

# 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.*

**E**ARLIER 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

## Molecular and Genetic Tests Get More Favorable Pricing

**T**HERE 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 8xxx 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.

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.*)

# 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)	\$0.1	\$27,356.01
b)	80050 (general health)	\$0.01	\$92,702.94
c)	80053 (comp. metabolic)	\$0.01	\$65,081.33
d)	80061 (lipid panel)	\$0.01	\$94,234.12
e)	80069 (renal function)	\$0.01	\$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 chromatography 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%
		<b>\$460.37</b>	<b>\$323.21</b>	<b>-29.8%</b>	<b>\$416.80</b>	<b>-9.5%</b>	<b>\$380.20</b>	<b>-17.4%</b>	<b>\$350.00</b>	<b>-24.0%</b>	<b>\$342.95</b>	<b>-25.5%</b>

\*\* 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 independ-

ent 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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