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.

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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