule, which will go into effect Jan. 1. The rates that CMS proposed were set under the requirements in the Protecting Access to Medicare Act (PAMA) of 2014.

The law required CMS to collect data on what health insurers pay labs for clinical laboratory tests. That market-price data collection effort was deeply flawed, said Xifin CEO Lâle White. As a result of the flaws in the collection effort, CMS is proposing much lower than expected payment rates beginning next year. Labs can comment on the proposal until Oct. 23.

The methodology CMS used to propose these rates was a deliberate manipulation, according to White and other experts who have reviewed the methods CMS used and the proposed rates for 2018.

CMS Happy With Outcome

"What CMS did to come up with these low rates is manipulative," she said. "CMS officials skewed the results toward the national labs because they wanted to get the pricing of the big labs. And that's exactly what they got. They're very happy with the outcome—which is three times what they projected the cuts would be. That should have been a red flag to them that the data was very flawed.

"We expected to see declines in the rates for the most common tests because—quite frankly—the government manipulated the data set to produce these results," White charged. "And from that manipulation, they got what they wanted, which is that data from the big labs drove the pricing.

"That leaves the rural and community labs, as well as community hospital labs, in the worst shape because those labs

don't have a mix of esoteric tests," White explained. "Those labs run the most commonly-ordered tests—the high volume tests. Thus, they will get the full brunt of the Medicare lab test fee cuts.

"At least the larger labs, because they perform genetic and esoteric tests, will get some benefit from the fact that, under the new Part B fee schedule, many genetic and esoteric tests pay better," she added.

Nursing Home Labs at Risk

"The other segment that will suffer are the community labs and hospital labs that service nursing homes," she said. "These price cuts will put them out of business because they don't have the margins to sustain themselves.

"Serving nursing homes is some of the highest cost lab work that any labs do in this business," noted White. "It is routine clinical work, but there is so much service involved with that work that it's just not cost-effective. Essentially those labs will all be put out of business.

"These are all the reasons we are concerned about the process that CMS used," she explained. "Chief among the concerns we have is that preliminary rate data is not market-based because it excludes rate information from the majority of acute care hospitals and community-based laboratories throughout the United States.

"The preliminary rate calculations that CMS issued on Sept. 22 are flawed due to the way the exercise was designed," stated White. "CMS did not conduct a true and accurate market study, nor was there appropriate industry participation in the rate setting.

"CMS required only 34% of the lab market to report and only a very small number of those labs actually submitted private payer price data," she continued. "For these reasons, the nation's two largest labs represent about 80% of the volume that CMS used to calculate the rates."

Another factor that biased CMS' market analysis is that the agency used a weighted median cost, as PAMA required, instead of a weighted average cost. This skewed the true market price downward, just as Xifin and other experts in lab test market pricing had predicted after CMS issued its draft rule in 2015 that laid out how it would conduct the private payer market study and cut what it pays labs.

"Xifin's previous detailed analysis of the financial impact of PAMA data predicted a 24% decrease for the top 20 tests using a weighted average, and noted that use of a weighted median would produce an even greater decrease," White said in a statement. "Our analysis of the rates CMS published Sept. 22 reveal a 28% decrease for those top tests. *[The 28% cuts for the 20 high volume tests will happen at 10% price cut per test per year during 2018, 2019, and 2020—Editor.]*

"While we were on the mark with our prediction, Xifin's estimate is slightly lower due to CMS' use of a weighted median instead of a weighted average to calculate rates, which skew the numbers marginally downward for the highest volume tests and could grossly alter the numbers for lower volume tests," she noted.

Many Labs Excluded

In particular, White was concerned that, although the PAMA statute mandates a true market study to establish accurate, market-based lab test prices, the market study that CMS conducted does not truly reflect what health insurers pay for clinical lab tests. That's because not all labs were able to submit data to CMS for its rate calculations, explained White.

"By deliberately limiting the number of, and type of labs, required to report private payer price data, CMS introduced clear bias into how it would analyze the data," White observed. "The less data collected from labs, the more the use of a weighted median skews the results toward lower pricing.

"It appears that the methodology used by CMS was purposely crafted to maximize price-cutting rather than ensuring that the CLFS reflects private payer market rates," she commented.

Prediction Was Accurate

In an interview with THE DARK REPORT, White said, "The entire clinical lab industry saw this coming. The only part of this that wasn't expected was that the decrease in what CMS proposes to pay would be 28% lower for the top 20 most common tests. Xifin estimated a 24% decrease in prices and the new rate of 28% is 4% points higher," she pointed out.

"Our analysis was correct, however, in that we showed how a weighted median would probably bring down the lab test prices more than a weighted average would," noted White. "We were correct about that."

Regarding other categories of lab tests, such as molecular, genetic, and toxicology assays, White said the proposed prices for 2018 represent a mix of good news and bad news.

"Xifin's analysis of the rates CMS proposed on Sept. 22 showed that molecular tests would not be affected as adversely as the top 20 clinical lab tests were," explained White. "This is true, in part, because the molecular test market is a better area for this market-price exercise. The proprietary tests for molecular labs did very well."

All Labs To Suffer Next Year

In the coming year, all labs will suffer financially, White said. This will be particularly true for smaller labs, community hospital labs, and labs in rural areas. *(See article on pages 15-16.)*

Turning to the subject of how clinical laboratories can challenge the proposed rates, White's advice is to understand and explain the methodology CMS used to develop its pricing. "First, the imposition of a retrospective data collection process through rulemaking has compromised the integrity of the data submitted," she said. "This represents an area in which the

(Story continues on page 14.)

Molecular and Genetic Tests Get More Favorable Pricing

THERE IS BETTER NEWS FOR LABS PERFORMING molecular and genetic tests. "We expected some increases in molecular test rates, and that's what CMS has proposed," stated Xifin CEO Lâle White.

"There was also no meaningful decline in what CMS proposed to pay for pharmacogenetic and CYP tests, which was great," she added. "The only problem is that many of those tests aren't covered.

"For toxicology, there is some good news and some bad news," stated White. "In general, the toxicology codes did fairly well. But the big hit for tox labs will come with the G-code tests. The lower prices CMS proposes to pay for many tests with G-codes is the bad news for tox labs.

"Again, the reason for this hit is that few labs contributed to the data that CMS used to set these rates," she explained. "And, during the data-collection period, many private payers were still paying the original 8xxxx codes because the G codes were not yet widely adopted, so there was little G code volume available.

"Essentially, CMS set rates that default down to what the largest pain management lab companies are getting paid for these G-code tests," White added. "For the first G-codes, meaning 1 to 7, CMS could be paying 60% less than what they pay now.

"For example, G0480, 0481, 0482, and 0483 all decline a lot. G0483 is the least used and that one has a 24% decline," she said. "The most used is G0480 and that one has a 59.2% decline. I don't think prices at that level will be sustainable.

"Similarly, CMS' proposed prices for HPV tests and Pap smears will be a problem for pathologists and pathology labs," White stated.

CMS to Cut Prices 28% for 20 High Volume Tests

First Look at 2018 Medicare Part B Clinical Laboratory Test Fees, Published by CMS on Sept. 22; Comment Period Ends Oct. 23

Data shown below was compiled by XIFIN, Inc., of San Diego and shows the top 20 high volume tests reimbursed by Medicare in 2016. XIFIN determined that the fee cuts for these top 20 tests averaged 28%. CMS will cut the price of individual lab tests by 10% each year in 2018, 2019, and 2020. For the years 2021, 2022, and 2023, CMS will conduct a new private payer market price study that will be used as the basis for setting rates for that three-year period.

When the Protecting Access to Medicare Act was passed in 2014, the Office of Management and Budget scored the savings from the private payer market price study to be $2.4 billion over 10 years. In 2016, when CMS issued the final rule for the private payer market price study, it estimated that the fee cuts would total $5.7 billion, more than double the amount of budget cuts scored by OMB in 2014. On Sept. 22, CMS stated that the lab price cuts would total $670 million just in 2018. Combined with fee cuts in future years, that projects to $7 billion in fee cuts over 10 years.

How many labs reported to CMS?

According to the OIG in 2015, about 5% of U.S. labs would be required to report, or 12,427 labs.

Category	Total labs	No. Labs required to report	No. Labs reported
Independent Labs	3,211	1,398	658
POLs	235,928	11,149	1,106
Hospital Labs	6,994	0	21

CMS said that only 0.7% of U.S labs submitted data. It acknowledged that its market study excluded 99.3% of all labs in the U.S.

Source: Centers for Medicare and Medicaid Services

Why use of weighted median biased the CMS analysis of price data

CMS reported the high-to-low price ranges for the first 30 codes on the CLFS, with samples shown below. These prices are clearly erroneous, yet there is no evidence that CMS officials went back to the submitting labs to request corrected and accurate pricing.

	Code	Test	lowest	highest
a)	80048	(metabolic panel)	$.01	$27,356.01
b)	80050	(general health)	$.01	$92,702.94
c)	80053	(comp. metabolic)	$.01	$65,081.33
d)	80061	(lipid panel)	$.01	$94,234.12
e)	80069	(renal function)	$.01	$51,061.49
f)	80081	(obstetric)	$.88	$69,711.77

ANALYSIS OF TOP 20 CODES

HCPCS Code	HCPCS Code Description	2017 NLA	Weighted Median	% Change Wtd Med vs. 2017 NLA	2018 Pmt w/Cap	% Change '18 Cap vs. 2017 NLA	2019 Pmt w/Cap	% Change '19 Cap vs. 2017 NLA	2020 Pmt w/Cap	% Change '20 Cap vs. 2017 NLA	XIFIN 5/17 Projection	% Change 'XIFIN 5/17 Proj vs. 2017 NLA
80048	Metabolic panel total ca	$11.60	$8.06	-30.5%	$10.44	-10.0%	$9.40	-19.0%	$8.46	-27.1%	$10.26	-11.6%
80053	Comprehen metabolic panel	$14.49	$9.08	-37.3%	$13.04	-10.0%	$11.74	-19.0%	$10.56	-27.1%	$10.28	-29.1%
80061	Lipid panel**	$11.73	$11.23	-4.3%	$11.23	-4.3%	$11.23	-4.3%	$11.23	-4.3%	$14.22	21.2%
82306	Vitamin d 25 hydroxy	$40.61	$26.37	-35.1%	$36.55	-10.0%	$32.89	-19.0%	$29.60	-27.1%	$27.62	-32.0%
82542	Col chromotography qual/quan	$24.77	$24.09	-2.7%	$24.09	-2.7%	$24.09	-2.7%	$24.09	-2.7%	$18.73	-24.4%
82607	Vitamin b-12	$20.68	$13.43	-35.1%	$18.61	-10.0%	$16.75	-19.0%	$15.08	-27.1%	$13.98	-32.4%
82728	Assay of ferritin	$18.70	$12.13	-35.1%	$16.83	-10.0%	$15.15	-19.0%	$13.63	-27.1%	$12.94	-30.8%
82746	Assay of folic acid serum	$20.17	$12.88	-36.1%	$18.15	-10.0%	$16.34	-19.0%	$14.70	-27.1%	$13.55	-32.8%
83036	Glycosylated hemoglobin test	$13.32	$8.50	-36.2%	$11.99	-10.0%	$10.79	-19.0%	$9.71	-27.1%	$10.63	-20.2%
83880	Assay of natriuretic peptide	$46.56	$39.26	-15.7%	$41.90	-10.0%	$39.26	-15.7%	$39.26	-15.7%	$38.26	-17.8%
83970	Assay of parathormone	$56.62	$36.76	-35.1%	$50.96	-10.0%	$45.86	-19.0%	$41.28	-27.1%	$41.35	-27.0%
84153	Assay of psa total	$25.23	$16.38	-35.1%	$22.71	-10.0%	$20.44	-19.0%	$18.39	-27.1%	$17.84	-29.3%
84439	Assay of free thyroxine	$12.37	$8.03	-35.1%	$11.13	-10.0%	$10.02	-19.0%	$9.02	-27.1%	$9.03	-27.0%
84443	Assay thyroid stim hormone	$23.05	$14.87	-35.5%	$20.75	-10.0%	$18.67	-19.0%	$16.80	-27.1%	$16.92	-26.6%
85025	Complete cbc w/auto diff wbc	$10.66	$6.88	-35.5%	$9.59	-10.0%	$8.63	-19.0%	$7.77	-27.1%	$7.33	-31.2%
85027	Complete cbc automated	$8.87	$5.91	-33.4%	$7.98	-10.0%	$7.18	-19.0%	$6.47	-27.1%	$6.47	-27.1%
85610	Prothrombin time	$5.39	$4.29	-20.4%	$4.85	-10.0%	$4.37	-19.0%	$4.29	-20.4%	$4.18	-22.4%
87086	Urine culture/colony count	$11.07	$7.19	-35.0%	$9.96	-10.0%	$8.97	-19.0%	$8.07	-27.1%	$7.59	-31.4%
87491	Chylmd trach dna amp probe	$48.14	$31.26	-35.1%	$43.33	-10.0%	$38.99	-19.0%	$35.09	-27.1%	$32.10	-33.3%
88175	Cytopath c/v auto fluid redo	$36.34	$26.61	-26.8%	$32.71	-10.0%	$29.44	-19.0%	$26.49	-27.1%	$29.67	-18.4%
		$460.37	**$323.21**	**-29.8%**	**$416.80**	**-9.5%**	**$380.20**	**-17.4%**	**$350.00**	**-24.0%**	**$342.95**	**-25.5%**

*** 80061, No NLA. Using a calculated reimbursement average. Analysis provided by XIFIN, Inc.*

(Story continued from page 11.)
clinical lab industry should challenge the agency's construct of an implementation method that resulted in the reporting of incomplete and inaccurate data that does not reflect market pricing.

Second Objection

"My second big objection involves how the analysis was statutorily constructed for use of the weighted median versus the weighted average," she said. "That was a huge mistake. From what I've heard, some of the lab associations will challenge the rates on those grounds, or at least request a delay on implementation of the new rates until a thorough review can be done of the methodology CMS used to collect the rate-payment data."

All lab professionals should send comments to CMS before the comment period closes on Oct. 23. "These comments should center on how the whole market-based price collection process was flawed because CMS did not collect data from the entire market," White said. "For example, in the proposed CLFS, CMS explains that it collected data from the hospital market. But it turns out that only 21 hospitals submitted private payer price data.

Small Sample Size Problems

"That's all the data CMS had, and it bases its analysis on 21 hospitals, which is a ridiculously small sample size," she explained. "The reason only 21 hospitals submitted data is because most hospitals do not have their own NPI numbers. It is a point of interest that those are the hospitals that get better pricing than the hospitals that do have their own NPI numbers.

"There's a reason for that," White added. "Hospitals that have their NPI numbers operate more like independent labs and payers contract with them like independent labs using CPT-code fee schedules.

"While the pricing is higher—definitely much higher than what independent labs get—it's not as high as the rates those hospital labs get that did not submit data," she explained.

"The hospital labs that did not submit usually piggyback off of the hospital's primary contract with a health insurer," she explained. "Those hospital labs generally are paid as a percentage of billed charges rather than at the CPT-code level. So they basically control their pricing, which means they are the only subset in the lab business besides molecular testing labs that actually have market-based pricing.

"This is an important point and it's one that CMS either deliberately overlooked or didn't understand," White said. "Hospital labs that bill under the hospital NPI have market-based pricing because they're getting a percentage of what they bill from private payers instead of the CPT-code fee schedules that most hospital labs get paid.

Data From 21 Hospitals

"Remember, there are thousands of hospital labs and the number keeps changing depending on the survey being used," she added. "So, we don't have a perfect number on how many hospital labs there are. But regardless, data from 21 hospitals is a very small sample size.

"CMS seems to have ignored the fact that there are almost 5,000 hospitals in the United States and about 80% of all hospital labs have a lab outreach business," she added. "Some of these hospital lab outreach programs are small, but there are a significant number that hold major market shares in their regions. CMS had private payer price data submitted from just 21 hospitals out of thousands. That's just not going to be an accurate reflection of the entire market and the lab test prices paid by private health insurers." TDR

—Joseph Burns

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Medicare Update

Labs Serving Nursing Homes, Rural Areas to Suffer Most

CLINICAL LABORATORIES WITH A HIGH percentage of Medicare Part B lab test reimbursement are expected to suffer the most under the Part B Clinical Laboratory Fee Schedule (CLFS) cuts that the **Centers for Medicare and Medicaid Services** proposed Sept. 22.

With the proposed rates scheduled to go into effect on Jan. 1, that leaves just 12 weeks for clinical labs to meet with legislators and government officials to argue that the 2018 Part B lab test price cuts could put a significant number of labs out of business. This would cause many Medicare beneficiaries to lose access to lab testing in their communities.

The proposed 2018 CLFS was established under the Protecting Access to Medicare Act (PAMA). Experts noted the irony that an act designed to protect Medicare beneficiaries may have the opposite effect because many clinical labs serving the most vulnerable Medicare beneficiaries could struggle financially under the lab test price cuts Medicare proposed.

$670 Million Fee Cut In 2018

The draft 2018 lab test prices would cut what CMS pays for clinical lab tests by $670 million, or about 10% of the $7 billion it pays for lab testing annually. This level of savings is a much deeper cut than CMS had estimated in 2016 when it said the market-based payment formula it developed under PAMA would cut about $400 million in 2018.

Although the average reduction in payment for all clinical lab tests will be 10% in 2018, the prices CMS pays for the 20 highest-volume lab tests will be cut by 28% over the years 2018, 2019, and 2020, according to an analysis from **XIFIN,** a healthcare IT company for clinical labs. Most of the labs serving small communities, rural areas, and nursing homes run the top 20 most common clinical lab tests every day. These 20 common tests make up the largest proportion of test volume at community and rural hospital labs.

A Death Knell For Many Labs

"These proposed rates will be the death knell for many labs throughout the United States and not just labs serving nursing homes and rural areas," observed Mark Birenbaum, PhD, Administrator of the **National Independent Laboratory Association**. "The survivability of small to medium-sized and community and hospital labs and even some large regional labs will be threatened."

"Labs that have a high percentage of Medicare Part B reimbursement are particularly vulnerable," Birenbaum said.

"If you're a small community lab doing $3 million to $5 million—and even if you're a bigger regional lab doing $25 million to $50 million—and 50% of your revenue is from Medicare, then this Part B price schedule threatens your financial viability," he added.

"If you have 50% Medicare, and you're facing a cut of about 30% over the next three years for most of the high-volume tests you run for Medicare patients, then you're facing a 15% cut to your bottom line," he explained. "The majority of labs don't have profit margins that exceed 15%. That's why this proposal threatens a large number of labs of all sizes.

Clinical Lab Professionals Need to Make Their Case Quickly to Members of Congress

"LAB DIRECTORS AND PATHOLOGISTS should tell their members of Congress that the proposed Clinical Laboratory Fee Schedule for 2018 will cause some labs to struggle financially and will be the death knell for many labs," stated Mark Birenbaum, PhD, Administrator of the National Independent Laboratory Association.

"The implementation date is only 12 weeks away," he said. "That is adequate time to write to members of Congress to explain the effect of these cuts," he continued. "In these letters, lab professionals need to explain three important reasons to delay implementation of the Part B lab test fee cuts.

"First, the letter should discuss the negative financial impact these proposed rates will have on their labs," he noted. "Second, the letter must describe how Medicare beneficiaries in the elected official's district will lose access to high quality, local lab testing services. Third, the letter should explain their lab's role in the senator's or representative's district or state and what will happen if those jobs leave the district.

"Labs need to ask their members of Congress to call on the acting secretary of the federal Department of Health and Human Services not to make these cuts," he added. "The secretary or acting secretary should put a hold on this proposal administratively.

"Or, Congress could pass a bill anytime between now and December that would affect the implementation date," he added. "The biggest problem for labs is that they have not yet made their voices heard collectively to members of Congress and to HHS. All the small, regional, hospital, and larger labs need to use their voices. When they have done so in the past, they have succeeded. But if lab professionals don't contact their elected officials, the chance of getting something done is diminished."

Some lab associations are considering challenging the CLFS in court. NILA is not doing so, Birenbaum said. "We're not considering a court action at the moment but we will certainly listen to what the other groups are saying and telling their members what to say," he added.

If labs that serve rural areas and nursing homes go out of business, it's unlikely that large lab companies will step in to fill that need, experts predict. The consequence will be the loss of quality lab testing services locally, the loss of well-paid medical technologist jobs, and the loss of access for Medicare beneficiaries.

"Even labs that do less Medicare work will feel these cuts because private health insurers will key their future payments on the 2018 Medicare Part B clinical lab fee schedule and reduce their payments accordingly," Birenbaum said.

"The only labs that will not be hurt by this proposal are specialty labs that do a small number of advanced diagnostic lab tests (ADLTs) or tests not paid by Medicare," he explained. "Other labs that will be okay are those that have alternative revenue streams, or labs that do only lab-to-lab referral work and get paid cash. But even those labs could be affected in the coming years if their client laboratories reduce their referrals or go out of business because of the fee cuts.

"It's hard to say when private payers will lower their rates for clinical lab tests," he added. "It will probably be when contracts run out and then get renewed. But you would expect that most private payers will reduce what they pay for lab tests at the first opportunity." TDR

—Joseph Burns

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Part B Fee Update

Lab Associations Comment on CMS Actions, Lab Fees

ACLA mentions possibility of a legal challenge; NILA predicts many small lab failures, bankruptcies

FOR THE LAB INDUSTRY, THE FEE CUTS proposed in the 2018 Clinical Laboratory Fee Schedule would be even more aggressive than what the federal **Centers for Medicare and Medicaid Services** had earlier predicted for Medicare Part B.

In the days following the Sept. 22 publication of the proposed fee schedule, major lab industry associations issued statements explaining how the proposal is flawed and the serious problems it could cause for labs and Medicare beneficiaries.

Community Lab Association

In a statement that day, Mark Birenbaum, PhD, Executive Director of the **National Independent Laboratory Association,** said, "The [PAMA] statute's intent was to establish private market-based laboratory payment rates within Medicare, but the regulatory agency has not done this.

"CMS imposed requirements that community laboratories could not meet, giving them only a few months to prepare reportable data, and threatening penalties up to $10,000 for each error they made," he continued. "CMS constructed a system where the national laboratories with the highest test volumes and highest discounts in the private market would dominate the data reported. Then they prohibited the segments of the laboratory market with high test volumes and higher payments in the private market from reporting their data."

Birenbaum predicted dire consequences for community laboratories and the Medicare beneficiaries living in the small towns and rural areas that labs serve. "This regulation will eliminate access to clinical laboratory testing services for many Medicare beneficiaries, particularly those living in rural and underserved areas and those with complex health conditions that rely on clinical laboratory tests to guide their care and treatment," he said.

"If these payments are not corrected, laboratories will be forced to lay off thousands of workers across the U.S., eliminate services, or close their businesses all together," he emphasized.

The same day, the **American Clinical Laboratory Association** also criticized the process CMS used and the proposed rates. "ACLA has conducted an initial review of the draft PAMA rates published by CMS today. With few exceptions, these rates are not market-based. If finalized, these rates will inflict severe cuts—well beyond those ever envisioned by Congress—and ACLA believes the impact will be unprecedented and far reaching. These rates will devastate many of our members and create severe disruptions in access to laboratory services, particularly for the most vulnerable Medicare beneficiaries.

"ACLA even submitted an analysis to CMS that showed how the inclusion of physician office labs and hospital labs

would meaningfully impact the rate determination," continued ACLA. "CMS simply ignored all such input. The result is proposed rates that will negatively impact Medicare beneficiaries, restrict access to necessary and life-saving clinical laboratory testing, and stifle innovation in the research and development of new diagnostic tools."

Legal Action Considered

ACLA also said that it would pursue all available remedies in an effort to delay implementation of the fee cuts and use that time to address the problems in the final rule. "ACLA is continuing to evaluate the draft rates and will advocate before all branches of government, including the courts if necessary, for a fair and effective market-based policy solution that encourages innovation and protects Medicare beneficiary access to lab services," ACLA stated.

Quest Diagnostics also issued a statement that day and specifically mentioned that it was considering legal action. "We are deeply disappointed that CMS has issued draft 2018 Medicare payment rates that are not market-based and derived from a flawed market data collection that excluded key components of the lab market," said Chairman, President, and CEO Steve Rusckowski.

Hospitals, POLs Excluded

"For example, hospitals and physician office labs [POLs] comprise half of Medicare CLFS volume and lab spending, but only accounted for 8.5% of the reported lab volume used by CMS to calculate the rates," he continued. "These draft rates are counter to the intent of Congress and will likely cause significant negative impacts to Medicare beneficiary access to lab services. These rates should not be finalized, and I fully support the American Clinical Laboratory Association's plan to explore all available options, including the courts if necessary, to ensure that patients have access to the services we provide."

The following Monday, Sept. 25, **Laboratory Corporation of America** issued a statement. "The new PAMA rates published by CMS do not reflect the intent of Congress when it directed CMS to implement market-based Medicare rates for lab testing," stated Chairman and CEO David P. King. "We join with the American Clinical Laboratory Association and others in our industry in calling on Congress to take swift action to prevent the harm that will occur if these rates take effect.

CMS Process 'Fatally Flawed'

"The process CMS followed to determine these rates was fatally flawed and failed to account for significant segments of the lab market by excluding 99% of all U.S. labs from reporting data and limiting data collection to 1% of laboratories, dominated by independent labs. The industry and LabCorp, as well as other healthcare groups, repeatedly pointed out to CMS in formal comments and multiple face-to-face meetings that the definition of 'applicable laboratories' in the rule would lead to exactly the flawed outcome that has occurred.

"We will continue to work with all stakeholders to delay implementation of these rates so that CMS can implement the intent of Congress and develop true market-based rates for laboratory services. We and ACLA will continue to explore all remedies, including legal action as appropriate, to prevent the infliction of serious harm on our industry and Medicare beneficiaries," King concluded.

To learn more about how hospital laboratories are responding to the publication of the Medicare Part B clinical lab test prices for 2018, THE DARK REPORT contacted the **Joint Venture Hospital Laboratory Network** and the **Great Lakes Laboratory Network** in Michigan. Their comments begin on page 7. TDR

CLFS Talking Points

Here Are the Arguments When Commenting on 2018 CLFS Rates

ALL LABORATORY PROFESSIONALS AND pathologists are encouraged to submit comments to CMS before the Oct. 23, as well as send letters to their elected officials in Congress to urge both to delay and to fix the market price study and revise the proposed Clinical Laboratory Fee Schedule for 2018.

Beneficiaries Will Lose Out

Among the most important points to cover are these:

1. The proposed rates are likely to cause Medicare beneficiaries to lose access to clinical lab tests.
2. The rates are not based on market-based price data, which is contrary to Congress' intent.
3. The weighted median that CMS used distorts the market-based price data.
4. Labs struggled to comply with the rule, and, therefore, CMS did not have the full market-based price data needed to set rates accurately.

In these comments and letters, it is important to explain that the Part B lab test prices set under the Patient Access to Medicare Act may actually cause many Medicare beneficiaries—particularly those in nursing homes and in rural areas—to lose access to quality clinical lab testing.

The loss of access to lab tests by Medicare beneficiaries is important to mention because members of Congress should be open to any problems that could affect senior citizens in their districts. Similarly, CMS should be concerned about not being able to serve seniors in nursing homes, rural areas, and any other areas where labs might not be able to provide lab tests.

Another key point to make is that one reason the Part B lab test rates are so low is because the data CMS used to set these rates did not come from a representative sample of the clinical lab marketplace. In an announcement about his opposition to the rates, Quest Chairman, President, and CEO Steve Rusckowski noted that hospitals and physician office labs (POLs) comprise half of Medicare's clinical lab testing volume and expenditures, but market-based pricing data from POLs and hospital labs make up only 8.5% of the data CMS used to calculate the CLFS rates for next year.

CMS's use of a weighted median calculation instead of a weighted average when setting the rates distorted market value, said **Xifin**, a healthcare IT company. "We have presented data to show how radically pricing can be skewed with a weighted median calculation based solely on the mix of submitting providers," Xifin said.

Distorted Market Value Data

Finally, because most labs struggled to comply with the rules CMS established for its data-collection effort, many did not submit data and others submitted inaccurate data, Xifin reported. Labs struggled in part because CMS did not publish the reporting criteria for data collection until after the data collection period closed.

Consequently, CMS did not receive private payer price data from a majority of the labs it required to report such data. In fact, CMS states that the private payer data it received from those labs that did report and that it used in its analysis came from only 0.7% of the nation's labs! TDR

—Joseph Burns

Can Fee Cuts Be Delayed? Courts Are One Option

➤Lab industry has 12 weeks to achieve a "delay and fix" agreement with HHS, CMS

➤➤CEO SUMMARY: Some lab companies may be prepared to challenge in court the methodology CMS used in setting the requirements of the Protecting Access to Medicare Act of 2014 to conduct a study of private payer market prices for lab tests and use that data to propose new prices for the Part B Clinical Laboratory Fee Schedule. Although labs prevailed in an important court challenge in 2008 involving Medicare competitive bidding, in this matter, there are substantial legal obstacles to overcome.

AFTER MEDICARE ANNOUNCED plans to cut Medicare Part B clinical lab test fees on Jan. 1, clinical laboratories and their associations began discussing ways to challenge the proposal.

In the letter sent Friday Oct. 6 to Seema Verna, Administrator of the federal **Centers for Medicare and Medicaid Services**, officials from 22 healthcare associations signed the letter and requested that her agency suspend the private payer lab test market price study and the Part B lab test fee cuts. The suspension would allow time for Medicare and interested stakeholders to address the flaws in the final rule that CMS crafted.

➤Associations In Support

Some of healthcare's most respected organizations signed the letter, including the **American Medical Association** and the **American Hospital Association**. Others included the **American Academy of Family Physicians**, the **Association of American Medical Colleges**, the **Association of Public Health Laboratories**, the **Medical Group Management Association**, and the **National Association for the Support of Long Term Care**.

These associations represent 5,000 hospitals, 700,000 physicians, and 17,000 nursing homes. They recognize the value of clinical lab testing and how the proposed fee cuts could cause Medicare patients to lose access to lab testing if CMS implements the Medicare Part B lab test fee cuts it published on Sept. 22.

➤An Unprecedented Coalition

Never before, to the knowledge of THE DARK REPORT, has a single issue involving clinical lab testing for Medicare patients spawned such a diverse and wide coalition of healthcare stakeholders. While clinical labs welcome the support, it is unknown whether federal officials will correct the inherent flaws in the methodology CMS used to gather data for its so-called market-based price setting initiative to avert the danger of setting prices so low on clinical lab tests that labs go bankrupt.

Clinical labs may know the answer in the coming weeks because there are only 83 days before the New Year. Since CMS has failed to respond to the industry's calls

for a delay to allow time to fix the flaws in its market study, there is a chance that some combination of plaintiffs representing the various stakeholders that want to suspend or postpone the fee cuts will challenge CMS in court.

Precedent For Using Courts

There is a precedent for court action winning some relief for the clinical lab industry. In 2008, CMS proposed a demonstration project for competitive bidding among clinical labs in the San Diego market. Several lab organizations filed a lawsuit in federal court in January 2008.

The labs won a temporary injunction that required CMS to stop the demonstration project and the federal **Department of Health and Human Services** chose not to appeal the ruling. By not appealing the ruling, there was no precedent at the appeals court level. Since that time, CMS has not attempted a competitive bidding project involving clinical lab tests. *(See TDRs, Feb. 3, 2008, and April 14, 2008.)*

As noted in this issue, on Sept. 22, the **American Clinical Laboratory Association** said it, "will advocate before all branches of government, including the courts if necessary, for a fair and effective market-based policy solution that encourages innovation and protects Medicare beneficiary access to lab services."

In a similar statement, **Quest Diagnostics** confirmed its support of the possibility of using the court. Quest Chairman, President, and CEO Steve Rusckowski said, "These rates should not be finalized, and I fully support the American Clinical Laboratory Association's plan to explore all available options, including the courts if necessary, to ensure that patients have access to the services we provide."

These statements indicate that ACLA and some of its members are prepared to use the courts in an effort to get an injunction to suspend the market price study and the proposed Medicare Part B lab test price cuts. For labs, however, both PAMA and the final rule on the lab market price study do not allow "judicial or administrative review of the payment amounts."

Using Courts To Challenge

Nevertheless, there are ways to use the courts to challenge CMS' actions in this case. "Yes, the PAMA statute's prohibition applies to challenges in how the rates are set," stated attorney Jeffrey J. Sherrin of **O'Connell and Aronowitz**, in Albany, N.Y.

"However, there can still be challenges to the methodology employed, such as the way data was collected and used," he continued. "Labs can challenge definitions, such as how an 'applicable laboratory' is defined in CMS' final rule and whether that definition is a reasonable interpretation and application of the statute, or whether it contravenes either the express language of the PAMA statute, or congressional intent.

Congressional Intent

"A successful challenge, therefore, will likely have to avoid simply attacking the inadequacy of the rates, but rather some other aspect of the implementation of the PAMA statute that is inconsistent with congressional intent," Sherrin added. "Labs will have to show that their challenge is outside the bar to challenges to the rates that are written in the law and the final rule.

"Labs will likely want to seek a preliminary injunction to stop the rates from going into effect, on the ground that once the rates take effect, irreparable harm will be caused to many labs," he noted. "But to succeed with this approach, plaintiff labs would need to show not only a likelihood of success on the merits of the lawsuit, but also that irreparable harm will be suffered.

"That might be difficult for ACLA labs to do, because financial losses do not usually suffice to establish irreparable harm,"

explained Sherrin. "This problem might be overcome by including as plaintiffs in the lawsuit smaller labs that can show they will be put out of business, and patients and their medical professionals or their associations who can speak to irreparable harm resulting from quality laboratory services becoming unavailable and the resulting detrimental effects on patient care.

Court Hurdles for Labs

"One hurdle for labs wanting to use the courts is this," he said. "While a challenge to methodology is not pre-empted by PAMA, there are cases—including from the U.S. Supreme Court—that say if the effect of the challenge to the methodology is to challenge the rates, the methodology challenge can also be preempted," he explained. "So plaintiff labs will need to walk a fine line in laying out the nature of their challenge, and to stay as far away as they can from appearing to be actually challenging the rates.

"These examples demonstrate that there are multiple ways for clinical labs to challenge how CMS is complying with the PAMA law," Sherrin observed. "But it is a difficult case when one considers the deference usually given by courts to CMS in its implementation of a complex statute, and the obstacle placed in the law that bars to challenges to the rates.

"On the other hand, litigation is always full of surprises and unexpected twists and turns," he continued. "It is feasible for plaintiff labs to prevail. Or, if they can defeat a motion to dismiss, then they have leverage to negotiate a better methodology.

Protecting Patient Welfare

"Ultimately," Sherrin added, "the plaintiff labs and any other groups or individuals that join in the lawsuit will want to convince the court that the challenge is not simply about protecting their financial position, but rather protecting patient welfare, good medical care, and not destroying patient access to necessary laboratory services.

"Since that is what these PAMA regulations will do, I am optimistic that the courts will reject hypertechnical defenses and critically analyze the way that CMS has chosen to implement a statute in the face of opposition and criticism from every sector of the healthcare industry," he concluded.

Questions To Be Answered

Did CMS follow the PAMA law in how it conducted the private payer lab test market price study? Did CMS meet the intent of Congress as it did so? It may take court action by labs and lab associations to get answers to these questions. Would clinical laboratories have a strong case? There is ample evidence to indicate that labs would bring a credible case to a judge. TDR

—Robert L. Michel

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Both PAMA Law, CMS Rule Forbid Admin, Judicial Review

BOTH THE **PAMA** LAW AND THE FINAL RULE state that no administrative or judicial review of the payment amounts will be allowed.

This is from the PAMA Statute:

"(h) IMPLEMENTATION.—

"(1) IMPLEMENTATION.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the establishment of payment amounts under this section.

This is from the PAMA final rule as published by CMS in Federal Register in 2016:

Section 1834A(h)(1) of the Act states that there shall be no administrative or judicial review under sections 1869, 1878, or otherwise, of the establishment of payment amounts under section 1834A of the Act.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Sept. 22 was the day that an agreement to sell **Miraca Life Sciences** (MLS) of Irving, Texas, was announced. **Miraca Holdings** will sell the anatomic pathology lab company to **Avista Capital Partners**. As part of the transaction, a new holding company, called **Symphony Buyer**, will be formed and will own MLS. Miraca Holdings will be a 15% shareholder in Symphony. Miraca said the enterprise value of the deal is approximately $175.6 million. The transaction is expected to close in November.

ADD TO: *Miraca Sale*

The enterprise value of Miraca Life Sciences of $175.6 million was a surprise to many in the pathology marketplace. In 2011, Miraca Holdings paid $725 million for **Caris Diagnostics**, which it renamed Miraca Life Sciences. Thus, Miraca has seen $550 million of its purchase price evaporate in the six years since it acquired Caris Diagnostics. Miraca told Wall Street analysts that reimbursement cuts, including a significant one in 2013, was a significant factor in the company's disappointing financial performance.

QUEST TO ACQUIRE SHIEL MED LAB FROM FRESENIUS

Fresenius Medical Care and **Quest Diagnostics** entered into an agreement on Sept. 28 for Quest to purchase **Shiel Medical Laboratory** of Brooklyn, N.Y., a division of Fresenius. The deal is expected to close during the fourth quarter. Part of the agreement will be a collaboration involving Quest and Fresenius that uses Quest's laboratory data analytics to identify patients with early-stage chronic kidney disease.

TRANSITIONS

- **Sunquest Information Systems** announced the appointment of Michael Epplen as its new President and CEO. Epplen had been COO at Sunquest. He formerly held positions at **Data Innovations**, **Healthvision**, **Hublink**, and **Anderson Consulting**.

- Matthew Hawkins was named CEO of a new revenue cycle management company formed by the merger of **Navicure** and **ZirMed**. His previous executive positions were with Sunquest Information Systems, **Vitera Healthcare Solutions**, **SirsiDynix**, **Henry Schein**, **McKinsey & Company**, and **EDS**.

- Paul Eros is now Commercial Director for **Novacyt**. Previously he worked at **DiaSorin**, **Roche Diagnostics**, and **Becton Dickinson**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 30, 2017.